TRANSDIAGNOSTIC INTERNET-DELIVERED COGNITIVE BEHAVIOURAL THERAPY FOR UNIVERSITY STUDENTS WITH SYMPTOMS OF ANXIETY AND DEPRESSION

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Abstract

Anxiety and mood disorders are prevalent among university students, but many do not seek treatment. The first two studies of the present thesis aimed to evaluate whether a transdiagnostic internet-delivered cognitive behavioural therapy intervention (iCBT), the *UniWellbeing Course*, is efficacious and acceptable to students with symptoms of anxiety and depression. Study III evaluated the implementation of iCBT in a student counselling service (SCS). In Study I university students (n = 52) with symptoms of anxiety or depression were randomly allocated to receive therapist-guided iCBT or to a waitlist-control group. At post-treatment mixed models analyses revealed outcomes for the treatment group were statistically and clinically superior to those of the waitlist-control group on the primary outcome measures, the Patient Health Questionnaire 9-Item (PHQ-9) and the Generalized Anxiety Disorder 7-Item (GAD-7), with gains sustained at 3-month follow-up. Clinically significant reductions in the number of diagnoses of anxiety and depression were also found, with a mean total of 27 minutes of clinician time required per participant during the program. In Study II, the waitlist-control group from Study I received a self-guided version of the *UniWellbeing Course*, using an open trial design. Outcomes were consistent with those from the treatment group in Study I. In Study III, the *UniWellbeing Course* was offered to students attending a SCS as an alternative to treatment as usual. This small open trial (n = 6) found no statistically significant improvements as measured by the primary outcome measures, the PHQ-9 and GAD-7. Study III also explored the implementation of iCBT at the SCS using a structured methodology which identified several barriers to implementation including clinician attitudes and student treatment preferences. Notwithstanding these challenges, students, as well as managers and clinicians of the SCS who used the intervention rated it as highly acceptable. The results provide preliminary support that transdiagnostic iCBT for university students has the potential to be clinically effective, and acceptable to consumers, therapists, and service managers.

Certification by Candidate

I certify that this thesis is an original piece of research and has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree to any other university or institution other than Macquarie University.

In addition, I certify that all information sources and literature used are indicated in the thesis, and that any help and assistance received in my research work and in the preparation of the thesis itself have been appropriately acknowledged.

The research presented in this thesis was approved by the Human Research Ethics Committee (HREC) of Macquarie University (Sydney, Australia). The protocol numbers are HREC 5201100795 and HREC 5201200552. The trials were registered with the Australian New Zealand Clinical Trials Registry as ACTRN12612000212853 and ACTRN12612000955819.

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The Efficacy and Acceptability of Transdiagnostic Internet-Delivered Cognitive Behavioural Therapy for University Students

CHAPTER ONE

Literature Review

The peak age of onset for mental health problems has been identified as prior to age 24 in 75% of cases (Kessler, Angermeyer, & Anthony, 2007; Slade, Johnston, Oakley Browne, Andrews, & Whiteford, 2009). Research indicates that university students have higher levels of psychological distress than age matched controls, are reluctant to engage with traditional psychological service providers, and would like to obtain health information online (Escoffrey et al., 2005). This suggests that delivering mental health treatments online may be a helpful strategy for reducing treatment barriers in this population (Ryan, Shochet, & Stallman, 2010). However, because of the paucity of research investigating online treatments as an option for the university student population, the overarching aim of this thesis was to develop an effective and acceptable internet-delivered cognitive behavioural therapy (iCBT) treatment for university students, and to subsequently explore barriers to the implementation of iCBT within the applied setting of a student counselling service (SCS).

The literature review in Chapter 1 of this thesis reviews characteristics of anxiety, depression, and psychological distress, and the currently available psychological treatments which have been developed for students. Specifically, prevalence rates of anxiety, depression and psychological distress are evaluated, as are barriers to seeking help. Additionally, barriers faced by a SCS in providing treatment, and the potential benefits of iCBT for this population are considered. Chapters 2 and 3 comprise empirical research studies that report on the development, efficacy, and acceptability of a transdiagnostic iCBT treatment, the *UniWellbeing Course*, administered with and without weekly therapist contact. Chapter 4, together with a brief review of the literature on implementation science, reports on a feasibility-implementation trial, and examines how a therapist-guided iCBT intervention could be incorporated into a SCS. Chapter 5 provides a general discussion that synthesises the key findings of this thesis relative to the extant literature.

Definition and Classification of Anxiety and Depression

The terms *anxiety* and *depressive disorders* as used in this thesis refer to the presence of the following disorders: panic disorder with or without agoraphobia (Pan/Ag); social anxiety

disorder (SAD); obsessive-compulsive disorder (OCD); generalised anxiety disorder (GAD); post-traumatic-stress disorder (PTSD); and major depressive disorder (MDD). The diagnostic criteria for these terms are based on those described in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition-Text Revision (DSM-IV-TR: APA, 2000), the most widely used psychiatric nosological classification system. Research has found significant co-morbidity between these disorders, which may imply shared risk factors, described below.

Age of Onset, Prevalence, and Co-Morbidity of Anxiety and Depressive Disorders

While prevalence rates vary by country (Kessler et al., 2009), Australian figures are comparable to prevalence rates across the western world (Gwynn et al., 2008; Kessler, Chiu, Demler, & Walters, 2005; Slade et al., 2009; Somers, Glodner, Waraich, & Hsu, 2006). In Australia, the 2007 National Survey of Mental Health and Wellbeing estimated the lifetime prevalence rate for any anxiety disorder to be 26.3%, with a 12-month prevalence rate of 14.4% (ABS: Australian Bureau of Statistics, 2008). PTSD was reported to be the most prevalent (12-month) anxiety disorder (6.4%), followed by social phobia (SAD; 4.7%); agoraphobia (2.8%); GAD (2.7%); panic disorder (2.6%), and OCD (1.9%). Lifetime prevalence rates of unipolar depressive episodes were estimated to be 11.6%, with a 12-month prevalence of 4.1% (ABS, 2008).

A large number of studies have found high levels of co-morbidity, that is co-occurrence, between mood and anxiety disorders (Barlow, Allen, & Choate, 2004; Kessler et al., 2005; Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007). Anxiety precedes the onset of depression in approximately two-thirds of cases, and anxiety increases the risk of subsequently developing depression (Brown, Campbell, Lehman, Grisham, & Mancill, 2001; Essau, 2003; Kessler et al., 2003). In addition to high rates of co-morbidity between mood and anxiety disorders, co-morbidity between anxiety disorders is also high (Brown et al., 2001; Kessler et al., 2003).

Although the first onset of mental disorders can occur at any age, they are most prevalent between the ages of 16–24 years (Slade et al., 2009). Recent epidemiological data suggests mental health problems affect 26% of young Australian adults aged 18–24 years and 25% of those aged 25-34 years (ABS, 2008). Most university students fall within these age groups (Australian Bureau of Statistics, 2007), with 42% of those aged 18–20 years in Australia attending tertiary institutions (Birrell, Healy, Edwards, & Dobson, 2008).

There has been considerable debate in the literature about the rates of psychological distress or disorder in students. Several studies have reported comparable rates of diagnosable

mental disorders in college students and age matched controls, and several studies suggest that students may be less likely to suffer from major psychiatric disorders and have a lower risk of suicide (Blanco et al., 2008; Royal College of Psychiatrists, 2003; Silverman, Meyer, Sloan, Raffel, & Pratt 1997). For example, Blanco and colleagues (2008) used a subsample of an epidemiological survey to compare the 12 month prevalence of psychiatric disorders (using DSM-IV criteria) in 2,188 college and 2,904 non-college attending 19-25 year-olds in the U.S. They reported almost half of the population had a psychiatric disorder in the last year, but found no significant difference in the overall rates between college and non-college students. The results of that study indicated that the 12 month prevalence rate for college students of MDD was 7.0% and of anxiety was 11.9%, and for non-college students was 6.7% and 12.7%, respectively.

Similar prevalence rates were reported in the 2007 Healthy Minds Study (Keyes et al., 2012), an online survey of 5689 American university students at 13 tertiary institutions. Although generalisability of these studies is limited by the use of self-selecting students who self-report symptoms, the prevalence rate for MDD was estimated at 7.9% using the Patient Health Questionnaire 9-Item (PHQ-9: Kroneke, Spitzer, & Williams, 2001), a valid and reliable measure of symptoms and severity of depression. Keyes et al., (2012) also reported a prevalence rate for panic disorder of 3.8% and for GAD of 5.9% using the Patient Health Questionnaire (PHQ: Spitzer, Kroneke, & Williams, 1999). These prevalence rates are higher than those reported in an older (2005) survey of 2,843 American students which used the same measures (Eisenberg, Gollust, Golberstein, & Hefner, 2007). In that study, 5.2% of undergraduates and 4.1% of post-graduate students screened positively for MDD using the PHQ-9, with prevalence rates for GAD (2.9% of undergraduates and 3.1% of post-graduate students) and panic disorder (1.8% of undergraduates and 1.1 % of post-graduate students) also found to be lower using the PHQ.

However, several studies have examined *psychological distress* rather than *psychiatric disorders* and have found psychological distress to be higher among university students than in the general population (Kadison, 2004; Roberts, Golding, Towell, & Weinreb, 1999; Royal College of Psychiatrists, 2003; Schweitzer, 1996; Stallman, 2008; Stewart-Brown et al., 2000). Increased rates of psychological distress may be associated with the range of academic, emotional, and social demands encountered by students entering universities (Palmer & Puri, 2006). For example, a longitudinal study of 16,460 U.K. undergraduate students found that psychological distress increased after commencing university (Bewick et al., 2010). The authors reported that at no point during university did levels of psychological distress fall to

pre-admission levels, that anxiety symptoms were significantly higher than depression symptoms at all time-points, and that depression symptoms rose steadily after admission, peaking at the end of the final year (Bewick et al., 2010). Consistent with this, MacCall et al., (2001) reported 65% of female and 54% of male students scored positively on the General Health Questionnaire, (GHQ: Goldberg & Williams, 2006) indicating elevated psychological distress, and Rosenthal and William (2008) rated 83% of students as moderately or severely distressed using the same measure. In Australia, a number of studies have used the Kessler 10-Item Scale (K-10: Kessler et al., 2003), a measure of global psychological distress. In one study, 48% of University of Adelaide students were reported to score in the psychologically distressed range compared to 11% of an age-matched population control (Leahy et al., 2010), and in another 84% of university students at two Australian universities reported elevated psychological distress (Stallman, 2010) significantly higher than the 29% reported for the general population on the K-10 by the ABS (ABS, 2008).

The literature also indicates that there are gender and age disparities in rates of distress. Several studies have reported that female students have a higher risk of psychological distress, although not consistently or for all disorders (Blanco et al., 2008; Eisenberg et al., 2007; Leahy et al., 2010; Stallman, 2010; Stewart-Brown et al., 2010; Verger, Guagliardo, Gilbert, & Kovess-Masfety, 2010). Studies have also reported that students aged 18–22 years may be at greater risk of mental disorders than students aged 25 years or over (Eisenberg et al., 2007; Stallman, 2010).

In summary, although rates of psychiatric disorders do not appear to be higher in the student population when compared to age-matched counterparts, psychological distress appears to be significantly higher. The disparity between studies which use DSM-IV criteria and those which use other measures highlights the difficulties in measuring dimensional conditions using categorical approaches. Brown and Barlow (2005) have suggested that categorical diagnosis may fail to address clinically the significant impairment of subclinical symptoms. Such subclinical symptoms include low mood, irritability, anxiety, withdrawal, apathy, changes in cognitive functioning, impaired concentration, constant worrying, rumination, and disturbances in sleep and appetite (Lewinsohn, Solomon, Seeley, & Zeiss, 2000; McGorry, Killackey, & Yung, 2008), which all have negative effects on quality of life (da Silva Lima & de Almeida Fleck, 2007; Goldney, Fisher, & Taylor, 2004). They also appear strongly predictive of future illness. For example, a review which estimated the prevalence of subclinical depression at 17% to 21% among Dutch adolescents concluded that subclinical depression may have a similar prognosis to that of MDD (Cuijpers & Smit, 2004).

This suggests subclinical symptoms are worthwhile targets for treatment. This is important, as research studies often exclude participants who do not meet diagnostic criteria for target disorders. Without treatment, outcomes appear poor. The course of these disorders is considered in greater detail below.

Course of Anxiety and Depression

Factors that influence the course of anxiety and depression include co-morbidity (Gaynes et al., 1999), severity (Ramana et al., 1995), duration (O'Leary, Costello, Gormley, & Webb, 2000; Yonkers, Bruce, Dyck, & Keller, 2003), length of illness before treatment (O'Leary et al., 2000), and treatment effectiveness (Simon, 2000). In addition, the literature suggests that working longer hours in paid employment correlates with student mental health difficulties (Roberts et al., 1999). Despite this, many students often need to work to meet basic needs, and face financial disadvantage if they need to repeat a unit of study. Students from a low socio-economic background are reported to have a higher risk of mental health disorders (Eisenberg et al., 2007; Verger et al., 2010), and not surprisingly, financial problems are consistently associated with psychological distress in tertiary students (Andrews & Wilding, 2004; Eisenberg et al., 2007; Stallman, 2010; Stewart-Brown et al., 2000).

A 12 year prospective study by Bruce and colleagues (2005) found anxiety disorders have a chronic clinical course, low rates of recovery and high reoccurrence rates. The quality of life of individuals with anxiety disorders is likely to be poor (Mendlowicz & Stein, 2000), with the extent of impairment in functioning positively correlated with symptom severity. A large longitudinal study of university students in Sweden (Vaez, de Leon, & Laflamme, 2006; Vaez & Laflamme, 2003, 2008) reported student quality of life to be strongly correlated with psychological health.

For individuals with depression, there appears to be a lower risk of relapse if symptoms remit within 3 months (Simon, 2000), however it has been reported that 50% of individuals will relapse within 5 years, and that 15% of individuals will relapse within 12 months (Andrews, 2001; Eaton et al., 2008). Ramana and colleagues (1995) reported that 70% of those treated for MDE achieved remission within 6 months; however, 40% of those relapsed within 10 months. In addition, even if symptoms remit, social functioning may not return to the normal range for 2 months (Farukawa et al., 2001), and brain imaging studies suggest that longer durations of depression may lead to greater hippocampal loss (Sheline, Gado, & Kramer, 2003).

The effects of anxiety and depression are associated with lower educational attainment, joblessness, poorer physical health, increased risk of self-harm and increased risk of suicide (Kessler, 2007). In relation to students, several studies have found that psychiatric disorders interfere with college attendance, and reduce the likelihood of successful college completion (Breslau, Lane, & Sampson, 2008; Hunt, Eisenberg, & Kilbourne, 2010). For example, in a U.S. survey of over 71, 000 college students, stress was found to be the leading factor affecting academic performance (American College Health Association, 2007), and significant correlations have been found between grade point average (GPO) and emotional health, regardless of gender (Pritchard & Wilson, 2003; Rosenthal & Wilson, 2008). In a U.S. study of 63 students who voluntarily sought help at a university mental health service, 92% of those with moderate to severe depression reported missed classes, decreased academic performance, and significant interpersonal problems (Heiligenstein, Guenther, Hsu, & Herman, 1996). Australian students with mental health problems have lower completion rates than any other disability group (Cavallaro, Foley, Saunders, & Bowman, 2005), with the literature suggesting up to 86% of students with a mental health disorder withdraw prior to completing their course (Andrews & Wilding, 2004; Hysenbegasi, Hass, & Rowland, 2010; Leahy et al., 2010; Stallman, 2010; Verger et al., 2010). Australian studies also indicate high levels of impairment (Martin, 2010; Stallman, 2010, 2008). Students experiencing high levels of psychological distress are reported to have a 23 times higher rate of being totally unable to attend to their responsibilities than students without mental health problems, with the number of days reduced for study and work reported to be ten times higher (Stallman, 2008). One study reported university students attending a university health service with high levels of psychological distress were "*unable to work or study on average for 8 days in the previous 4 weeks and had on average another 9 days of reduced capacity for work, resulting in some impairment for around 60% of the time*." (Stallman, 2008, p. 123).

Summary

In the general population, anxiety, depression and associated subclinical symptoms are highly prevalent, frequently co-morbid, and indicate a chronic and disabling course (Goldberg, Krueger, Andrews, & Hobbs, 2009). Although the factors leading to the development of anxiety and depression are still under debate, the functional impairment is costly and results in considerable disability. For the student population, mental ill health has an ongoing impact on academic, occupational and interpersonal functioning if left untreated (Brown et al., 2001). Although it is unclear whether prevalence rates between student and

non-student populations differ for anxiety and depressive disorders, prevalence rates may be considered conservative as they fail to consider subclinical symptoms which affect a greater proportion of the population (Kessler et al., 2009). Further, there is evidence for significantly higher psychological distress in the student population, and this is correlated with considerable functional impairment. Delays in treatment are associated with a more chronic course (Post, 2007; Ramsawh, Weisberg, Dyck, Stout, & Keller, 2011), and early identification and referral to treatment may reduce serious consequences (Wang et al., 2007). Effective treatments are available. These include the use of pharmacology, as well as those based on psychological models, particularly CBT interventions, and are considered below.

Effective Treatments for Anxiety and Depression

Biological treatments. Biological treatments are not the focus of this thesis, but will be considered briefly here. Neurobiological models of anxiety indicate the amygdala, hippocampus, and anterior cingulate play a key role in mediating anxiety disorders, with research demonstrating common neural circuits are relevant to symptoms of anxiety. Anxiety disorders share hyperactive noradrenergic systems, and selective serotonin deficiencies (increasing hyperactive neurons). Corticotrophin-releasing hormone, cortisol receptors, glutamate, and g-aminobutyric acid (GABA), play a central role in the mediation of fear and anxiety and are the targets for a number of widely prescribed anxiolytic medications. Current guidelines for the treatment of anxiety recommend selective serotonin re-uptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors. Additionally, tranquillisers such as benzodiazepines, (which have an immediate effect) are commonly used, although use of these is associated with significant safety issues (Cloos & Ferreira, 2009; Ravindran & Stein, 2010).

Brain structure abnormalities occurring in mood disorders include a reduced number of glia; reduced neuron size; reduced volume in the prefrontal cortex; reduced numbers of GABA interneurons; reduced volume in the hippocampus, and over-activation of the amygdala (Drevets, Price, & Furey, 2008). Numerous studies of neurotransmitter activity have found depressed people have an overall reduction in monoamines (the neurotransmitters serotonin, noradrenalin and dopamine). Current Australian National Health and Medical Research Council (NHMRC) guidelines (*beyondblue*, 2010) suggest combining a pharmacological approach (typically an SSRI) with cognitive behavioural therapy (CBT). As some studies have found increases in suicide rates of adolescents using SSRIs (Masi et al., 2012), guidelines currently recommend young adults with mild to moderate depression should

be provided with CBT or interpersonal psychotherapy (IPT) as a first line treatment in preference to an SSRI. Other available treatments include lithium, anticonvulsants and electroconvulsive therapy which may be used to stabilise neurons and even mood. First generation tricyclics antidepressants and monoamine oxidase inhibitors have risks such as cardiotoxicity, increased suicidality, overdose toxicity, food and drug interactions, and high levels of non-compliance. Biological models of depression are helpful in contributing to the development of effective medical treatments. However, one significant limitation is that not all people respond to antidepressants (Beck & Alford, 2009), and the model currently fails to explain co-morbidity, or indicate whether biological changes cause or produce symptoms. As the focus of this thesis is psychological treatment, biological treatments will not be discussed further.

Psychological treatments. Although there are several evidence-based psychological treatments for anxiety and depressive disorders, the focus of this thesis is on CBT. Cognitive therapy was pioneered by Beck (1970) and Ellis (1962) but is now often used in combination with behavioural therapy, that is, CBT. CBT interventions aim to change the thoughts and behaviours that are considered to contribute to anxiety and depression, with the core premise that maladaptive cognitions and behaviours contribute to the maintenance of emotional distress and behavioural problems. CBT is widely used, with a recent review of meta-analyses indicating an enormous evidence base supporting the effectiveness of CBT in treating anxiety disorders and depression (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012). This review revealed strong support for the treatment of anxiety disorders, and mixed evidence for the efficacy of CBT for treating depression. Some authors have suggested that a publication bias in conjunction with low study qualities may have led to an overestimation in the efficacy of CBT for depression (Cuijpers, Andersson, Donker & van Straten, 2011). However, given the extensive evidence base, CBT is recommended as a first line treatment for depression and anxiety (Butler, Chapman, Forman, & Beck, 2006; Campton, March, Brent, Albano, Weersing, & Curry, 2004; Rachman & Wilson, 2008).

Evidence from systematic reviews and meta-analyses (Butler et al., 2006; Hofmann et al., 2012) indicates that disorder-specific treatment protocols which target one disorder result in both statistically and clinically significant changes in symptoms of anxiety and depression, with large effect sizes. In addition, there has been growing recognition that anxiety and depressive disorders share similar symptoms and temperamental antecedents such as negative affect or neuroticism (Clark & Watson, 1991; Griffith et al., 2011), are highly co-morbid, and

respond to similar treatments (Klein, Kotov, & Bufferd, 2011). This has influenced the development of unified or transdiagnostic approaches to treatments (Barlow et al., 2004; Craske et al., 2009; Wilamowska, Thompson-Hollands, Fairholme, Ellard, & Farchione, 2010). Such treatments use core CBT skills such as problem-solving; regulating negative affect; regulating arousal; cognitive restructuring, and increasing social behaviours to target common elements in one protocol (Dobson & Dozois, 2001). Although based on a relatively small number of trials and relatively small sample sizes, meta-analyses suggest that outcomes for transdiagnostic CBT treatments are comparable to those of traditional disorder specific treatments (McEvoy, Nathan, & Norton, 2009; Norton & Price, 2007), with large pre-treatment to post-treatment effect sizes observed on measures of anxiety and mood, and high ratings of acceptability from participants.

In addition to good treatment outcomes, the use of transdiagnostic protocols offers several pragmatic advantages. For example, for individuals with co-morbid disorders, the targeting of core symptoms may reduce the need for further disorder specific treatment (Boisseau, Farchione, Fairholme, Ellard, & Barlow, 2010; Wilamowska et al., 2010). This may potentially reduce waiting lists, and increase access to treatment (Barlow et al., 2004; Craske et al., 2009). Such protocols may also reduce the training burden for services which manage a range of clinical presentations (McHugh, Murray, & Barlow, 2009). Consistent with this, improved treatment fidelity, and increased flexibility were reported by Craske et al., (2011) in a large effectiveness trial comparing a transdiagnostic CBT component with care as usual. This was attributed to the reduced need for clinicians to have a high level of competency with multiple treatment protocols.

Psychological Treatments for Students

CBT approaches appear to be effective for prevention and early intervention with a tertiary student population, but are time consuming and costly to implement (Reavley & Jorm, 2010). A recent systematic review and meta-analysis (Regehr, Glancy, & Pitt, 2013) examined the effectiveness of 24 cognitive, behavioural and /or mindfulness-based interventions aimed at reducing stress in university students. In five of the six studies assessing mood, a significant reduction in depression was reported and significant reductions in anxiety were found in all 16 studies which used cognitive or behavioural interventions. These findings were observed despite wide variation in the length and specific components of the interventions. In another review, Reavley and Jorm (2010), identified eleven interventions used in prevention of, or early intervention with anxiety and depression in a higher education

setting. Of these, only 4 were CBT or skill-based interventions (Peden, Hall, Rayens, & Beeb, 2000; Seligman, Schulman & Tryon, 2007; Steinhardt & Dolbier, 2008; Tillfors et al., 2008). These were associated with positive outcomes, compared to interventions such as online support groups which were found to have no evidence of positive outcomes, or personalised feedback which had mixed evidence.

Most universities offer student counselling as part of student wellbeing services. The Association for University and College Counselling Centre Directors (AUCCCD) survey of counselling centre directors in the U.S., Canada, Europe and Asia (AUCCCD: 2012) reported the most common problems identified on presentation at student counselling services (SCSs) were anxiety (42%), depression (36%), relationship problems (36%). However, for students who approach a SCS, the theoretical orientation of the counsellor may determine the type of treatment offered. For example, Connell, Barkham and Mellor-Clark (2008), assessed the effectiveness of 7 U.K. SCSs. In this study the main presenting problems were anxiety (61%), interpersonal problems (55%) and depression (50%). However, only 27% of students received a structured therapy such as CBT. Relatively more students received psychodynamic therapy (32%), or integrative therapy (23%), and 43% received more than one type of therapy, reflecting the diversity of models used by therapists in the SCSs.

In summary, the literature indicates that disorder-specific and transdiagnostic CBT interventions are efficacious, evidence based treatments for anxiety and depression, and appear effective for students who seek help. However, students who seek help may not be offered CBT, as the theoretical orientation of the counsellor may determine the treatment offered. Other barriers to treatment have also been identified and are discussed below.

Barriers to Seeking Help in the Student Population

Resources. There is evidence that Australian SCSs are under-resourced, and are experiencing rising numbers of students presenting with serious mental health difficulties. A recent survey of eight Australian and New Zealand SCSs (Stallman, 2011) found counsellors were reported to be working at a ratio of 1 to 4,340, which is significantly higher than the 1:1,000-1,500 ratio proposed as a standard by the International Association of Counselling Services (IACS: 2013). Consistent with U.S. surveys (Gallagher, 2009; Gallagher, Gill, & Sysco, 2000), Stallman (2012) reported increases in the numbers of students presenting with serious psychological problems. Similarly, a survey of over 80% of U.K. higher education institutions found demand for mental health provision had significantly increased over the last five years (Royal College of Psychiatrists, 2011), which was consistent with a longitudinal

survey in the U.K. which reported increasing demand (Benton, Robertson, Tseng, Newton, & Benton, 2003). Some researchers have argued for brief therapy models to manage demand (Kitzrow, 2003). However, one study indicated the mean number of sessions provided to a student is 2.9 (Stallman, 2012) and evidence suggests close to 50% of students drop out of therapy prematurely (Hatchett, 2004). Other recommendations have included providing better links between the university and external mental health providers, increasing students' awareness of existing support services external to the university, and offering universal wellbeing programs (Martin, 2010; Storrie, 2010).

An unpublished study (Jackson & Connelley, 2009, cited in Stallman, 2012) found that students perceive university counselling services to have a number of benefits over other community services for students, including convenience; ease of access; cost, and knowledge of student issues. Even so, student counselling services have low utilisation rates. Utilisation rates are reported to be between 2 to 4% of all students (Raunic & Xenos, 2008), suggesting there may be important barriers that interfere with help seeking behaviours in this population. A number of factors influencing individual help-seeking are explored below.

Mental health literacy, beliefs and attitudes. Although effective treatments are available, several studies have indicated that between 34 to 55% of university students with mental illness seek help (Cooke, Bewick, Barkham, Bradley, & Audin, 2006; Eisenberg, Golberstein, & Gollust, 2007; Kahn & Williams, 2003; Stallman, 2010). How and when individuals will seek help appears to be determined by individual factors such as mental health literacy, attitudes and stigma (Rickwood, Dean, & Wilson, 2007). Jorm et al., (2000) argued that mental health literacy, that is, knowledge about symptoms and possible treatment options, are important determinants in help-seeking behaviour. Consistent with this, Downs and Eisenberg (2012) reported the most significant barriers to seeking help among suicidal college students included: Preferring to deal with stress alone (73%); beliefs that stress is normal in university (52%); not considering their needs as serious (52%), and lack of time for treatment (47%).

Motivation and treatment preferences. Individuals with symptoms of anxiety or depression may experience difficulty with both low energy and motivation, and this may interfere with their ability to seek help (Cigularov, Chen, Thurber, & Stallones, 2008). Investigations suggest that individuals with poor emotional management skills may be less willing to seek help from family, friends or health professionals (Ciarrochi & Deane, 2001).

Several studies indicate that rather than consult a doctor or psychologist, many people would prefer to seek help from informal sources like family, friends, books or the internet (Hodges, O'Brien, & McGorry, 2007; Kelly, Jorm, & Wright, 2007; Rickwood et al., 2007). Consistent with these findings, a recent survey of over 50,000 young Australians (Mission Australia, 2011) reported that the internet was ranked as the next preferred option for advice and support after parents, relatives and friends. Ryan and colleagues (2010) who surveyed students at an Australian university found evidence of a preference to seek help from informal sources, with 47% of respondents likely to use an online program. A study which investigated the attitudes of 122 university students in the U.K. towards computerised cognitive behavioural therapy (CCBT) for depression found a small number of students (9.8%) reported a preference for CCBT over other interventions, however students preferred not to go to a clinic to access such programs (Mitchell & Gordon, 2007). Despite poor initial credibility ratings for the intervention by students, the authors also found that a demonstration of the program significantly increased credibility, expectancy-for-improvement and the perceived likelihood of using CCBT amongst the target population.

Stigma and regret. Stigma is associated with a reluctance to seek professional help (Barney, Griffiths, Jorm, & Christenson, 2006), and appears to be a significant barrier for the student population. A large North American national survey of higher education students (Collins & Mowbray, 2005) found fear of disclosure and stigma were significant barriers to disclosing a psychiatric disability. Similarly, a study of students at an Australian university (Martin, 2010) reported that despite considerable difficulties, stigma prevented most students in the study disclosing their mental health condition, or the problems they were experiencing. Although based on a small and self selecting sample (n = 34), and limited by a brief questionnaire, this study is reflective of a body of work indicating perceived stigma is a significant barrier in help seeking for university students (Eisenberg, Downs, Golberstein, & Zivin, 2009; Schwenk, Davis, & Wimsatt, 2010). Consistent with these findings, a study looking at retention rates reported that feedback from students with a mental health disability and their teaching and support staff (McLean & Andrews, 1999) indicated that alternative treatments which do not require disclosure may be one way to overcome stigma.

In summary, individual factors such as mental health literacy, attitudes and stigma create barriers to treatment seeking, which may interact with structural factors (Barker, Olukoya, & Aggleton, 2005) to stop students with mental illnesses accessing treatments that can help. Students indicate a preference for seeking help online and there may be potential to increase

the availability of evidence based treatment by delivering it online to students. A review of the efficacy of online CBT is discussed below.

Online and Computerised CBT

The internet has had a significant impact on health care (Barnett & Sheetz, 2003; Eysenbach, 2001), and a large number of computer and internet-delivered CBT interventions have been developed and evaluated (for a review, see Barak, Hen, Boneil-Nissim, & Shapira, 2008). CCBT self-help interventions are now increasingly being delivered over the internet, as online CBT (iCBT). In the remainder of this thesis, the terms iCBT and CCBT will be used to refer to CBT interventions that are delivered via the internet or via a standalone computer, respectively. In iCBT, information is typically presented via a website to allow individuals to systematically read structured lessons which contain the treatment components that would be taught in face-to-face CBT. Supplementary resources and homework assignments may also be provided (Andersson, Carlbring, Ljotsson, & Hedman, 2013). There is considerable variation in the amount and types of support offered (e.g., online discussion forums, emails, telephone calls), and interventions are often categorised as entirely *self-guided*, or as *therapist-guided*, with the latter including some level of regular contact with a trained support person or therapist.

By virtue of the reduced amount of therapist contact required in most iCBT interventions, iCBT is often considered to be a *low intensity* treatment, in contrast to face-to-face interventions which often require more therapist time, and may be described as *high intensity* treatments. Low intensity treatments may offer advantages for both providers and users in addition to reducing the amount of therapist time required (Marks, Cavanagh, & Gega, 2007). One additional advantage of iCBT compared to face-to-face therapy is that providers have considerable control of the sequencing and presentation of materials, ensuring high levels of treatment fidelity. In addition, the provider can easily update, extend and modify material to appeal to different cultures, and genders, increasing treatment flexibility. Technology can prevent the release of new information until previous content is completed, or until a pre-specified time has elapsed, and continue to offer increasing opportunities to present material in engaging ways. Other advantages may include economic benefits when compared to treatment as usual (Griffiths & Christenson, 2006; Tate, Finkelstein, Khavjou, & Gustafson, 2009); increased convenience as participants and therapists may log on to the program at a time of their choosing (Abbott, Klein, & Ciechomski, 2008; Griffiths & Christenson, 2006); increased communication (Abbott et al., 2008), and improved accessibility, with internet

access potentially overcoming a number of barriers relating to geography and limited therapist resources (Andersson, 2009; Barak et al., 2008). Limited therapist resources are a difficulty faced by most service providers, and services using stepped care models (Piling, Whittington, Taylor, & Kendrick, 2011) such as the Improved Access to Psychological Therapies (IAPT) model in the UK have demonstrated good outcomes using CCBT protocols to step consumers from low to high intensity treatments as clinically required (Clark et al., 2009; Learmonth, Trosh, Rai, Sewell, & Cavanagh, 2008; Proudfoot et al., 2004). Consistent with this, a growing body of research indicates that the use of CCBT and iCBT for common mental health problems is effective (Cuijpers et al., 2009; Kaltenthaler, Parry, Beverley, & Ferriter, 2008a) and acceptable (Kaltenthaler et al., 2008b). This research is outlined below.

Efficacy and effectiveness. A large evidence base indicates that CCBT can be used to treat individuals with common mental health problems. A meta-analysis of 22 CCBT and iCBT treatments found moderate effect sizes for depression, and large effect sizes for anxiety (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010). Similar outcomes were reported in Barak et al.'s (2008) review and meta-analysis which also supported the efficacy of iCBT. A meta-analytic review reported computer-aided psychotherapy for anxiety disorders had similar outcomes to face-to-face therapy, and was effective across several anxiety disorders, with large effect sizes (Cuijpers et al., 2009). Similar but more modest results have been reported for CCBT and iCBT interventions targeting depression. For example, a meta-analysis of 12 studies by Spek et al., (2007) found a small-to-moderate effect size for the treatment of depression, with further support provided in a meta-analysis by Andersson and Cuijpers (2008) who reported larger effect sizes when treatment was supported by a therapist. Consistent with this, a review recently reported effect sizes for iCBT treatment of depression to be 0.42 to 0.65, which is similar or larger than meta-analyses of psychological treatment in primary care (0.31), and to antidepressant treatments (0.37), relative to controls (Griffiths, Farrer, & Christenson, 2010). Outcomes for transdiagnostic treatments for anxiety and depression delivered using iCBT also appear to produce results equivalent to those from disorder specific programs (Titov, Andrews, Johnston, Robinson, & Spence, 2010; Titov et al., 2013).

In summary, the meta-analytic literature indicates good outcomes for CCBT and/or iCBT courses. However, some barriers have been identified in the provision of low intensity treatments. These are considered below.

Barriers to the Provision of iCBT and CCBT

Access. Not everyone has access to a computer, or the internet, or has the technological sophistication to effectively navigate sites. However, these disadvantages are less likely to apply to university students who are reported to have a high level of comfort with computers, and a very high level of use of the internet (Salaway, Caruso, Nelson, & Ellison, 2008). Moreover, students typically have free wifi and computer facilities provided by their university, further facilitating access (Gordon, Juang, & Syed, 2007; Hanauer et al., 2004).

Clinician attitudes. Several studies indicate that there may be clinician barriers to the provision of low intensity treatments such as iCBT and CCBT. Results of earlier studies and surveys indicate that many therapists are not aware of the evidence relating to computerised self-help, and may consider it less effective than face to face therapy (Whitfield & Williams, 2004). Further, even when training is provided, therapists may not adhere to treatment recommendations. For example, Clarke (2011) noted that at mid-point in the roll of out IAPT, a number of patients presenting with anxiety received counselling, despite IAPT training being based on the National Institute for Health and Clinical Excellence (NICE) guidelines, which recommend anxiety is treated only with CBT (NICE, 2011, 2013), structured around a stepped-care model.

Adherence. Adherence issues are a significant problem, with few individuals completing computerised self-guided interventions without supervision (Christensen, Griffiths, & Farrer, 2009; Christensen, Griffiths, & Korten, 2002). For example, a publicly available website, the *Panic Centre* (www.paniccentre.net), which offered a disorder specific, self-guided treatment for panic disorder, recorded more than 99,695 individuals visiting during an 18 month period. Despite high apparent interest, only 1,161 users registered for the program, and of those, only 12 users (1.03%) completed all 12 sessions (Farvolden, Cunningham, & Selby, 2009). Similar experiences have also been reported for *MoodGYM* (www.moodgym.anu.edu.au), which has reported completion rates of approximately 2% (Christensen, Griffiths, Mackinnon, & Brittliffe, 2006).

Research investigating the factors that determine acceptability and adherence to iCBT and CCBT is in the early stages. A number of factors including site useability, the level of difficulty of the content, the use of automated emails, the initial severity of symptoms, and the length of the program may be related to outcomes (Christensen et al., 2009; Kelly et al., 2007; Lauder, Chester, & Berk, 2007; Tate & Zabinski, 2004; Titov et al., 2013).

One important research finding is that therapist contact improves clinical outcomes (Andersson & Cuijpers, 2009; Gellatly et al., 2007; Spek et al., 2007). In a recent review of therapist contact in 135 technology based treatments for anxiety and depression (Newman, Szkodny, llera, & Przeworski, 2011), the authors concluded that lower compliance was associated with the use of technologies at home with little human contact, that structured contact with a therapist is important, and that efficacious levels of therapist contact may vary by disorder. This contact may be provided by clinicians without traditional specialist training, including nurses, administrators, and others, providing they are well supervised (Cuijpers, Donker, Van Straten, Li, & Andersson, 2010; Gellatly et al., 2007; Learmonth et al., 2008; Proudfoot et al., 2004). However, the most efficacious level of contact is not yet known, although a number of studies suggest that increasing therapist contact time beyond an unknown threshold may not facilitate further gains. Hirai and Clum (2006) argue that there is no evidence that the method of contact has any significant correlation with outcomes, suggesting that minimal therapist contact such as emails may be adequate. However, the most effective format for emails is unknown, and there is considerable variability in formats. For example, one transdiagnostic iCBT course (Day, McGrath, & Wojtowicz, 2013) reported providing emails which were 1-2 pages long as part of clinical contact, whereas another transdiagnostic iCBT course (Titov et al., 2013) described effective emails as concise, although warm and supportive in tone. Although the most effective format is as yet unclear, iPT for adults with social phobia has shown that automated reminder emails increase completion rates and effect sizes, when compared to trials without automated reminders (Titov, Andrews, Choi, Schwencke, & Johnston, 2009; Titov et al., 2010b). Further, Titov and colleagues (2013) recently reported that the use of automatic emails increased completion rates in an 8 week iCBT program, particularly for those with co-morbid or elevated symptoms of anxiety and depression.

In summary, further dismantling studies are required to understand the therapeutic effects of email components, clinician time and other related variables including ideal treatment length and treatment components. These factors are important for implementation and further studies will help maximise the potential of online interventions. Overall, it appears that self-guided CCBT and iCBT interventions are effective, and that some contact with a therapist will enhance the intervention. The research assessing iCBT and CCBT interventions for the university student population is discussed below.

CCBT and iCBT For Students

Online interventions may improve access to treatment to a large number of students, including those with impaired mobility, and those who live off campus or who attend remotely. However, relatively few studies have focused on online interventions for anxiety, depression, or psychological distress in this population. A self-guided public access website (www.thedesk.org.au) aimed at Australian tertiary students (Stallman, Kavanagh, & Ralph, 2012) was recently launched but as yet, no data is available to evaluate the utility of the site. A recent systematic review identified 27 technology based interventions for mental health in tertiary students (Farrer et al., 2013). Of these, the majority (n = 24) targeted anxiety or stress, and a small number (n = 7) targeted anxiety and depression. However, the authors noted that less than half of the studies provided enough data to allow the calculation of effect size. In addition, some of the technologies, such as virtual reality (Villani & Riva, 2008), mobile phones (Grassi, Gaggioli, & Riva, 2009) and pulsed audio-photic stimulation (Wolitzky-Taylor & Telch, 2010), were not relevant to this thesis, while other studies focused on very specific problems such as examination anxiety.

Several studies indicate that disorder specific CCBT and iCBT programs may produce good clinical outcomes in university students. For example, research indicating preliminary efficacy and acceptability in student populations has been found for social phobia (Botella et al., 2010; Tillfors et al., 2008); bulimia (Sanchez-Ortz et al., 2011); PTSD (Lange, van de Ven, Schrieken, & Emmelkamp, 2001); and perfectionism (Radhu, Daskalkis, Arpin-Cribie, Irvine, & Ritvo 2012). A further nine studies (Table 1) have evaluated CCBT or iCBT for anxiety, depression or psychological distress in a tertiary student population, with student populations in Australia (n = 3), the U.S. (n = 3), Canada (n = 1), Ireland (n = 1) and the U.K. (n = 1). The overall results reported in Table 1 provide preliminary support for iCBT and CCBT interventions in this population. However, the generalisability of some of the results described in Table 1 are limited somewhat by reliance on generally small sample sizes, low completion rates, the provision of course credit for participation, and limited levels of acceptability of some of the interventions.

For example, as indicated in Table 1, Richards, Timulak, and Hevey (2012) randomly allocated 80 students to either 8 sessions of email-based CBT with a therapist, or access to self-guided CCBT using the *Beating the Blues* (BtB) program. This study found no significant difference in outcomes on a primary measure of depression, with large effect sizes reported for both groups. However, completion rates were low, at 26% for CCBT and 14% for email-based CBT. In comparison, a study which provided access over 5 weeks to a website to

complete questionnaires, with personalised psycho-education and motivational feedback as a treatment was not effective in reducing stress (Chiauzzi, Brevard, Thurn, Decembrele, & Lord, 2008).

As indicated in Table 1, several other studies also reported results supporting the use of CCBT interventions in students. For example, Braithwaite and Fincham (2007) developed two online interventions, with the primary target to improve relationship dysfunction. In a study of 91 students, both CBT protocols (relationship focused; depression and anxiety focused) were associated with significantly improved scores on measures of anxiety and depression, relative to a control group. These authors conducted a replication study with a sample of 77 students using only the relationship focused intervention, and found improvements sustained at 10 months relative to a control group (Braithwaite & Fincham, 2009). Another study used a simple single session format, providing one CCBT session of 2 hours and 10 minutes (Cukrowicz & Joiner, 2007). This format was associated with significant reductions in anxiety and depression, and medium effect sizes on the primary measures at 2-month follow-up relative to a control group.

Medium effect sizes were also reported on primary measures of anxiety for moderately stressed or depressed students in a study which compared 3 formats of CBT with a control group (Sethi, Campbell, & Ellis, 2010). In this study, 5 sessions of iCBT were compared to face-to-face CBT, and with face-to-face CBT with iCBT. Although limited by a small total sample of 38 participants who received course credit, face-to-face CBT was found to be more effective than iCBT, and the combined treatment was slightly superior to both. However, as *MoodGYM* was used in this study, the limited attractiveness and difficulty of the *MoodGYM* site and material (Christensen et al., 2006) may have been a confounding factor in comparing these conditions.

Overall, there is little evidence for the efficacy of online support groups in improving outcomes for students. Freeman, Barker, and Pistrang (2008) randomly allocated a large sample (n = 283) of students with stress to a website containing text information about student problems, or to the same condition with an online support group. Only 41% of participants provided with access to the support group used it, with no significant difference in outcomes on the subjective measures of wellbeing, problems, life functioning and risk to self or others. In contrast, positive outcomes for anxiety but not mood were reported for the use of a support group in another study (Ellis, Campbell, Sethi, & O'Dea, 2011). However, the small sample size (N = 39) of students in this study who were allocated across three conditions which compared CCBT (*MoodGYM*) to an online forum (*MoodGarden*), and to a control group,

limits the conclusions that can be drawn from these results. Further, the students received course credit for participation, and although significant improvements in symptoms of anxiety were found for both groups relative to control, a confounding factor was the low levels of satisfaction reported by participants, with the authors reporting that only 38% of participants enjoyed using *MoodGYM*, and that only 38% of students would use *MoodGarden* again.

Using an engaging interface may improve adherence and treatment satisfaction, as studies that have used different online interventions have reported higher retention rates and higher acceptability. For example, the entirely self-guided *Online Anxiety Prevention Program*, used by Kenardy, McCafferty and Rosa (2003), had excellent retention rates (90%) and higher ratings of acceptability in a RCT testing an internet delivered prevention for anxiety, although some caution must be taken in interpreting these outcomes as the students received credit for participation. This study recruited 83 University of Queensland students with high anxiety sensitivity, and the 8 students who dropped out citied time constraints as a main reason. A 6 session structure was used, and the study found preliminary efficacy for self-guided iCBT in the reduction of anxiety related cognitions and negative effect in a non-clinical sample compared to a control group.

Only two studies have not provided course credit to participants. The first (Mitchell & Dunn, 2007), reported good outcomes for a small sample of 12 depressed students using the CCBT course *BtB*. They reported high completion rates (83%), good acceptability, and statistically significant reductions in depression scores at post treatment, although changes in anxiety scores were not significant. The other is a recently published RCT (Day et al., 2013) that evaluated the efficacy of a novel five session, self-guided iCBT course (*Feeling Better*) for anxiety, depression and stress in 66 university students. Significant reductions in anxiety, depression and stress were reported, with moderate effect sizes found for anxiety and depression, and results maintained at 6- month follow-up for those who responded, and a completion rate of 61%.

Table 1

CCBT and iCBT Interventions Used With University Student Populations

Author	Targeted	Country	*n*	Intervention Description	Outcome	Completion rate	Course Credit
Day, McGrath, & Wojtowicz (2013)	Depression anxiety & stress	Canada	66	University students who replied to advertising. RCT compared 5 sessions of iCBT (*Feeling Better*) program to waitlist-control. Included weekly telephone contact and emails.	Significant improvements pre-post for anxiety (mod ES), depression (moderate ES) and stress (large ES) on the DASS, sustained at 6 months. Satisfaction not reported.	61%	No
Richards, Timulak, & Hevey (2012)	Depression	Ireland	80	University students who scored in the mild –moderate range on the BDI-II. RCT compared 8 sessions of email-CBT (eCBT) with therapist contact to 8 sessions of self-guided CCBT (*Beating the Blues*).	No significant difference between groups; large pre-post within-group ES in both conditions on CORE-OM and BDI-II. Mean sessions completed eCBT = 3.97; CCBT=4.05. 60% would recommend.	CCBT 26%; Email-CBT 14%	Yes
Ellis, Campbell, Sethi, & O'Dea (2011)	Depression & anxiety	Australia	39	University students aged 18-25. RCT compared 5 modules of CCBT (*MoodGYM*) completed in 3, 60 minute sessions; 3, 60 minute sessions using an online support group (*MoodGarden*); control group.	No significant change for depression, significant improvements in symptoms of anxiety for both groups on K-10 and DASS. MoodGYM satisfaction = 6/13 enjoyed using course; 69% would recommend.	100%	Yes
Sethi, Campbell, & Ellis (2010)	Depression & anxiety	Australia	38	First year university students who scored in the mild–moderate range on the DASS. RCT compared CCBT (*MoodGYM*); face-to-face CBT; face-to-face + CCBT, and control. 5 sessions over 3 weeks.	Significant improvements on DASS-21 for face-to-face, CCBT and face-to-face + CCBT (all moderate ES). Satisfaction not reported.	100%	Yes
Braithwaite & Fincham (2009)	Relationship dysfunction, depression & anxiety	USA	77	Introductory psychology students in romantic relationships. Replication and extension of 2007 study. RCT compared computer based prevention of relationship dysfunction, depression and anxiety (*ePREP*) to control.	Significant reductions in symptoms of anxiety and depression at 8 weeks post-treatment using BDI and BAI, sustained at 10 months. Satisfaction not reported.	100%	Yes

Author	Targeted	Country	*n*	Intervention Description	Outcome	Completion rate	Course Credit
Cukrowicz & Joiner (2007)	Depression & anxiety	USA	152	University Psychology Department's undergraduate student participant pool. Computer-based CBT intervention (*CBASP*) delivered over 2h 10 minutes, in one session.	Significant improvements on the BAI and BDI at 2 month follow-up. At 2-month f/u 80% of participants found information helpful.	100%	Yes
Braithwaite & Fincham (2007)	Relationship dysfunction, depression & anxiety	USA	91	Introductory psychology students in romantic relationships. RCT compared a relationship focused preventive intervention (*ePREP*) with a depression and anxiety focused computer–based preventive CBT intervention (*CBASP*) and a control group.	Significant reductions in symptoms of anxiety and depression at 8 weeks post-treatment using BDI and BAI. Satisfaction not reported.	100%	Yes
Mitchell & Dunn (2007)	Depression	UK	12	University students. CCBT (*Beating the Blues*). Open trial with 8 weekly sessions.	Significant reductions in BDI scores were found following completion, BAI score changes not significant. Two-thirds would recommend to a friend.	83%	No
Kenardy, McCafferty, & Rosa (2003)	Anxiety symptoms	Australia	83	University students with high ASI scores who received credit for participation. RCT compared treatment to waitlist control for a 6 lesson iCBT prevention (*Online Anxiety Prevention Program)*.	Significant reduction in anxiety related cognitions and in negative effect in a non-clinical sample. Mean general satisfaction score of 15.2 (*SD* = 2.14) range 0-21	Treatment 86%; Control 95%.	Yes

Note: CCBT = Computerised Cognitive Behavioural Therapy; iCBT = Online Cognitive Behavioural Therapy; ASI = Anxiety Sensitivity Index; BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; CORE-OM = Clinical Outcomes in Routine Evaluation Outcome Measure; DASS = Depression, Anxiety and Stress Scale; K-10 = Kessler, 10-Item; PCI = Perfectionism Cognitions Inventory; PSS = Perceived Stress Scale; Course Credit = students who received credit towards their university course for participating and completing.

Summary

University students have significantly higher levels of psychological distress than age matched controls, and are predominantly at an age when the incidence of anxiety and mood disorders are peaking. Prevalence studies suggest these problems are increasing, which is increasing demands on under-resourced university counselling services. In addition, a number of barriers including stigma and treatment preferences interfere with help seeking behaviours. This creates a high level of burden for students, who indicate a preference to seek health information online, or from informal sources, rather than consult a doctor or psychologist. For those who seek help, CBT appears effective; however they may not be able to easily access CBT. Online CBT may be highly relevant for student populations, as it takes into account help-seeking preferences, as well as offering benefits of high treatment fidelity, privacy, confidentiality and cost effectiveness.

There is emerging evidence that students with anxiety and depression can be treated effectively with iCBT and CCBT, however, at the time of planning the studies for this thesis there was a paucity of research in this area. These studies indicated preliminary evidence of the efficacy and acceptability of therapist-guided CCBT and iCBT interventions for the student population in reducing anxiety and depression, whilst indicating the importance of using an intervention which is acceptable to consumers. Unfortunately, the majority of studies in this field had provided participants with course credit for participation, and had small sample sizes, which limits the conclusions that can be made. Although iCBT treatments are publicly available, very few individuals complete them, and others which may be available through research trials are typically limited to individuals meeting diagnostic criteria for specific DSM-IV criteria. The literature indicated that acceptability of the intervention is important, and no studies at that time had developed or adapted an intervention specifically for university students. A further issue is that the majority of iCBT treatments were only available through research clinics. Although iCBT may be a good fit to the needs of the student population, little research has explored how to integrate iCBT with existing services, and it is acknowledged that few treatments are successfully disseminated into real-world clinical settings (Proctor et al., 2009). Thus implementation research is important for research teams and organisations, in order to understand how to best integrate evidence-based health interventions (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005; Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; Grol, Wensing, & Eccles, 2005).

Given this background, the overarching aim of this thesis was to develop an effective iCBT intervention for students, and to explore implementation of the intervention as an

alternative treatment option for students. The aims of the studies were to address gaps in knowledge and are detailed below.

Aims of the Current Studies

While it is important that interventions are tested and not simply assumed to generalise to all populations, very little research in the field of iCBT has focused specifically on the student population. Importantly, the effectiveness of iCBT in a real world setting such as a SCS has yet to be examined. To achieve this purpose, a new online intervention, the *UniWellbeing Course* was developed, based on an existing evidence-based intervention, the *Wellbeing Course* (Titov et al., 2013). The *UniWellbeing Course* was designed as a transdiagnostic iCBT treatment for anxiety and depression, and specifically developed to have high content relevance for university students. As the student population is considered to be one where emergent subclinical symptoms are highly likely, it was decided to include students with subclinical symptoms who did not meet DSM-IV criteria for anxiety or depression.

The literature is as yet unclear as to how much, and what form of therapist contact is most efficacious. The potential for iCBT to be offered as a type of open access educational course suggested exploration of the level of therapist contact would be important. Therefore, Studies I and II were designed to investigate the efficacy and acceptability of the *UniWellbeing Course,* with and without weekly therapist contact. In Study I, a RCT, it was predicted that students with either clinical or subclinical levels of anxiety and depression who participated in a therapist-guided version of the *UniWellbeing Course* which included weekly telephone support from a therapist in addition to automated reminder emails, would report a reduction in symptoms of anxiety and depression, relative to a waitlist-control group.

Study II employed an open-trial design using the waitlist-control group from Study I. This group accessed the same version of the *UniWellbeing Course,* including automatic emails, but did not receive weekly telephone support from a therapist. It was predicted that this group would also report a significant reduction in symptoms of anxiety and depression following treatment, and would find the treatment acceptable. In both studies, the secondary objectives were to obtain advice from students about how to modify the content and materials, in order to enhance acceptability within the student population.

Study III was designed to explore implementation of the *UniWellbeing Course* within a SCS. It aimed to explore barriers and other influential factors in moving a treatment into a real-world clinical setting. At October 2012, there were no published studies evaluating the implementation of iCBT in this type of setting, and therefore, Study III was exploratory in

nature. As such, the implementation study aimed to be naturalistic, that is, a treatment that students may have received regardless of whether they participated in a research trial. This study used the Consolidated Framework for Implementation Research (CIFR: Damschroder et al., 2009) to document barriers, and included participant, clinician and service management perspectives. Concurrently, student outcomes were assessed through an open trial design, where clinicians from a SCS provided weekly support to participants who self-selected to participate in the *UniWellbeing Course* as an alternative to treatment-as-usual. The acceptability of the *UniWellbeing Course*, to student consumers of the service, and to clinicians and managers of the SCS as an alternative to face-to-face treatment was assessed. It was predicted that the student participants would report a significant reduction in symptoms of anxiety and depression following treatment, and find the treatment acceptable. It was also predicted that the clinicians and management team would rate the intervention as acceptable. By completing these studies it was hoped that an effective and acceptable iCBT treatment would be created for university students, and that dissemination would be facilitated, increasing the availability of evidence based treatments.

CHAPTER TWO

Study I: A Randomised Controlled Trial of Transdiagnostic Internet Delivered Cognitive Behavioural Therapy for University Students with Symptoms of Anxiety and Depression.

Abstract

Anxiety and mood disorders are prevalent among university students. University counselling services offer free treatments, but many students experience barriers that prevent access to evidence based treatment. This randomised controlled trial examined whether administering transdiagnostic, therapist-guided cognitive behavioural therapy via the internet (iCBT) for students is efficacious and acceptable. Fifty-two university students were randomly allocated to a treatment group that received a five week course of iCBT or to a waitlist-control group. Treatment group participants received weekly clinical contact provided by a therapist, and automated emails. Primary outcome measures were the Patient Health Questionnaire 9-Item (PHQ-9) and the Generalized Anxiety Disorder 7-Item (GAD-7). Reductions in the numbers of diagnoses of anxiety or depression were assessed using the Mini International Neuropsychiatric Interview (MINI). At post-treatment, mixed models analyses revealed outcomes for the treatment group to be superior to the waitlist-control group on the PHQ-9 and GAD-7 measures. These outcomes were associated with large within-group effect sizes for the treatment group on both the PHQ-9 (Cohen's d = 1.13) and GAD-7 (d = 0.96) at post-treatment, with further improvements found at 3-month follow-up. Moderate between-group effect sizes on the PHQ-9 (d = 0.67) and GAD-7 (d = 0.52) were observed at post-treatment. Clinically significant reductions in the number of diagnoses of anxiety and depression were observed using the MINI. Importantly, less than 27 minutes of clinician time was required per participant during the course, and students rated the intervention as highly acceptable. The results provide preliminary support indicating that therapist-guided transdiagnostic iCBT for university students is effective, acceptable, and associated with significant improvements.

Introduction

Prevalence rates of psychiatric illness in youth have been estimated at between 20-39% by age 17-18 years (Costello et al., 2003; Jaffee et al., 2005; Romano et al., 2001), with three quarters of first diagnoses occurring between the ages of 16 and 25 (Andrews, 2002; Andrews

& Wilkinson, 2002). High co-morbidity between mood and anxiety disorders is common (ABS, 2009), with delays in treatment for anxiety and depression associated with a more chronic course (Post et al., 2006; Ryan, 2003). In most developed countries, over 50% of young people are in higher education (Birrell & Edwards, 2007; USDOE, 2009), and there is evidence that internationally, elevated psychological distress among university students may be significantly higher than in the general population (Brimstone et al., 2007; Roberts et al., 1999; Royal College of Psychiatrists, 2003; Stewart-Brown et al., 2000). However, despite the high prevalence of psychological distress, the majority of students with depression and anxiety either do not seek treatment, or delay seeking professional help (Eisenberg et al., 2007b; Stallman, 2010). Barriers such as stigma, wait times for treatment, and a preference to seek help from family, friends, or the internet (Rickwood et al., 2007; Ryan et al., 2010) interfere with seeking help from mental health services. In addition, student counselling services report increasing demands for services (Benton et al., 2003), despite low worldwide utilisation rates for student counselling services of between 2 to 4% (Raunic & Xenos, 2008). This suggests a need to offer acceptable, cost effective treatments, and that new and innovative treatment options which utilise the internet may hold potential.

Over the last decade, efficacious CCBT and iCBT has been developed and administered in primary care settings (Barak et al., 2008; Cuijpers et al., 2009; Marks et al., 2007). Meta-analyses have found iCBT to be effective across several anxiety disorders, and for depression (Andrews et al., 2010; Barak et al., 2008; Cuijpers et al., 2009), with outcomes of a similar clinical magnitude to face-to-face therapy (Barak et al., 2008; Bergström et al., 2010; Cuijpers et al., 2009; Hedman et al., 2011; Kiropoulos et al., 2008; Wright et al., 2005). Transdiagnostic iCBT interventions have recently been developed which are based on the premise that anxiety and depressive disorders share similar symptoms and temperamental antecedents such as negative affect or neuroticism, are highly co-morbid, and respond to similar treatments (Goldberg, 2010). Such treatments have demonstrated efficacy at treating both anxiety and depressive disorders using content that targets multiple disorders (Johnston Titov, Andrews, Spence, & Dear, 2011; Titov et al., 2011). For example, a recent study of a self-guided transdiagnostic iCBT intervention designed to treat anxiety and depression in the general population, the *Wellbeing Course*, reported large effect sizes at 3-month follow-up, with results sustained at 12-month follow-up (Titov et al., 2013). At the time of preparing this research, no studies were identified which had evaluated an iCBT intervention specifically for the university student population, although earlier reports indicated that iCBT may be suitable for students with anxiety (Kenardy et al., 2003), and depression (Mitchell & Dunn, 2007).

Several authors have recommended that online interventions should be tailored to users (Ybarra & Eaton, 2005), and there is emerging evidence that where this has not happened that users can report dissatisfaction with the intervention (Ellis et al., 2011; Sethi et al., 2010).

The present study explored the efficacy of a brief version of the *Wellbeing Course*, the *UniWellbeing Course*, adapted specifically for university students. The primary aim of this study was to evaluate the efficacy and acceptability of the *UniWellbeing Course* in a randomised controlled trial (RCT) comparing a treatment group, who received weekly therapist-contact, with a waitlist control group. A secondary objective was to obtain advice from participants about how to modify the content and materials, in order to enhance acceptability.

Method

Design and power. The design involved a CONSORT compliant two-group randomised controlled trial (n = 55) comparing an immediate treatment group (treatment group) (n = 29) with a waitlist deferred-treatment control group (control group) (n = 23) from pre to post treatment. The treatment group was followed through to 3-month follow-up, whereas the control group received treatment at the post-treatment time-point of the treatment group. Treatment consisted of a 5 week therapist-guided iCBT course which included weekly contact from a therapist and automated emails.

Power calculations indicated that a sample size of 26 participants in each group was sufficient to detect a between-groups effect size (*ES*) of 0.7 with power of 80% (one-tailed), which was the minimum based on similar studies (Robinson et al., 2010; Titov, Andrews, Choi, Schwencke, & Mahoney, 2008; Titov et al., 2010c; Wims, Titov, Andrews, & Choi, 2010), but more were recruited to hedge against attrition. The study was not powered to detect small differences between the groups.

Ethical approval for the trial was provided by the Human Research Ethics Committee of Macquarie University, protocol HREC 5201100795. The trial was registered on the ANZCTR trial registry as ACTRN12612000212853.

Hypotheses. The hypotheses were that: 1) Significant improvements for those in the treatment group on primary measures of depression and anxiety will be found at post-treatment and at 3-month follow-up on the primary outcome measures, the PHQ-9 and GAD-7, and the secondary measures of psychological distress and disability, the K10 and SDS, respectively; 2) reductions will be observed in the numbers of those in the treatment group

meeting diagnostic criteria for diagnoses of major depressive disorder (MDD), generalised anxiety disorder (GAD), social phobia (SP), or panic with or without agoraphobia (Pan/Ag) and; 3) Participants will rate the treatment as acceptable.

Participants and recruitment. Participants with clinical or subclinical levels of anxiety or depression were recruited from the student population of Macquarie University (MQ), Australia, which has an enrolment of 38,000 students across four faculties (Universities Australia, 2013). Applicants applied online to a clinical research website, www.ecentreclinic.org, after reading details about the study, the inclusion and exclusion criteria, and a participation incentive (an iPad was offered in a prize draw to students who completed the follow-up questionnaires). Recruitment commenced in early March 2012. Promotions of the trial were conducted through multiple mediums, including social media such as the MQ Facebook page, MQ Welfare Facebook page, via MQ websites including the MQ homepage, library page, and welfare sites, via print advertising in a MQ postgraduate magazine, the distribution of over 3000 leaflets, a poster campaign involving more than 50 posters across faculties and local General Practitioner (GP) services, posters in Student Counselling Services (SCS), marketing to the Heads of Colleges, and presentations and information sessions for student counsellors, student advisers and student mentors. Information about the study was also provided to the International Student Office and the MQ Postgraduate Representative Association office. In addition 2000 flyers were hand distributed to university students at MQ orientation days at the beginning of semester.

Due to the volume of applications being lower than initially anticipated, the recruitment period continued over a six month period. In total, 95 individuals applied and 63 met the following inclusion criteria:(1) Enrolled as a student at MQ; (ii) Currently living in Australia; (iii) 18+ years of age; (iv) Have access to a computer, the internet, and use of a printer; (v) Not currently participating in CBT; (vi) Not currently experiencing a psychotic mental illness or severe symptoms of depression (defined as a total score ≥23 or responding >2 to Question 9 (suicidal ideation) on the Patient Health Questionnaire-9 item (PHQ-9; Kroenke, Spitzer, & Williams, 2001); (vii) If taking medication (people taking benzodiazepines were excluded), had been taking the same dose for at least 1 month and did not intend to change that dose during the duration of the course; (viii) Provided informed consent; (ix) Were not Chinese students studying at MQ (all Chinese students who applied were redirected to a similar clinical trial specifically for Chinese students).

Applicants who did not meet these criteria (*n* = 32) were informed via an on-screen message and were sent an email thanking them for their application and encouraging them to discuss their symptoms with their GP. Of these, 15 participants were excluded for incomplete applications; 6 applicants were excluded for severe symptoms of depression; 5 were excluded as they were not MQ students, and 6 were redirected to the online CBT course for Chinese students. The details of participant flow are included in Figure 1. Participants who met the inclusion criteria (*n* = 63) subsequently completed a 10-item questionnaire enquiring about demographic details.

Successful applicants were contacted within two working days by telephone and administered a diagnostic interview using the Mini International Neuropsychiatric Interview 5.0.0 (MINI: Sheehan et al., 1998), to assess whether they met DSM-IV criteria for an anxiety disorder or depression. Participants were randomised using a true randomisation process (www.random.org) and a list generated by an independent person, to either the treatment or control group. Allocation preceded the MINI interview, and the dependence on self-report measures precluded blinding. Participants who could not be contacted (*n* = 7) or who withdrew without completing the MINI (*n* = 1) were sent an email thanking them for their application and encouraging them to discuss their symptoms with their GP or with the SCS at MQ. Applicants who satisfied all criteria, and who completed a consent form and the MINI were included in the study (*n* = 55), with an exception made for one participant in the control group who was hearing impaired and unable to complete the telephone MINI due to disability. These assessments were conducted by the candidate, who was not blinded to the participant's condition. The time taken to conduct and score each telephone-based diagnostic interview (*n* = 54) was approximately 60 minutes.

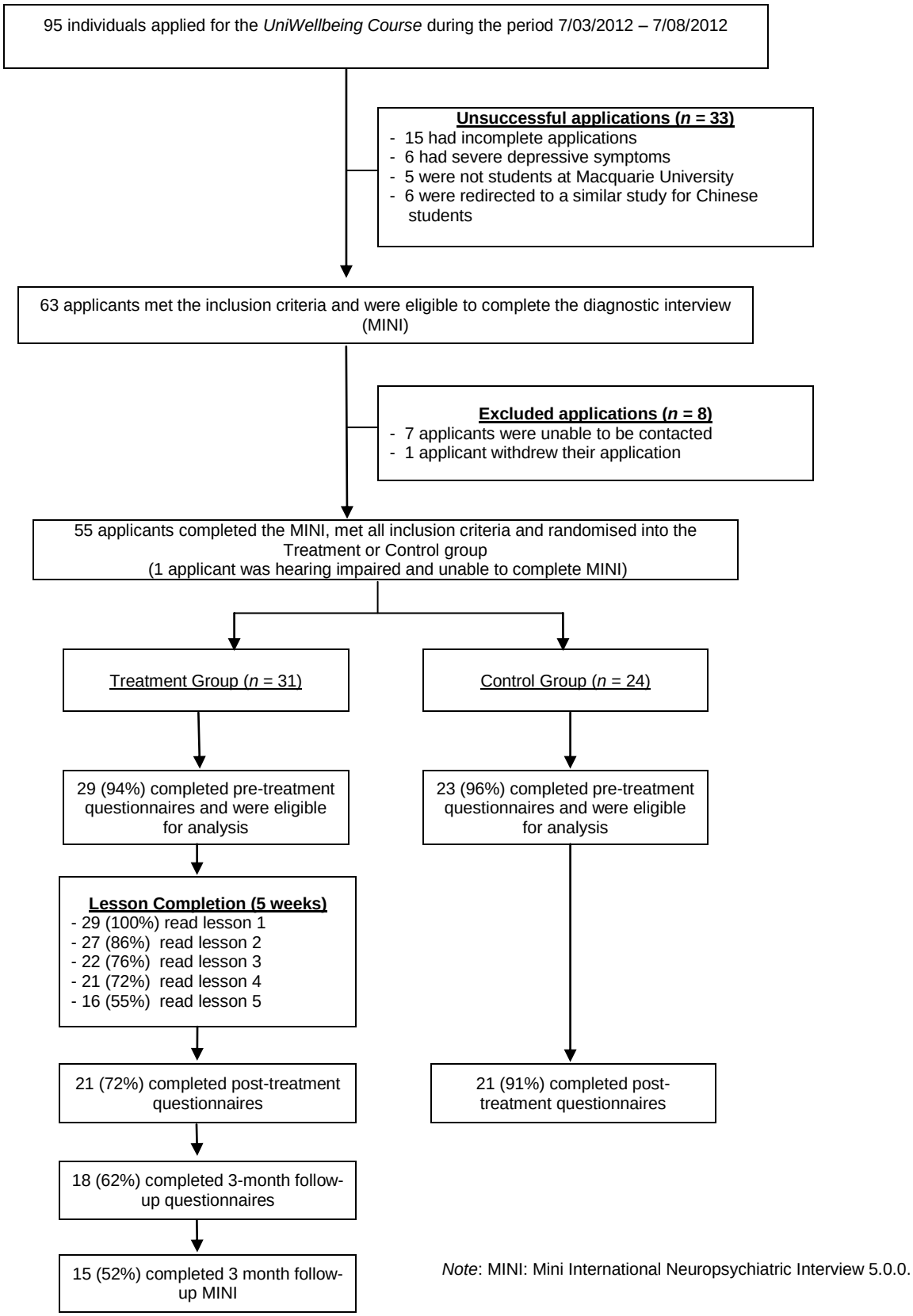

Figure 1. Randomised controlled trial flow chart. Illustrates participant flow from application to 3-month follow-up.

Primary outcome measures

Diagnostic interviews. The Mini International Neuropsychiatric Interview Version 5.0.0 (MINI: Sheehan et al., 1998) is a brief diagnostic interview developed to determine the presence of current and lifetime Axis 1 disorders using DMS-IV diagnostic criteria. Psychometric evaluations (Lecrubier et al., 1997) indicate it has excellent inter-rater reliability (*k* = .88-1.00) and adequate concurrent validity with the Composite International Diagnostic Interview (CIDI: World Health Organisation, 1990).

Patient Health Questionnaire - Nine Item (PHQ-9: Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a nine-item measure of the symptoms and severity of major depressive disorder based on the DSM-IV criteria for depression. A total score of 10 on the PHQ-9 has been identified as an important threshold for identifying DSM-IV congruent depression, and increasing scores indicate greater symptom severity (Kroenke et al., 2001). Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) with a maximum score of 27. Scores ranges represent mild (5-9); moderate (10-14); moderately severe (15-19), and severe (20-27) levels of depression. Psychometric studies indicate a high internal consistency of .86-.89 (Kroenke et al., 2001) and the measure is sensitive to change (Kroenke et al., 2010) with a drop of at 5 points or more considered a clinically significant response (Kroenke & Spitzer, 2002). The internal consistency of the PHQ-9 in the current study was Cronbach's $\boldsymbol{\alpha}$ = .82.

Generalized Anxiety Disorder – 7 Item Scale (GAD-7: Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 comprises 7 items measuring symptoms and severity of GAD based on the DSM-IV diagnostic criteria for GAD. Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) and severity ranges are described as: 5 - 9 *mild;* 10 - 14 *moderate*; and 15-21 *severe* anxiety (Löwe et al., 2008). The GAD-7 has high internal consistency (.89), a test retest correlation of 0.83, correlates highly when administered as self-report or via a clinician, and has good convergent validity with other anxiety scales (Kroenke, Spitzer, Williams, & Löwe, 2010; Spitzer et al, 2006). Evidence indicates the GAD-7 is sensitive to DSM-IV congruent GAD, social phobia, and panic disorder with increasing scores indicating greater severity of symptoms (Löwe et al., 2008). The GAD-7 is increasingly used in research and in large scale dissemination studies as a generic measure of change in anxiety symptoms (Clark et al., 2009; Richards & Suckling, 2009). The internal consistency of the GAD-7 in the current study was Cronbach's α = .88.

Secondary outcome measures.

Sheehan Disability Scales (SDS: Sheehan, 2000). The SDS comprises five items with a maximum score of 50 and higher scores indicating greater impairment. Scores ranging from 0 (*not at all*), 1-3 (*mildly*), 4-6 (*moderately*), 7-9 (*markedly*) to 10 (*extremely*) that measure impairment in psychosocial functioning across three domains (work/study, family, social) with high internal consistency (Cronbach's α = .89; Leon, Olfson, Portera, Farber, & Sheehan, 1997), a sensitivity of 83% and a specificity of 69% (Leon et al., 1997). The internal consistency of the SDS in the current study was Cronbach's α = .86.

Kessler-10 Item (K-10: Kessler et al., 2002). The K-10 is a 10 item measure of psychological distress, with strong evidence supporting the relationship between the K-10 and a diagnosis of anxiety and depressive disorders (Andrews & Slade, 2001). Items are scored on a 5-point scale from 0 (*none of the time*) to 5 (*all of the time*) with a maximum score of 50. Higher scores reflect increased symptoms. The K-10 has been reported as having excellent internal consistency, even with ethnically diverse populations (Fassaert et al., 2009). The internal consistency of the K-10 in the current study Cronbach's α = .86.

Administration of outcome measures. The MINI was administered by telephone at pre-treatment and 3-month follow-up. Primary and secondary outcome measures were administered over the internet at application, pre-treatment; post-treatment and at 3-month follow-up. Primary outcome measures were also administered weekly to monitor participant wellbeing. Research indicates that the online administration of self-report questionnaires is reliable and equivalent to pen and paper versions of self-report questionnaires (Carlbring et al., 2007; Donker, van Straten, Marks, & Cuijpers, 2010; Hedman et al., 2010).

Procedure. Following MINI administration, applicants who met all inclusion criteria were randomised into the Treatment or Control group. On the start date for their group, participants received an email welcoming them to the *UniWellbeing Course*. This email provided login details and answers to frequently asked questions about system requirements and using the course.

Participants were directed to login and complete the online questionnaires within 7 days, to read one lesson each week, to make use of additional resources, and to practice the homework tasks. Participants were sent a maximum of two email reminders to complete the pre-treatment questionnaires. Two participants did not complete these questionnaires and were excluded on day 8. These participants were sent an email thanking them for their interest

in the *UniWellbeing Course* and encouraging them to discuss their symptoms with their GP or with MQ SCS. All participants in the treatment group who completed the pre-treatment questionnaires and who began lessons (n = 29), and all participants in the control group who completed pre-treatment questionnaires (n = 23) were eligible for analysis. Participants were telephoned once each week by the therapist who discussed the lesson content, encouraged completion of homework tasks and provided clinical assistance to the participant. The frequency and duration of each contact was recorded. In addition, participants received at least two automated emails each week during the course: A notification email was sent when new lessons became available, and up to two reminder emails were sent if participants did not start a lesson within 7 days. Participants also received emails when they completed a lesson that reinforced progress. They also received an additional email during the week in which graded exposure was introduced, which normalised increases in anxiety due to beginning exposure exercises.

At post-treatment and at 3-month follow-up, participants in the treatment group were sent an email asking them to log in and complete the post-treatment questionnaires. Two further email reminders were sent if questionnaires were not completed. In addition, at 3-month follow-up, the therapist telephoned participants to encourage completion of the questionnaires, and to complete the MINI interviews. At the post-treatment time-point, additional questions regarding treatment satisfaction were administered to participants in the treatment group. At this time, the participants in the control group were also sent a welcome email inviting them to complete the post-treatment questionnaires and to begin a self-guided version of the *UniWellbeing Course* (described in Study 2). Since the control group participants began treatment at the treatment group post-treatment point, they did not complete the 3-month follow-up measures.

Intervention. The treatment group received access to the therapist-guided *UniWellbeing Course*. This was based on an existing transdiagnostic iCBT course, the *Wellbeing Course,* a five-lesson online intervention based on models of cognitive behavioural and interpersonal therapies (Titov et al., 2013) delivered over 8 weeks. The course systematically teaches core psychological skills that aim to increase the frequency of cognitions and behaviours that promote emotional health, and reduce those that maintain distressing symptoms. Participants are strongly encouraged to practice the psychological skills taught in the course, and to adopt these into their everyday lives. Material from the *Wellbeing Course* was modified to make it more relevant for a student population. These changes included replacing existing images

with images depicting students and younger people, and modifying case vignettes to include issues and scenarios relevant to students. The total time taken to source new material, review the existing material, rewrite and condense material in various formats was five weeks. The content was refined twice, based on feedback from three students during pilot testing who read and provided feedback about the material. Additional changes to the *UniWellbeing Course* included moving some information from the lessons to the resources section where it could be more easily downloaded. Each *UniWellbeing Course* lesson comprised a series of PowerPoint slides, which included text and graphics, with between 54 to 63 slides in each lesson. Examples are shown in Figures 2, 3, and 4.

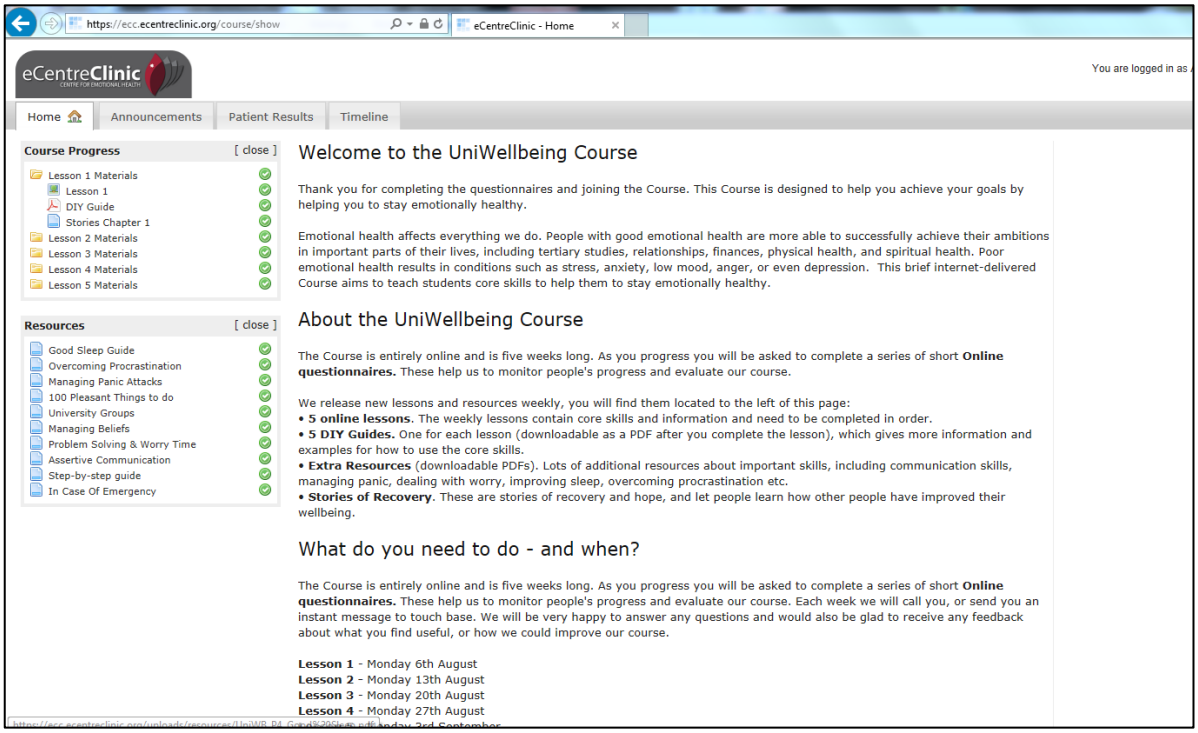

Figure 2. Website homepage. This figure illustrates the website page viewed by participants after logging in to the *UniWellbeing Course*.

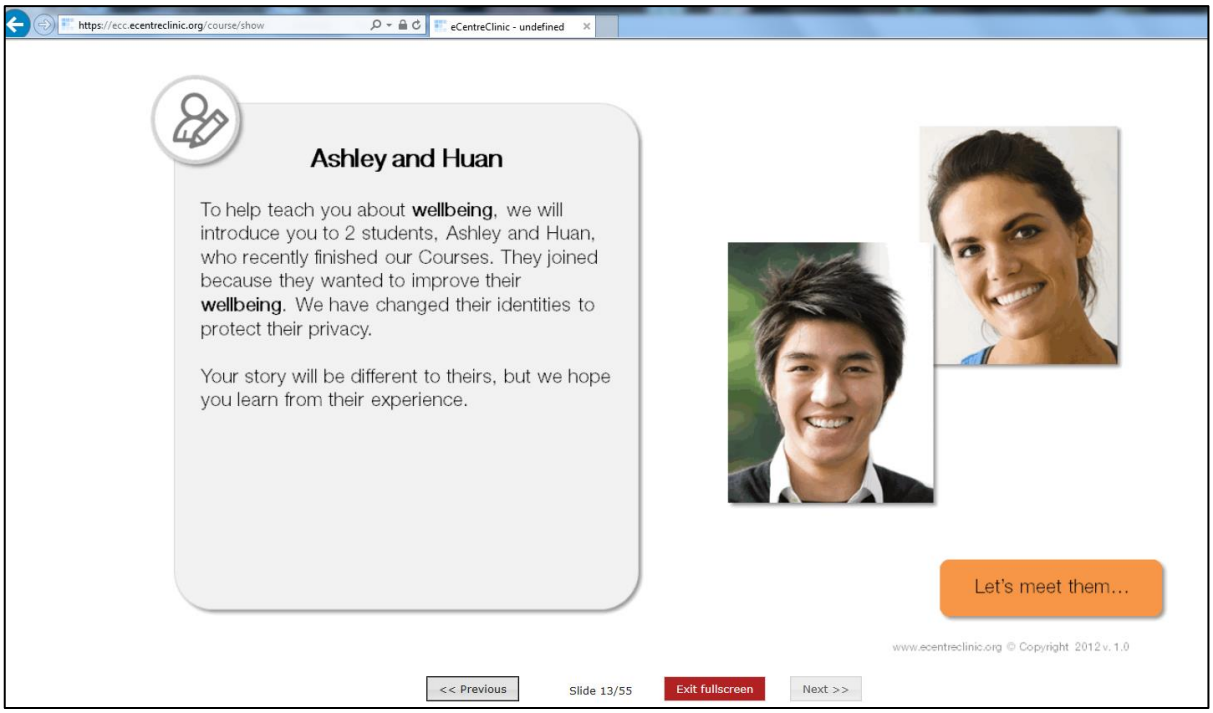

Figure 3. Vignette characters. This figure illustrates how the vignette characters were introduced to participants using the *UniWellbeing Course* slides.

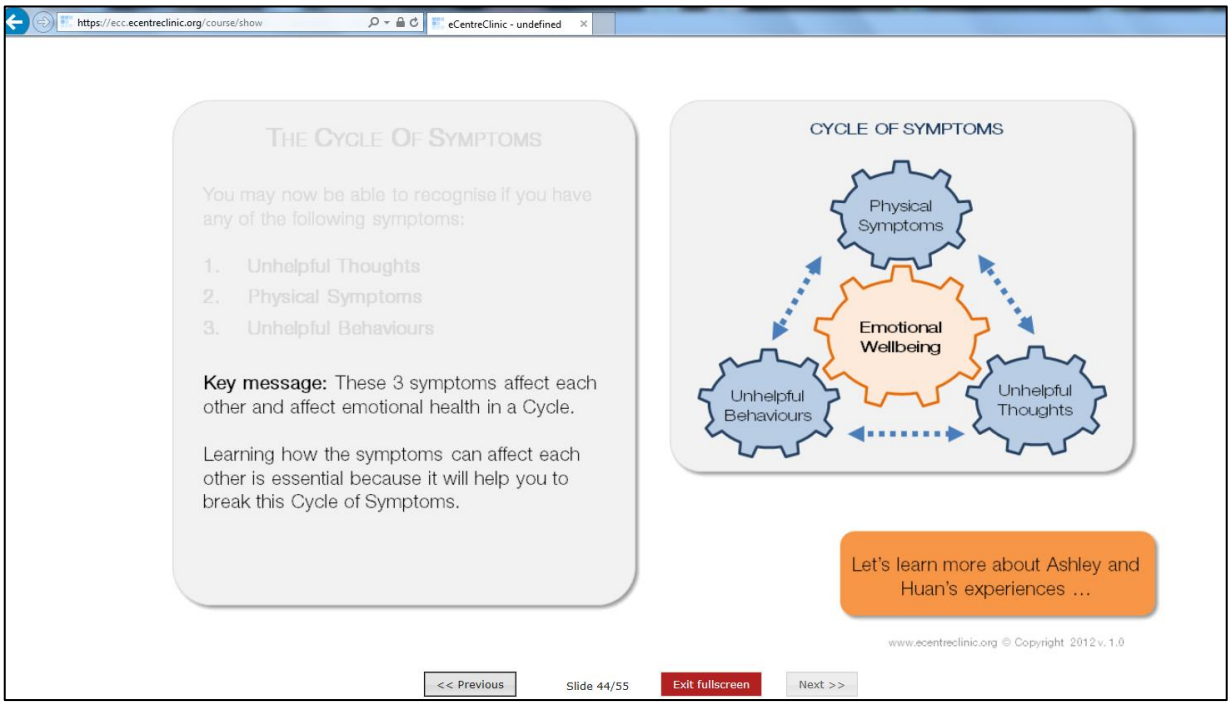

Figure 4. *UniWellbeing Course* lesson example. This figure illustrates how psycho-education was presented to participants using the *UniWellbeing Course* lesson 1 slides.

The 5 online lessons were available over 5 weeks and a new lesson was available to read each Monday of the course. The content of the lessons and additional resources is described in Table 2. Each lesson contained a review of the skills described in previous lessons, an introduction to the skills described in that lesson, examples and vignettes of students with depression and anxiety practicing those skills, and a summary of the main points described in that lesson. Participants also had access to a Do-It-Yourself (DIY) Guide, which was downloadable as a PDF document. This contained a summary of the main points in that lesson and recommended homework tasks. Additional written resources were delivered in PDF format, and became available as the course progressed. These comprised additional skills that were not discussed in detail in the lessons, but which are often helpful to people with anxiety and depression, including information about problem solving skills, pleasant event scheduling, (which incorporated a list of social activities and clubs available to students at MQ), sleep hygiene, overcoming procrastination, and other skills relevant to psychological wellbeing strategies.

With the exception of lesson 1, clinical terms such as GAD, social phobia, or panic disorder were not used in the course; rather, the terms anxiety, stress, low mood, worry, anxiety about panic, or anxiety about social situations were used throughout the course. Communication with the therapist occurred at least weekly. This contact was conducted via telephone or a private text-based messaging facility which allowed for secure email-type messages between the participants and the therapist. In addition, at least two automated emails per week were sent to participants at specific times during treatment to notify them of new resources that had become available or to encourage them to complete tasks.

Table 2

UniWellbeing Course Lesson Content

Lesson	Primary Lesson Content (slides)	Additional PDF Resources (downloadable resources)
1	Education about the prevalence, symptoms and treatment of depression and anxiety, including an explanation of the functional relationship between symptoms.	1. FAQ's about logging into and using the course. 2. Emergency contact information. 3. Education about techniques for structured problem solving. 4. Education about techniques to improve assertive communication skills. 5. Lesson 1 DIY Guide (Lesson summary and homework guide).
2	Basic principles of cognitive therapy, including strategies for monitoring and challenging thoughts.	6. Education and guidelines about challenging dysfunctional beliefs, including positive, negative and core beliefs. 7. Lesson 2 DIY Guide (Lesson summary and homework guide).
3	Instructions about controlling physical symptoms including de-arousal strategies and pleasant event scheduling.	8. Education about techniques for managing panic attacks. 9. 100 Pleasant things to do resource, including a list of social, sporting, and support groups at MQ. 10. Lesson 3 DIY Guide (Lesson summary and homework guide).
4	Education and guidelines about practicing graded exposure.	11. Education about techniques for good sleep hygiene. 12. Education about techniques for overcoming procrastination. 13. Lesson 4 DIY Guide (Lesson summary and homework guide).
5	Information about relapse prevention and constructing relapse prevention plans.	14. Lesson 5 DIY Guide (Lesson summary and homework guide).

Therapist. The candidate, an experienced and provisionally registered Psychologist, provided all clinical contact with participants (telephone calls, private messaging, and diagnostic interviews) and collated all data with supervision from Clinical Psychologists experienced in delivering online treatments. Therapist contact was delivered using a secure messaging system or by telephone calls, with participants in the treatment group encouraged to engage in weekly contact, limited to approximately 15 minutes per participant, except if more time was clinically indicated.

The aim of this contact was to reinforce progress, to summarise key skills described in the lesson for that week, to encourage practice of homework tasks, to encourage the completion of further lessons, to normalise challenges during recovery, to normalise study and exam anxiety, and to describe content and materials that was to be released. Participants were invited to engage in discussion of the materials, including how to apply them, and to provide feedback about the material to the clinician.

Safety. Participants' responses to the PHQ-9 were automatically monitored, and those whose PHQ-9 total scores increased during the course from pre-treatment by more than 5 points, and who also had a total score of ≥15, indicating the presence of moderately severe depression were contacted by the therapist via an email providing instructions about how to contact crisis services in the event of a mental health emergency. However, those with PHQ-9 scores of 20 or more, indicating severe depression, or scoring '3' to question 9 of the PHQ-9 indicating suicidal ideation, were telephoned by the therapist who carried out a risk assessment and implemented a safety management plan.

Negative outcomes. The number of times safety protocols were triggered because of elevated PHQ-9 scores, and the proportion of participants with significant deterioration in PHQ-9 or GAD-7 scores were recorded. The latter was calculated based on a completer analysis and defined as an increase in PHQ-9 or GAD-7 scores of 5 or more points from pre-treatment. This was based on the classification suggested by Kroenke and Spitzer (2002).

Clinical significance. Three criteria of clinical significance were employed, using an intention-to-treat model, with pre-treatment data carried forward if data was missing. Measures of remission and recovery were as described in recent dissemination studies (Richards & Suckling, 2009).

Remission. Pre-treatment, post-treatment, and 3-month follow-up PHQ-9 and GAD-7 scores were compared with clinical cut-offs to provide an index of remission. This was defined as the proportion of participants who initially scored at or above, and subsequently below, the following cut-offs: GAD-7 total score ≥8 (Löwe et al., 2008), and PHQ-9 total score ≥10 (Gilbody, Richards, Brealey, & Hewitt, 2007; Kroenke et al., 2001, 2010).

Recovery. An estimate of recovery was made by identifying the proportion of participants in each group who demonstrated a significant reduction in their symptoms. This was defined as a reduction of 50% of pre-treatment PHQ-9 or GAD-7 scores.

Prevalence. Changes in the prevalence of principal and additional disorders of anxiety or depression in the treatment group from pre-treatment to 3-month follow-up were calculated based on the results of diagnostic interviews using the MINI. These were analysed with chi-square tests.

Statistical analysis. Participants who did not complete pre-treatment questionnaires were not included in analyses. Group differences in demographic data were analysed with independent *t*-tests and chi-square tests. A mixed-models approach with an autoregressive covariance structured and using maximum likelihood estimation was identified as the best way to handle missing data at post-treatment and 3-month follow-up (Verbeke & Molenberghs, 2009).

Differences in questionnaire scores between groups were compared from pre-treatment and post-treatment, with outcomes compared from post-treatment and 3-month follow-up using pairwise comparisons. In order to preliminarily explore the differences between the treatment group and the control group with regards to the inclusion of asymptomatic participants, the primary outcome measures were also analysed following exclusion of participants who scored <10 on the PHQ-9 and <8 on the GAD-7. Effect sizes (Cohen's *d*) and 95% effect size confidence intervals were calculated using the estimated marginal means for within and between-group changes, based on the pooled standard deviation with an effect size of 0.2 to 0.5 described as small, between 0.5 to < 0.8 as medium, and ≥ 0.8 as large (Cohen, 1988). All analyses were performed using SPSS version 21.0.

Results

Baseline data. As indicated in Table 3, chi-squared and independent *t*-tests revealed there were no significant between-group pre-treatment differences in gender, age, level of education, mode of study, hours worked, marital status, education, employment, or other

demographic characteristics (all *p*s > .05). At pre-treatment, there was a statistically significant difference in mean number of diagnoses between the treatment and control groups, t (49) = 2.12, p = .039. The treatment group had a higher number of mean diagnoses of anxiety or depression (M = 2.31; SD = 1.42) than the control group (M = 1.45; SD = 1.44). Two participants (7%) in the treatment group and 5 participants (23%) in the control group did not meet criteria for a diagnosable disorder of anxiety or depression at pre-treatment. ANOVA's indicated no differences at pre-treatment on the PHQ-9, GAD-7, K-10 or SDS (all *p*s > .05).

Demographic characteristics of the sample. The sample included students with a range of demographic characteristics, but as indicated in Table 3, comprised mostly full time students in undergraduate programs, who were confident using the internet.

Adherence and attrition. In the treatment group, Lesson 1 was read by 100% of participants; Lesson 2 by 86% of participants; Lesson 3 by 76% of participants; Lesson 4 by 72% of participants, and Lesson 5 by 55% of participants. Sixteen participants (55%) completed the course, defined as starting all lessons within 5 weeks. This definition was chosen as it was not possible to accurately establish whether participants read the entire lesson. Post-treatment data was collected from 21/29 (72%) participants in the treatment group and from 19/23 (83%) participants in the control group. In the treatment group at 3-month follow-up, MINI data was obtained for 15/29 (52%) participants, and 3-month follow-up questionnaire data was obtained for 18/29 (60%) participants.

Table 3

Demographics of the Treatment and Control Groups

Demographic	**Treatment Group**		**Control Group**		**Total**		**Significance**
	n	%	*n*	%	*n*	%	
Gender							
Male	10	65.5	8	34.8	18	34.62	$X^2(1,N = 52) = 0.01$, $p = .982$
Female	19	65.5	15	65.2	34	65.38	
Age							
Mean (years)	27.6	(9.79)	28.1	(11.50)	27.7	(10.43)	t (50) = 0.16, $p = .875$
Range (years)	18-55	-	18-68	-	18-68	-	
Marital Status							
Single/Widowed	23	79.3	13	56.5	36	69.2	$X^2(1, N = 52) = 3.13$, $p = .077$
Married/defacto	6	20.7	10	43.5	16	30.8	
Student Status							
Full Time Student	22	75.9	17	73.9	39	75.00	$X^2(1, N = 52) = 0.03$, $p = .872$
Part Time Student	7	24.1	6	26.1	13	25.00	
Type of Degree Program							
Undergraduate	25	86.2	15	65.2	40	76.9	$X^2(1, N = 52) = 3.18$, $p = .074$
Post Graduate	4	13.8	8	34.8	12	23.1	
Number of semesters enrolled at MQ							
Mean	4.28	(3.22)	3.65	(3.39)	3.87	(3.30)	t (50) = 1.01, $p = .318$
Range	1-15	-	0-16	-	0-16	-	
Number of semesters enrolled elsewhere							
Mean	2.21	(3.16)	2.96	(4.64)	2.54	(3.86)	t (50) = 0.69, $p = .492$
Range	0-10	-	0-16	-	0-16	-	

Demographic	**Treatment Group**		**Control Group**		**Total**		**Significance**
	n	%	*n*	%	*n*	%	
Study Mode							
Internal study mode	27	93.1	19	82.6	46	88.46	$X^2(1, N = 52) = 1.38, p = .239$
External study mode	2	6.9	4	17.4	6	11.54	
Faculty							
Arts	11	27.9	5	21.7	16	30.77	$X^2(3, N = 52) = 1.76, p = .623$
Science	6	20.7	5	21.7	11	21.15	
Business	5	17.2	6	26.1	11	21.15	
Human Sciences	7	24.14	7	30.5	14	26.92	
Enrolment type							
Local	25	86.2	19	82.6	44	84.62	$X^2(2, N = 52) = 0.60, p = .742$
International	3	10.3	4	13.8	7	13.46	
Other	1	3. 5	1	4.4	2	3.85	
Living arrangements							
At home with family	20	69.0	17	73.9	37	71.2	$X^2(1, N = 52) = 0.15, p = .696$
By self/share accommodation	9	31.0	6	26.1	15	28.8	
Hours of internet use per week							
0-9 per week	3	10.3	0	0.0	3	5.77	$X^2(2, N = 52) = 5.49, p = .064$
10 -19 per week	13	44.8	6	26.1	19	36.54	
20+	13	48.8	17	73.9	30	57.69	
Confidence with the internet							
Very confident	18	62.1	17	73.9	35	67.31	$X^2(3, N = 52) = 2.00, p = .572$
Confident	10	34.5	5	21.7	15	28.85	
Average	1	3.5	1	4.4	2	3.85	
Mildly confident	1	3.5	0	0.00	1	1.9	

Note: Standard deviations are shown in parentheses.

Primary outcome measures. Pre-treatment to post-treatment observed and estimated means; standard deviations; confidence intervals and effect sizes (Cohen's *d*) for each group are shown in Table 4.

PHQ-9.

Between Group. The analyses examining PHQ-9 scores (Table 4) revealed a significant effect for Time ($F_{2, 75.11} = 24.869$, $p < .001$) and a significant Time by Group interaction, ($F_{1, 105.75} = 4.00$, $p = .048$), but no significant effect for Group ($F_{1, 92.87} = 2.73$, $p = .102$). The pairwise comparisons revealed significant differences between the treatment and control groups at post-treatment ($p < .017$) with the treatment group reporting lower symptoms on the PHQ-9.

Within Group. Pairwise comparisons also revealed that the treatment group improved significantly from pre-treatment to post-treatment ($p < .001$), with further improvements observed from post-treatment to follow-up ($p < .010$). The pairwise comparisons revealed the control group did not improve significantly from pre-treatment to post treatment ($p = .184$).

PHQ-9, symptomatic sample.

Between Group. Participants in the treatment group ($n = 19$) who scored ≥10 on the PHQ-9 at pre-treatment were compared to participants in the control group ($n = 11$) who scored ≥10 on the PHQ-9 at pre-treatment. This analysis revealed significant main effects for Time ($F_{2, 49.60} = 19.64$, $p < .001$) but no significant Time by Group interaction ($F_{1, 57.48} = 3.71$, $p = .059$), or significant Group effect, ($F_{1, 49.24} = 3.69$, $p = .060$). The pairwise comparisons revealed significant differences between treatment and control groups at post-treatment ($p = .011$).

Within Group. The pairwise comparisons revealed that the treatment group scores at post-treatment were significantly lower than pre-treatment ($p < .001$) and that their scores at 3-month follow-up were significantly lower again than at post-treatment ($p = .034$). The pairwise comparisons revealed that the control group scores at post-treatment were not significantly lower than pre-treatment ($p = .336$).

GAD-7.

Between Group. The mixed-models analyses examining GAD-7 scores (Table 4) revealed significant main effects for Time ($F_{2, 70.36} = 15.73$, $p < .001$) and Group ($F_{2, 80.51} = 4.73$, $p = .033$), but these were subsumed under a significant Time by Group interaction, ($F_{1, 101.05} = 7.80$, $p = .006$). The pairwise comparisons revealed significant differences between the treatment and control groups at post-treatment ($p = .001$) with the treatment group reporting lower symptoms on the GAD-7.

Within Group. The pairwise comparisons revealed that the treatment group scores at post-treatment and 3-month follow-up were significantly lower than pre-treatment ($p > .001$) but that their scores at 3-month follow-up were not significantly lower again than at post-treatment ($p = 0.31$).

GAD-7, symptomatic sample.

Between Group. Participants in the treatment group ($n = 16$) who scored ≥8 on the GAD-7 at pre-treatment were compared to participants in the control group ($n = 12$) who scored ≥8 on the GAD-7 at pre-treatment. This analysis revealed a significant effect for Time ($F_{2,\ 45.90} = 19.87$, $p < .001$) and a significant effect for Group, ($F_{1,\ 51.85} = 7.47$, $p = .009$), but these were subsumed under a significant Time by Group interaction ($F_{1,\ 64.31} = 10.10$, $p = .002$). The pairwise comparisons revealed significant differences between treatment and control groups at post-treatment ($p < .001$) with the treatment group reporting lower symptoms on the GAD-7.

Within Group. Pairwise comparisons also revealed that the treatment group improved significantly from pre-treatment to post-treatment ($ps < .001$), with further improvements observed from post-treatment to 3-month follow-up ($p > .008$).

Secondary outcome measures. Pre-treatment to post-treatment observed and estimated means, standard deviations, confidence intervals and effect sizes (Cohen's *d*) for each group are shown in Table 4.

***K-10*.**

Between Group. The analyses examining K-10 scores (Table 4) revealed significant main effects for Time ($F_{2,\ 73.24} = 29.81$, $p < .001$) and a significant effect for Group ($F_{1,\ 81.76} = 0.34$, $p = .029$), but no significant Time by Group interaction, ($F_{1,\ 101.53} = 1.22$, $p = .271$). The pairwise comparisons revealed no differences between the control group K-10 scores at pre-treatment ($p = .745$) or post-treatment ($p = .272$).

Within Group. The pairwise comparisons revealed that the treatment groups scores at post-treatment were significantly lower than pre-treatment ($p = .002$) and that their scores at 3-month follow-up were significantly lower again than at post-treatment ($p < .001$). Pairwise comparisons revealed that the control group scores at post-treatment were not significantly lower than pre-treatment ($p = .160$).

SDS.

Between Group. The analyses examining SDS scores (Table 4) revealed significant main effects for Time ($F_{2, 75.82} = 18.52$, $p < .001$), but no significant effect for Group ($F_{1, 93.82} = 0$ .93, $p = .338$), or Time by Group interaction, ($F_{1, 106.10} = 2.50$, $p = .117$). The pairwise comparisons revealed no differences between the treatment and control group SDS scores at pre-treatment ($p = .670$) or at post-treatment ($p = .094$).

Within Group. The pairwise comparisons revealed that the treatment groups scores at post-treatment and 3-month follow-up were significantly lower than pre-treatment ($p > .001$) and that their scores at 3-month follow-up were significantly lower again than at post-treatment ($p = .003$). Pairwise comparisons revealed that the control group scores at post-treatment were not significantly lower than pre-treatment ($p = .544$).

Table 4

Results of Outcome Measures for the Treatment and Control Group.

Measure & Group	n	Observed Means			Estimated Means			Effect Sizes (Cohen's *d*, based on estimated means)		
		Pre	Post	Follow-Up	Pre	Post	Follow-Up	Within Group Pre to Post	Post Between Group TG vs. CG	Within Group Pre to Follow-Up
PHQ-9										
Treatment	29	10.79 (5.18)	8.28 (5.46)	7.03 (5.60)	10.28 (2.99)	6.59 (3.51)	4.30 (3.75)	1.13 (0.56 to 1.67)	0.67 (1.23 to 0.10)	1.76 (1.14 to 2.34)
Control	23	10.04 (5.36)	9.17 (6.29)	-	10.10 (2.97)	8.89 (3.28)	-	0.39 (-0.20 to 0.96)	-	-
GAD-7										
Treatment	29	9.41 (5.52)	7.48 (4.94)	6.45 (5.00)	9.02 (2.97)	5.90 (3.48)	4.04 (3.68)	0.96 (.41 to 1.49)	0.52 (-0.04 to 1.07)	1.49 (0.89 to 2.05)
Control	23	8.39 (3.89)	8.91 (5.56)		8.78 (2.97)	9.06 (3.28)	-	0.09 (-.67 to 0.49)	-	-
K-10										
Treatment	29	24.93 (6.49)	22.62 (7.38)	20.28 (7.71)	23.86 (3.81)	20.59 (4.45)	16.40 (4.70)	0.79 (0.24 to 1.31)	0.31 (-0.25 to 0.85)	1.74 (1.12 to 2.32)
Control	23	22.52 (6.53)	20.21 (7.13)	-	23.51 (3.80)	21.93 (4.21)	-	0.47 (-.09 to 1.01)	-	-
SDS										
Treatment	29	19.48 (9.32)	16.28 (9.26)	13.38 (10.01)	17.88 (5.78)	13.04 (6.75)	7.76 (7.23)	0.77 (.23 to 1.29)	0.47 (-0.09 to 1.01)	1.55 (0.94 to 2.11)
Control	23	16.57 (11.10)	16.61 (11.24)	-	17.19 (5.75)	16.12 (6.37)	-	0.18 (-0.41 to 0.75)	-	-

Note: Standard deviations and 95% confidence intervals are shown in parentheses. TG = Treatment Group; CG = Control Group; Pre = Pre-Treatment; Post = Post-Treatment; Follow-up = 3-month follow-up; GAD-7 = Generalised Anxiety Disorder, 7-Item; K-10 = Kessler 10-Item; PHQ-9 = Patient Health Questionnaire, 9-Item; SDS = Sheehan Disability Scale

Effect sizes. Within- and between-group effect sizes for the primary and secondary outcome measures are shown in Table 4.

Within-group effect sizes. In the treatment group, pre-treatment to post-treatment scores revealed a large effect size on the PHQ-9 (*Cohen's d* = 1.13) and GAD-7 (*d* = 0.96), and a medium effect size on the K-10 (*d* = 0.79) and SDS (*d* = 0.77). In the treatment group, pre-treatment to 3-month follow-up scores revealed a large effect size on the PHQ-9 (*d* = 1.76), GAD-7 (*d* = 1.49), K-10 (*d* = 1.74) and SDS (*d* = 1.55). In the control group, pre-treatment to post-treatment scores revealed a small effect size on the PHQ-9 (*d* = 0.39) and K-10 (*d* = 0.47), and no significant change on the GAD-7 or SDS.

Between-group effect sizes. At post-treatment, a medium effect size was found between the treatment and control groups on the PHQ-9 (*d* = 0.67) and GAD-7 (*d* = 0.52), and a small between-group effect sizes was found for the K-10 (*d* = 0.31) and SDS (*d* = 0.47).

Clinical significance. At pre-treatment, chi-square tests indicated no significant difference between the number of treatment group participants (*n* = 19; 66%) and control group participants (*n* = 11; 48%) scoring over clinical cut-offs (score ≥10) on the PHQ-9 (X^2 (1, *N* = 52) = 1.65, *p* = .200). In addition, there was no significant difference between the numbers of treatment group participants (*n* = 17; 59%) and control group participants (*n* = 12; 52%) scoring over clinical cut-offs (score ≥8) on the GAD-7 (X^2 (1, *N* = 52) = 0.22, *p* = .642).

Remission.

PHQ-9. At post-treatment, there was no significant difference in the numbers of participants in the treatment group (*n* = 8; 42%) estimated as in remission (score <10) compared to the control group (*n* = 3; 27%) using the PHQ-9 scores (X^2 (1, *N* = 30) = 0 .66, *p* = .341). At 3-month follow-up, 9 participants (47%) in the treatment group were estimated as in remission.

GAD-7. At post-treatment, a significantly higher number (n = 8; 47%) of participants in the treatment group were estimated as in remission (score <8) using GAD-7 scores (X^2 (1, N = 29) = 4.93, p = .032), when compared to the control group (n = 1; 8%). At 3-month follow-up, 9 participants (47%) in the treatment group were estimated as in remission.

Recovery. Chi square tests revealed no significant difference between the groups on estimates of recovery (≤ 50% pre-treatment score) using PHQ-9 scores (X^2 (1, N = 52) = 2.64, p = .104), or using GAD-7 scores (X^2 (1, N = 52) = 0.35, p = .405). At 3-month follow-up, 13 participants (45%) in the treatment group were estimated as recovered using the PHQ-9 scores and 8 participants (28%) were estimated as in recovered using the GAD-7 scores.

Prevalence. The frequency data of participants' principal and co-morbid diagnoses are shown in Table 5. From pre-treatment – 3-month follow-up in the treatment group, there was a statistically significant reduction in the mean number of diagnoses from pre-treatment to 3-month follow-up, t (28) = 3.78, p = .001, with the mean number of diagnoses reduced at 3-month follow-up (M = 1.59; SD = 1.59). Nine participants (31%) in the treatment group did not meet criteria for a diagnosable disorder at 3-month follow-up. Thirteen participants (45%) no longer met diagnostic criteria for their original principal diagnosis, which was 87% of participants who completed the MINI (n = 15).

Table 5

Frequency of Co-Morbid Diagnoses

	Pre-Treatment												3-Month Follow-Up					
	Treatment Group (*n* = 29)						Control Group (*n* = 22)						Treatment Group (*n* = 29)					
Principal Diagnosis	MDD	GAD	Pan/Ag	SP	OCD	PTSD	MDD	GAD	Pan/Ag	SP	OCD	PTSD	MDD	GAD	Pan/Ag	SP	OCD	PTSD
	3	18	1	2	1	2	1	13	0	2	1	0	3	7	3	4	1	2
Co-morbid disorder																		
MDD	-	6	1	1	1	1	-	4	0	0	0	0	-	2	0	1	1	1
GAD	2	-	2	2	1	2	0	-	0	2	0	0	2	-	1	2	1	2
Pan/Ag	2	3	-	1	0	1	0	4	-	0	0	0	2	0	-	1	0	1
SP	1	5	1	-	1	2	1	3	0	-	0	0	2	1	1	-	1	2
OCD	0	3	1	0	-	1	0	2	0	0	-	0	0	0	1	0	-	1
PTSD	1	0	1	0	0	-	0	1	0	0	0	-	0	0	0	0	0	-
TOTAL DIAGNOSES	9	35	7	6	4	9	2	27	0	4	1	0	9	10	6	8	4	9

Note: An intention to treat model was employed with pre-treatment diagnoses being carried forward (*n* = 14) if follow-up data was not available. Diagnostic interviews used the Mini International Neuropsychiatric Interview Version 5.0.0 (MINI: Sheehan et al., 1998) and were not repeated with the control group as they had begun treatment. Abbreviations: MDD: Major Depressive Disorder; GAD: Generalised Anxiety Disorder; Pan/Ag: Panic Disorder with or without agoraphobia; SP: Social phobia; OCD: Obsessive Compulsive Disorder; PTSD: Post Traumatic Stress Disorder.

Treatment satisfaction. At post-treatment, of the 21/29 (72%) participants in the treatment group who completed post-treatment questionnaires, 16/29 (55%) completed satisfaction questionnaires. A lower response rate to this specific questionnaire was due to a system error that prevented some participants receiving this questionnaire at the post-treatment time-point. Despite telephone follow-up, not all participants were able to be contacted to complete this questionnaire. Using a five point scale, 14 participants (87.5%) reported their satisfaction as *very satisfied*/*mostly satisfied* and 2 participants (12.5%) reported being *neutral*/*somewhat satisfied*. No participants rated the course as *unsatisfactory*. In relation to learning to manage symptoms of stress, anxiety and low mood, 15 participants (94%) reported participating had *increased* their confidence, and 1 participant (6%) reported their confidence had *reduced*. Fifteen participants (94%) reported they *would recommend the course to a friend*, and 15 participants (94%) reported it was *worth their while to do the course*. One participant (6%) rated the course as *not worth their while*, and reported they would *not recommend it to a friend*. This participant provided feedback that "Some parts seemed a little too simplified and repetitive". Thirteen participants (81%) reported feeling *mostly*/*very satisfied* with the quality of clinician correspondence and 2 participants (12.5%) reported feeling *neutral* about the quality of clinician correspondence.

Participant feedback. Overall, participants were generally enthusiastic and positive in their comments about the intervention, and the qualitative feedback converged with the quantitative data. Participants appeared to identify with the vignettes, and several mentioned the inclusion of the vignettes as beneficial. Several students gave feedback that exam periods interfered with adherence to the course, and several students gave feedback that advertising of the intervention should be increased.

Clinical contact. The mean total clinical contact time per participant in the treatment group to deliver the course was 26.29 minutes (*SD* = 15.37) per participant. This included sending and reading messages and telephoning participants. During the course, the treatment group participants received at least 2 automated emails per week and the therapist sent a total of 75 private messages (mean of 2.6 per participant) and made 69 telephone contacts (mean of 2.4 per participant). Telephone calls made by the therapist to complete the MINI at assessment and follow-up, and when encouraging participants to complete questionnaires at post-treatment and 3-month follow-up were not included in the counts above. However, this required approximately 2 hours per participant. Participants were provided with feedback

about their progress in the course at the 3-month follow-up, and thanked for their participation.

Safety and negative outcomes. Data was not provided by 8 participants at post treatment and 11 participants at follow-up, limiting conclusions about negative outcomes. A clinically significant deterioration in symptoms (an increase in PHQ-9 or GAD-7 scores of 5 or more points from pre-treatment) was recorded for two participants in the treatment group during the course. These participants reported the university exam period as a stressor during the risk assessment, they remained in the course, symptoms were subsequently noted to resolve and they no longer met criteria for a negative outcome at post-treatment or follow-up.

Discussion

The aim of the present study was to evaluate the efficacy and acceptability of a therapist-guided version of the *UniWellbeing Course* using a randomised controlled trial (RCT), with a secondary objective to obtain advice from participants about how to enhance acceptability.

Main findings.

Support was obtained for the hypothesis that improvements in primary measures would be observed in the treatment group when compared to the control group. Statistically significant reductions in symptoms of anxiety and depression were observed in the treatment group, with large within-group effect sizes on the PHQ-9 (*Cohen's d* = 1.13) and GAD-7 (*d* = 0.96) at post-treatment, and sustained at 3-month follow-up. Similarly, improvements on secondary outcome measures of psychological distress and disability were found, with a medium effect size at post-treatment on the K-10 (*d* = 0.79) and SDS (*d* = 0.77), and some further improvements at 3-month follow-up. For the control group, an improvement from pre-post treatment was observed on the PHQ-9 (*d* = 0.39), and the K-10 (*d* = 0.47) however the improvements for the treatment group were significantly greater, indicating preliminary efficacy for the *UniWellbeing Course*.

Overall, these results are encouraging, and are similar to those reported in meta-analyses of guided self-help delivered over the internet in the general population (Andersson & Cuijpers, 2009; Andrews et al., 2010; Coull & Morris, 2011; Cuijpers et al., 2010; Spek et al., 2007) and guided transdiagnostic iCBT (Titov et al., 2011). They are also consistent with those reported in a recent 5-week therapist-guided transdiagnostic iCBT program developed

for students (Day et al., 2013) which found medium effect sizes for anxiety and depression, and improvements sustained at 6-month follow-up.

It was also hypothesised that reductions would be observed in the numbers of those in the treatment group meeting diagnostic criteria for diagnoses of MDD, GAD, SP, or Pan/Ag. Converging with the primary outcome measures, a statistically significant reduction in the mean number of DSM-IV disorders was found at 3-month follow-up in the treatment group, with the number of participants who did not meet criteria for a DSM-IV disorder increasing from 7% to 31%. The small sample size prevented comparison of outcomes by principal diagnosis and limits conclusions about its efficacy for specific disorders. However, 45% of participants no longer met diagnostic criteria for their original principal diagnosis, and at pre-treatment, most participants (62%) had a primary diagnosis of GAD, whereas only 24% of participants met this criteria at 3-month follow-up. Deterioration rates were consistent with similar iCBT studies (e.g. Titov et al, 2013). Further support for the efficacy of this treatment for anxiety was indicated in the clinical estimates of remission: At post-treatment significantly more participants (47%) in the treatment group met the remission criteria for anxiety than in the control group (8%). Clinical estimates of remission for depression and for anxiety were not significant between the groups at post-treatment, however this may have reflected the inclusion of several participants who scored below the cut-off criteria at pre-treatment on the PHQ-9 (42%) and GAD-7 (44%).

The hypothesis that participants would rate the treatment as acceptable was supported, with 94% of participants who completed the satisfaction questionnaires reporting they would recommend the *UniWellbeing Course* to a friend. The completion rate of 55% was low compared to similar therapist-guided interventions in the general population (Titov et al., 2011) however, it is comparable to the 61% reported by Day and colleagues (2013), in a study that targeted anxiety, stress and depression in the student population. Reported completion rates in the student population are highly variable, even using the same CCBT or iCBT intervention. For example, one study using the *BtB* CCBT intervention reported a completion rate of 83% (Mitchell & Dunn, 2007) while another study using the same intervention reported a completion rate of 26% (Richards et al., 2013), suggesting external factors may be involved. Based on student feedback it appears likely that one important external factor affecting adherence is exam stress, which is likely to influence both lesson completion rates and levels of general psychological distress.

The results of this study indicated that this treatment appears clinically effective for those who engage, and these outcomes were achieved with less than 27 minutes of therapist time,

considerably less than the 1.5 hours proposed by Newman et al (2011) to be most efficacious. This is considerably less than is typically required in face-to-face treatment, and was achieved by using the online lessons and other resources to present skills and information usually taught by a therapist. This reduction in demand on the therapist allowed the therapist to spend time supporting the participant in understanding, applying, practicing and consolidating key skills rather than providing psycho-education. Despite the relatively small amount of therapist time, an important and outstanding question is whether this intervention could be administered as a purely self-guided intervention. The answer to this question holds implications for the future implementation of iCBT in SCSs and the potential of iCBT as an educational resource, particularly in a population who may have some preference to seek help online, and given the number of students with subclinical symptoms who applied to the course.

Implications.

These results indicate that a therapist-guided iCBT treatment for students with symptoms of anxiety and depression may have potential as an efficacious and acceptable treatment option, at least for students attracted to online clinical trials. These results indirectly support a model of psychotherapeutic change that places emphasis on systematically learning and practising skills to change unhelpful thoughts and behaviours (Titov et al., 2013). The therapist time savings may hold considerable benefit for a SCS, potentially increasing the capacity of the service, and reducing waiting times during periods of peak demand. However, significant recruitment issues and lower than anticipated completion rates suggest that there may be unknown barriers in servicing this population which require further investigation.

Limitations.

Whilst it would have been beneficial to have conducted a 6-month follow-up in order to gain further information about the stability of any changes, and to more validly test the GAD criteria of being symptom free for 6 months or more, this was precluded by ethical considerations, resource constraints and pragmatic reasons.

Blinded diagnostic assessments were not possible given research constraints and the requirement of the Candidate to conduct all clinical work. It is possible that the lack of therapist blinding together with the lack of follow-up interviews with the control group may have led to under-estimating diagnostic symptoms in the treatment group at follow-up. However, the consistency and robustness of the effects found with the self-report

questionnaires mitigates some of this concern, although the statistically significant higher mean number of diagnoses of anxiety and depression in the treatment group at pre-treatment, and missing data at post-treatment and follow-up limits conclusions about both positive and negative outcomes. Another important potential limitation concerns the self-selecting bias in the sample who applied, as it is possible that the results are not reflective of the wider student population. This study may have been most representative of students in undergraduate programs who were confident in using the internet. Although there is some evidence that results of participants in internet trials may generalise to the wider population (Titov, Andrews, Kemp, & Robinson, 2010), further research with the student population is required.

Conclusions.

This study investigated the efficacy and acceptability of a transdiagnostic, therapist-guided iCBT intervention for university students with symptoms of depression and anxiety, using a RCT design to compare a treatment group to a waitlist-control group. The results indicated clinically and statistically significant positive improvements on primary measures of anxiety and depression between and within the groups. Large effect sizes were found on the PHQ-9 and GAD-7 at post-treatment, and were sustained at 3-month follow-up in the treatment group. Coupled with high levels of acceptability, these promising outcomes provide preliminary support for the efficacy of this protocol in the treatment of depression and anxiety disorders for university students. This study indicates there may be potential for dissemination of iCBT treatment to increase student access to evidence based treatment. Further attention to developing strategies which facilitate interest in the treatment may increase the potential applicability of iCBT treatments for this population.

CHAPTER THREE

Study II: An Open Trial of Self-Guided Transdiagnostic Internet Delivered Cognitive Behavioural Therapy for University Students with Symptoms of Anxiety and Depression

Abstract

Anxiety and mood disorders are prevalent among university students. Study I of the present thesis provided preliminary support for a therapist-guided, transdiagnostic, internet-delivered cognitive behavioural therapy (iCBT) intervention, the *UniWellbeing Course*, for university students with anxiety and depression. The present study employed an open trial design to evaluate the efficacy and acceptability of a self-guided version of the *UniWellbeing Course* with 16 participants from the waitlist-control group of Study 1. Primary outcome measures were the Patient Health Questionnaire 9-Item (PHQ-9) and the Generalized Anxiety Disorder 7-Item (GAD-7). At post-treatment, mixed models analyses revealed participants had statistically significantly lower PHQ-9 and GAD-7 scores compared with pre-treatment. Large effect sizes were found on the PHQ-9 (Cohen's d = 1.05) and GAD-7 (d = 1.48) at 3-month follow-up. Students rated the intervention as acceptable, with 100% of students who completed feedback questionnaires reporting they would recommend the intervention to a friend. The results provide preliminary data indicating that a self-guided, transdiagnostic iCBT course for university students is clinically efficacious and acceptable to university students.

Introduction

University students have higher levels of psychological distress than age matched controls (Stallman, 2008). Although the effects of anxiety and depression are associated with poor physical health, increased risk of self-harm, increased risk of suicide (Clark & Goebel-Fabbri, 1999), and poorer rates of college completion (Hunt et al., 2010), many students either do not seek treatment, or delay seeking professional help (Eisenberg et al., 2007). Further, evidence suggests that many would prefer to seek help from family, friends, books or the internet (Hodges et al., 2007; Ryan et al, 2010), rather than consult a mental health professional. University students typically have a high level of use of the internet (Caruso & Salaway, 2008) and iCBT may hold promise in meeting consumer preferences, while offering the benefits of high treatment fidelity, privacy, confidentiality and cost effectiveness.

There is some evidence that many individuals prefer self-guided to clinician-guided interventions (Klein, Meyer, Austin, & Kyrios, 2011). Consistent with this, publicly available online interventions such as the *Panic Centre* (www.paniccentre.net) and *MoodGYM* (www.moodgym.anu.edu.au) are popular, and have good outcomes for those who adhere (Cavanagh, 2010; Christenson et al., 2006; Farvolden et al., 2009). However, the literature suggests adherence is a problem with self-help interventions, and there is currently no consensus about the optimal amount or type of support required in self-guided online psychotherapy. A meta-analysis by Hirai and Clum (2006) concluded that some therapist contact was important, and significantly improved the effectiveness of self help treatments, generally making them as effective as therapist guided interventions. In addition, a recent review of clinician contact in 135 technology based treatments for anxiety and depression (Newman et al., 2011), and several systematic reviews (Andersson & Cuijpers, 2009; Cuijpers et al., 2010; Gellatly et al., 2007; Spek et al., 2007) have concluded that effect sizes appear to be increased through the provision of guidance. A recent meta-analysis of self-help interventions (Haug, Nordgreen, Öst, & Havik., 2012) found no significant association between the amount or type of therapist contact, concluding minimal direct therapist contact was sufficient, and it has been suggested that minimal therapist contact such as emails may be adequate (Hirai & Clum, 2006; Huag et al., 2012). Consistent with this, a recent study reported large effect sizes following a fully automated transdiagnostic iCBT course for anxiety and depression which used automated emails (Titov et al., 2013).

The RCT reported as Study I of this thesis found a therapist-guided version of the *UniWellbeing Course*, a transdiagnostic iCBT intervention targeting symptoms of anxiety and depression, to be both efficacious and acceptable to university students. An important question is whether the intervention can be administered in a self-guided format. Therefore, the focus and primary aim of the present study was to explore the efficacy and acceptability of a self-guided version of the *UniWellbeing Course.* To meet this aim, a self-guided version of the *UniWellbeing Course* was administered to eligible participants from the waitlist control group of Study 1. This question is important for several reasons. First, a self-guided intervention is likely to simulate the lowest level of care likely to be provided by a SCS and, second, there is evidence that some individuals prefer self-guided interventions. Thus there is a need to evaluate the self-guided model of implementation. A secondary objective was to obtain advice from tertiary students about how to modify the content and materials, in order to enhance acceptability within the student population.

Method

Design and power. A single group open trial design comparing pre-treatment to post-treatment results and to 3-month follow-up results was used. Power calculations indicated that a sample size of 15 participants was sufficient to detect a within-groups effect size (*ES*) of 0.7 with power of 80% (one-tailed), which was the minimum based on similar studies (Robinson et al., 2010; Titov, Andrews, Choi, Schwencke, & Mahoney, 2008; Titov et al., 2010c; Wims, Titov, Andrews, & Choi, 2010). Treatment consisted of a 5 lesson self-guided iCBT course administered over 5 weeks.

Ethical approval for the trial was provided by the Human Research Ethics Committee of Macquarie University, protocol HREC 5201100795. The trial was registered on the ANZCTR trial registry as ACTRN12612000212853.

Hypotheses. The hypotheses were that: 1) Significant improvements in symptoms of depression and anxiety will be found at post-treatment and at 3-month follow-up on the primary outcome measures, the PHQ-9 and GAD-7, and the secondary measures of psychological distress and disability, the K10 and SDS, respectively, and; 2) Participants will rate the treatment as acceptable.

Participants. Nineteen participants from the waitlist control group (n = 23) of Study I completed the post-treatment questionnaires of Study I, which were also the pre-treatment questionnaires for this study, and were eligible to participate. Consistent with the exclusion criteria used in Study 1, there was no minimum threshold of severity of symptoms of anxiety or depression. Three participants who completed the questionnaires but did not begin lessons were formally excluded on Day 8, leaving 16 participants eligible for analysis. See Figure 5 for participant flow.

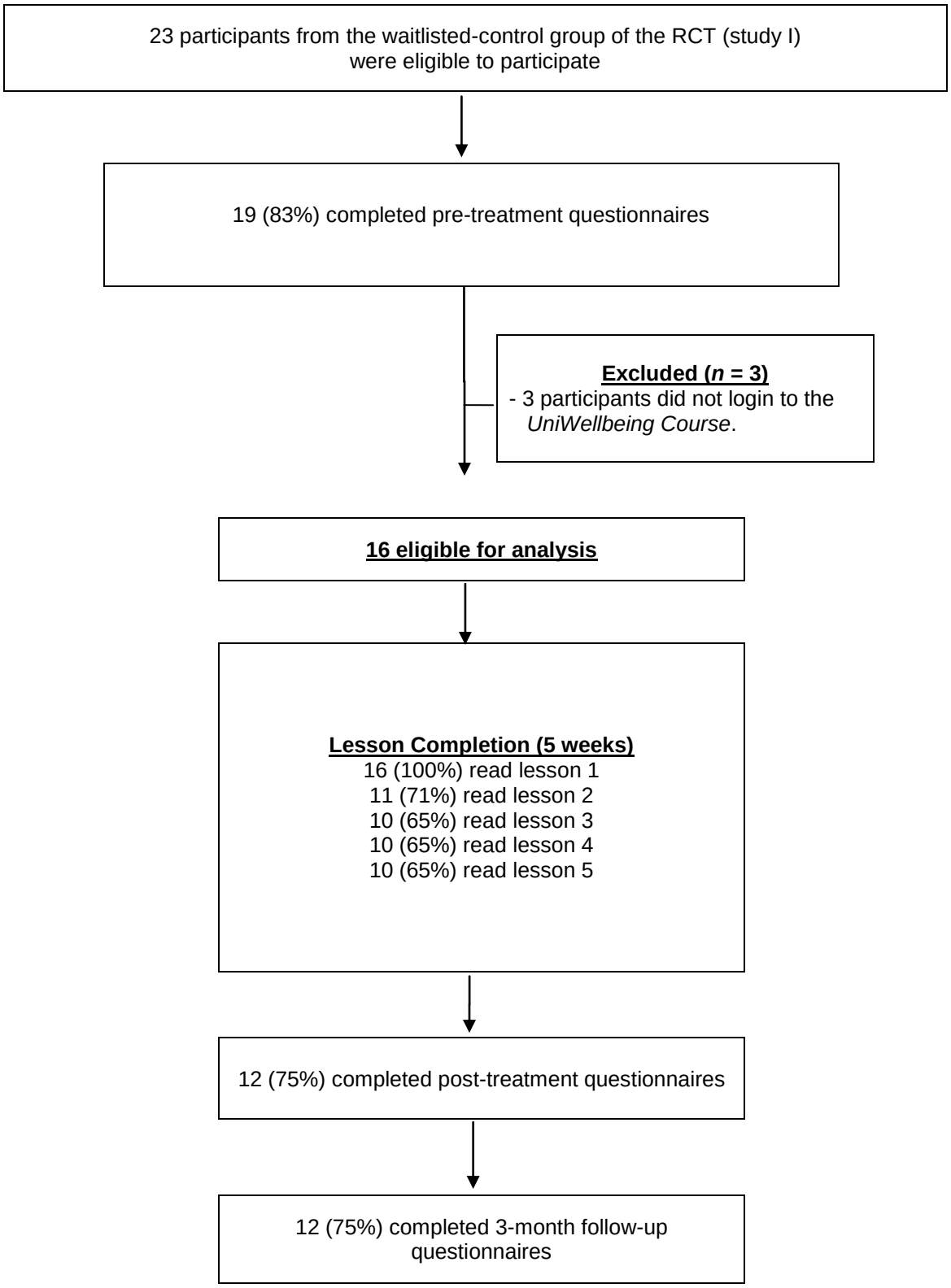

Figure 5. Open trial flow chart. Illustrates participant flow from the waitlisted-control group of the RCT to 3-month follow-up.

Primary outcome measures.

Patient Health Questionnaire - Nine Item (PHQ-9: Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a nine-item measure of the symptoms and severity of major depressive disorder based on the DSM-IV criteria for depression. A total score of 10 on the PHQ-9 has been identified as an important threshold for identifying DSM-IV congruent depression, and increasing scores indicate greater symptom severity (Kroenke et al., 2001). Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) with a maximum score of 27. Scores ranges represent *mild* (5-9); *moderate* (10-14); *moderately severe* (15-19), and *severe* (20-27) levels of depression. Psychometric studies indicate a high internal consistency of .86-.89 (Kroenke et al., 2001) and the measure is sensitive to change (Kroenke et al., 2010) with a drop of at 5 points or more considered a clinically significant response (Kroenke & Spitzer, 2002). The internal consistency of the PHQ-9 in the current study was Cronbach's $\alpha = .85$.

Generalized Anxiety Disorder - 7 Item Scale (GAD-7: Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 comprises 7 items measuring symptoms and severity of GAD based on the DSM-IV diagnostic criteria for GAD. Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) and severity ranges are described as: 5 - 9 *mild;* 10 - 14 *moderate*; and 15-21 *severe* anxiety (Löwe, B., et al, 2008). The GAD-7 has high internal consistency (.89), a test retest correlation of 0.83, correlates highly when administered as self-report or via a clinician, and has good convergent validity with other anxiety scales (Kroenke et al., 2010, Spitzer,., et al, 2006). Evidence indicates the GAD-7 is sensitive to DSM-IV congruent GAD, social phobia, and panic disorder with increasing scores indicating greater severity of symptoms (Löwe et al., 2008). The GAD-7 is increasingly used in research and in large scale dissemination studies as a generic measure of change in anxiety symptoms (Clark et al. 2009; Richards & Suckling, 2009). The internal consistency of the GAD-7 in the current was Cronbach's $\alpha = .88$.

Secondary outcome measures.

Sheehan Disability Scales (SDS: Sheehan, 1983). The SDS comprises five items with a maximum score of 50 with higher scores indicating greater disability. Scores range from 0 (*not at all*), 1-3 (*mildly*), 4-6 (*moderately*), 7-9 (*markedly*) to 10 (*extremely*). Items enquire about disability in psychosocial functioning across three domains including work/study, family, and social domains. The SDS has high internal consistency (Cronbach's $\alpha = .89$; Leon et al., 1997), a sensitivity of 83% and a specificity of 69% (Leon et al., 1997). The internal consistency of the SDS in the current study was Cronbach's $\alpha = .82$.

Kessler-10 item (K-10: Kessler et al., 2002). The K-10 is a 10 item measure of psychological distress, with strong evidence supporting the relationship between the K-10 and a diagnosis of anxiety and depressive disorders (Andrews & Slade, 2001). Items are scored on a 5-point scale from 0 (*none of the time*) to 5 (*all of the time*) with a maximum score of 50. Higher scores reflect increased symptoms. The K-10 has been reported as having excellent internal consistency, even with ethnically diverse populations (Fassaert et al., 2009). The internal consistency of the K-10 in the current study Cronbach's $\alpha = .89$.

Administration of outcome measures. Primary and secondary outcome measures were administered over the internet at application, pre-treatment; post-treatment and at 3-month follow-up. Primary outcome measures were also administered weekly to monitor participant wellbeing. Research indicates that the online administration of self-report questionnaires is reliable and equivalent to pen and paper versions of self-report questionnaires (Carlbring et al., 2007; Donker et al., 2010; Hedman et al., 2010).

Procedure. Participants were the Control group of Study 1. On the start date for their group, participants received an email welcoming them to the *UniWellbeing Course*. This email provided login details and answers to frequently asked questions about system requirements and using the course.

Participants were directed to login and complete the online questionnaires within 7 days, to read one lesson each week, to make use of additional resources, and to practice the homework tasks. Participants were sent a maximum of two email reminders to complete the pre-treatment questionnaires. Participants who did not complete these questionnaires or login to begin the course ($n = 3$) were excluded on day 8. These participants were sent an email thanking them for their interest in the *UniWellbeing Course* and encouraging them to discuss their symptoms with their GP or with MQ SCS. All participants who completed the pre-treatment questionnaires and who began lessons ($n = 16$) were eligible for analysis.

Participants received at least two automated emails each week during the course: A notification email was sent when new lessons became available, and up to two reminder emails were sent if participants did not start a lesson within 7 days. Participants also received an email when they completed a lesson that reinforced progress. An additional email was sent during the week in which graded exposure was introduced, which normalised any increase in anxiety due to beginning exposure exercises.

At post-treatment and at 3-month follow-up, participants were sent an email asking them to log in and complete the post-treatment questionnaires. Two further email reminders were sent if questionnaires were not completed. In addition, at 3-month follow-up, the therapist telephoned participants to encourage completion of the questionnaires, and to complete the MINI interviews. At the post-treatment time-point, additional questions regarding treatment satisfaction were administered.

Intervention. Participants received access to the self-guided version of the *UniWellbeing Course*, which comprised the 5 lessons and content described in Study I, administered over 5 weeks. However, participants did not receive weekly therapist contact, or access to the private messaging system which was used by the treatment group in Study 1 to communicate with the therapist.

Therapist. The Candidate, an experienced and provisionally registered psychologist, provided all clinical contact with participants, with contact initiated for safety reasons only. The Candidate was supervised by clinical psychologists experienced in delivering online treatments.

Safety. Participants responses to the PHQ-9 were automatically monitored. Those whose PHQ-9 total scores increased during the course from pre-treatment by more than 5 points, and who also had a total score ≥15, indicating the presence of moderately severe depression, were contacted by the therapist via an email providing instructions about how to contact crisis services in the event of a mental health emergency. However, those with PHQ-9 scores of 20 or more, indicating severe depression, or scoring '3' to question 9 of the PHQ-9 indicating suicidal ideation, were telephoned by the therapist who carried out a risk assessment and implemented a safety management plan.

Negative outcomes. The number of times safety protocols were triggered because of elevated PHQ-9 scores, and the proportion of participants with significant deterioration in PHQ-9 or GAD-7 scores were recorded. The latter was calculated based on a completer analysis and defined as an increase in PHQ-9 or GAD-7 scores of 5 or more points from pre-treatment. This was based on the classification suggested by Kroenke and Spitzer (2002).

Statistical analysis. Participants who did not complete pre-treatment questionnaires or read Lesson 1 were not included in analyses. A mixed-models approach with an autoregressive covariance structure and using maximum likelihood estimation was identified as the best way to handle missing data at post-treatment and 3-month follow-up (Verbeke & Molenberghs, 2009). Quantitative analyses were completed with this small sample in order to allow comparison with similar but larger data sets.

Differences in questionnaire scores were compared from pre-treatment and post-treatment, with outcomes compared at post-treatment and 3-month follow-up using pairwise comparisons. Effect sizes (Cohen's *d*) and 95% effect size confidence intervals were calculated using the estimated marginal means for within-group changes, based on the pooled standard deviation with an effect size of 0.2 to 0.5 described as small, between 0.5 to < 0.8 as medium, and 0.8 ≥ as large (Cohen, 1988). All analyses were performed using SPSS version 21.0.

Results

Demographic characteristics of the sample. The sample (*n* = 16) had a mean age of 27 years (*range* = 19-67 years), and 56% of participants were female. The majority of participants (69%) were single, and 31% of participants were married or in de-facto relationship. All participants were students at MQ, studying within the faculties of Human Sciences (38%), Arts (19%), Science (25%) or Business (19%), with 75% of participants studying full time. The majority of participants were undergraduate students (59%), and the remainder were completing post-graduate degrees (41%). In relation to use of the internet, 94% of participants rated themselves as *very confident* or as *confident* in using the internet, with 6% rating their confidence as *average.* The majority of participants (69%) reported using the internet over 20 hours per week, and 31% of participants reported using the internet between 10-19 hours a week.

Adherence and attrition. All participants (100%) started Lesson 1, and 10 participants (63%) began all 5 lessons within the 5 weeks of the course (*M* = 3.6; *SD* = 1.93). Post-treatment data was collected from 12/16 participants (75%), and 3-month follow-up data was collected from 12/16 participants (75%).

Primary outcome measures. Observed and estimated means, standard deviations and confidence intervals and effect sizes (Cohen's *d*) are shown in Table 6 below.

PHQ-9. Analyses examining PHQ-9 scores revealed a significant main effect for Time ($F_{7,\ 58.29} = 3.33$, $p = .005$). Pairwise comparisons revealed a significant improvement from pre-treatment to post-treatment ($p = .039$), and significant improvements from pre-treatment to 3-month follow-up ($p = .001$). Scores at 3-month follow-up were not significantly lower again than those at post-treatment ($p = .306$).

GAD-7. The mixed-models analyses examining GAD-7 scores revealed a significant main effect for Time ($F_{7,\ 60.81} = 4.52$, $p < .001$). Pairwise comparisons revealed that participants improved significantly from pre-treatment to post-treatment ($p = .003$) and from pre-treatment to 3-month follow-up ($p < .001$). Scores at 3-month follow-up were not significantly lower again than those at post-treatment ($p = .277$).

Secondary outcome measures. Observed and estimated means, standard deviations and confidence intervals and effect sizes (Cohen's *d*) are shown in Table 6 below.

K-10. Analyses examining K-10 scores revealed a significant main effect for Time ($F_{2,\ 26.76} = 9.37$, $p = .001$). Pairwise comparisons revealed no significant improvements from pre-treatment to post-treatment ($p = .87$), but significant improvements from pre-treatment to 3-month follow-up ($p < .001$), which was significantly lower again than at post-treatment ($p = .029$).

SDS. Analyses examining SDS scores revealed a significant main effect for Time ($F_{2,\ 30.14} = 6.48$, $p = .005$). Pairwise comparisons revealed significant improvements from pre-treatment to post-treatment ($p = .004$), and significant improvements from pre-treatment to 3-month follow-up ($p = .006$). Scores at 3-month follow-up were not significantly lower again than the scores at post-treatment ($p = .999$).

Effect Sizes. As indicated in Table 6, moderate to large effect sizes were found on all outcome measures from pre-treatment to post-treatment. From pre-treatment to 3-month follow-up, a large effect size was found for all outcome measures.

Table 6

Results of Outcome Measures

Measure	*n*	Observed Means			Estimated Means & Confidence Intervals			Effect Sizes (Based on estimated means)	
		Pre	Post	Follow-up	Pre	Post	Follow-up	Pre-post	Pre-Follow –Up
PHQ-9	16	8.06 (5.79)	5.75 (3.94)	4.50 (4.76)	8.53 (3.92)	5.57 (4.36)	4.19 (4.34)	0.71 (-0.02 to 1.41)	1.05 (0.29 to 1.76)
GAD-7	16	8.13 (5.26)	4.56 (3.56)	3.94 (3.26)	8.59 (3.21)	4.86 (3.68)	3.49 (3.68)	1.08 (0.31 to 1.79)	1.48 (0.66 to 2.22)
K-10	16	20.19 (6.67)	17.63 (5.56)	15.38 (4.18)	20.99 (3.95)	18.35 (4.54)	14.82 (4.52)	0.62 (-0.10 to 1.31)	1.45 (0.64 to 2.19)
SDS	16	14.81 (10.40)	8.56 (7.26)	8.88 (9.24)	15.60 (6.32)	8.21 (7.30)	8.21 (7.30)	1.08 (0.32 to 1.79)	1.08 (0.32 to 1.79)

Note: For observed means, an intention to treat model was employed with pre-treatment data being carried forward where post-treatment or follow-up data was not available. Estimated means were obtained using the mixed model analyses. Standard deviations and confidence intervals are shown in parentheses. Pre: Pre-Treatment; Post: Post-Treatment; Follow-up: 3-month follow-up; PHQ-9: Patient Health Questionnaire, 9-Item; GAD-7: Generalized Anxiety Disorder, 7-Item; K-10: Kessler 10-Item; SDS: Sheehan Disability Scales.

Clinical significance.

Recovery. With respect to PHQ-9 scores, 5 participants (31%) met the criteria for recovery (score ≤ 50% of pre-treatment score) at post-treatment, and 6 participants (38%) met the criteria at 3-month follow-up. With respect to GAD-7 scores, 7 participants (44%) met the criteria for recovery at post-treatment and 10 participants met the criteria (63%) at 3-month follow-up.

Remission. With respect to the PHQ-9, 4 participants (25%) had scores above the cut-off criteria (pre-treatment score ≥10). Of these, 1 participant (25%) at post-treatment, and 3 participants (75%) at 3-month follow-up met the criteria for remission (score <10). With respect to the GAD-7, 9 participants (56%) had scores above the cut-off criteria (pre-treatment score ≥8). Of these, 5 participants (56 %) at post-treatment, and 9 participants (100%) at 3-month follow-up met the criteria for remission (score <8). Small cell sizes precluded reliable statistical analyses of change for recovery and remission and thus such analyses were not conducted.

Treatment satisfaction. At post-treatment, 7 participants (44%) completed satisfaction questionnaires. A lower response rate to this specific questionnaire was due to a system error which prevented some participants receiving this questionnaire. Of participants who completed the questionnaire, a moderate level of satisfaction with the overall course was reported, with 29% reporting they were *very satisfied*, 43% reporting they were *mostly satisfied*, and 14% reporting they were *somewhat dissatisfied*. Using a five point scale, 29% of participants reported the *UniWellbeing Course* had *greatly increased* their confidence that they can learn to manage symptoms of stress, anxiety and low mood, 57% reported their confidence had *increased*, and 14% reported *no change* in their confidence. One hundred percent of participants reported they *would recommend the course to a friend*, and that it was *worth their while to do the course*.

Written comments and feedback from participants appeared consistent with these ratings, with participants generally positive in their comments about the intervention. Participants suggested technological improvements, including use of video, iOS technology, and SMS alerts for lesson alerts. Participants also described difficulty adhering to the course due to conflict in managing time during exam periods.

Safety and negative outcomes. Data was not provided by 4 participants at post-treatment and 4 participants at follow-up, limiting conclusions about negative outcomes. The

therapist initiated contact to conduct a risk assessment with four participants for safety reasons. This was a total of five phone calls, and a total of 47 minutes of clinician time (*M* = 9.4 minutes per call). Clinical feedback in each case reflected an increase in participants exam stress, or an increase in anxiety due to attempting exposure exercises contained in the *UniWellbeing Course*, with no participants considered to be at significant risk. These participants remained in the course, symptoms were subsequently noted to resolve and they no longer met criteria for a negative outcome at post-treatment or follow-up.

Discussion

This study examined a self-guided version of the *UniWellbeing Course* (Study I) and is the first study to investigate the efficacy and acceptability of a self-guided transdiagnostic iCBT intervention in a university student population.

Main Findings. Support was obtained for the hypothesis that statistically significant reductions in primary measures of anxiety and depression would be observed. Consistent with this, significant improvements were observed on the GAD-7 (d = 1.08) and PHQ-9 (*Cohen's* d = 0.71) at post-treatment, and further improvements were observed at 3-month follow-up. Partial support was found for the hypothesis that improvements in secondary outcome measures would be observed, as there was no statistically significant improvement in psychological distress (measured using the K-10) at post-treatment, although significant improvements in disability were found on the SDS (d = 1.08) at post-treatment, and sustained at 3-month follow-up. However, a significant improvement in the K-10 scores (d = 1.45) was observed from pre-treatment to follow-up. Clinical estimates of recovery and remission were consistent with these findings. The magnitude of the effect sizes observed in Study II are consistent with the effect sizes obtained in Study I. Overall, these outcomes provide preliminary evidence that a self-guided version of *UniWellbeing Course* is efficacious in treating symptoms of anxiety and depression in this population.

These outcomes are also consistent with results reported for guided self-help programs (Andersson & Cuijpers, 2009; Coull & Morris, 2011; Spek et al.,2007), and with results obtained in iCBT programs for GAD (Robinson et al., 2010) and transdiagnostic iCBT interventions (Dear et al., 2011; Titov et al., 2013; Titov, et al., 2010a). Additionally, the effect sizes are consistent with those reported for transdiagnostic face-to-face treatments (McEvoy, Nathan, & Norton, 2009; Norton & Price, 2007). However, it should be noted that differences in the outcome measures, differences in the methods for calculating outcomes and

differences in the populations reported by these studies place limits around the extent of the validity of these comparisons.

An interesting finding from this Study was that the lesson completion rate of 63% was marginally higher than the completion rate in Study I (55%). The reason for this is unclear, although anecdotal feedback from students suggests that the timing of the intervention in relation to the examination period may have been a factor. However, this completion rate is higher than the completion rate of 58% reported for a similar intervention in the most recent self-guided *Wellbeing* study (Titov et al., 2013), although that study did not include any therapist contact until post-treatment. It is also marginally higher than the completion rate of 61% reported for a student population in a recent clinician-guided iCBT study (Day et al., 2013). Further research which deconstructs factors that may contribute to improved adherence and completion rates in self-guided interventions is recommended to explore this further.

Importantly, and in support of the hypothesis, participants reported moderate to high levels of acceptability. All students, including those who may traditionally be considered sub-clinical (e.g. beginning the course with a PHQ-9 <10, or a GAD-7 score <8) reported it was worth their time doing the course, and that they would recommend it to a friend. Combined with the results from Study 1, these findings provide further evidence for the acceptability of the *UniWellbeing Course* for the student population.

Implications. This study provides support for the argument that increasing therapist contact time beyond a threshold may not facilitate further gains (Vernmark et al., 2006), and that it may be possible to provide the majority of support using automated systems such as emails (Hirai & Clum, 2006; Huag et al., 2012; Titov et al., 2013). This has significant implications for therapist time requirements and the cost effectiveness of treatments. Although formal cost-effectiveness analyses were not conducted, the significantly reduced therapist time in this study may make it attractive to service providers. Entirely self-guided protocols may also offer considerable potential to reduce stigma, particularly in a population who prefers to seek help online.

Limitations. There are several limitations in the design of this study, including an uncontrolled open trial design, and a small sample of self-selecting participants. These features of the design limit the reliability and generalisation of results. Although participants were randomly allocated to this group in Study 1, they were not blinded to the self-guided versus therapist-guided nature of this study, and this may have had an effect on motivation. In

addition, examination anxiety was reported to be the cause of elevated scores when risk assessments were initiated, which suggests that examination periods may have been a confounding variable. Further research which explores the impact of examination periods on both adherence and outcomes is warranted.

Conclusions. The results of this study indicate administration of the self-guided version of the *UniWellbeing Course* was associated with moderate to high levels of acceptability, and good clinical outcomes. Primary outcome measures revealed a large effect size on the GAD-7, and a medium effect size on the PHQ-9 at post-treatment, with further gains at 3-month follow-up. Satisfaction ratings were also high, with 100% of participants reporting they would recommend the course to a friend. Importantly, these outcomes are both consistent with the broader results reported in the iCBT literature, and consistent with those obtained in Study 1, providing preliminary efficacy and acceptability for this self-guided treatment. These findings are encouraging and indicate the importance of exploring the implementation and utility of iCBT treatments within student counselling services.

CHAPTER FOUR

Study III: Evaluation of the Implementation of a Transdiagnostic Internet Treatment for Students with Symptoms of Anxiety and Depression in a University Student Counselling Service

Abstract

Many treatments which are effective in research settings are not disseminated into real world settings. Study I and Study II of the present thesis provided preliminary evidence of the efficacy and acceptability of online cognitive behavioural therapy (iCBT) for anxiety and depression within a student population. The present exploratory study, Study III, describes the implementation of iCBT in a student counselling service (SCS) as an alternative to face-to-face treatment. An open trial examined whether administering therapist-guided iCBT to students presenting to a SCS is efficacious, acceptable to students, and acceptable to clinicians. Primary outcome measures were the Patient Health Questionnaire 9-Item (PHQ-9) and the Generalised Anxiety Disorder 7-Item (GAD-7). Extensive difficulties with recruitment resulted in a small sample size (n = 6), and outcomes were not statistically significant. However, moderate to high levels of acceptability were reported by participants and clinicians who used the intervention and gave feedback, and by the managers of the SCS. In parallel with the open trial, the Consolidated Framework for Implementation Research (CFIR) was used to systematically organise and collate information evaluating the implementation of iCBT into the SCS. This methodology allowed the identification of barriers, including student treatment preferences and clinician attitudes towards iCBT, although poor study design limited the conclusions that could be drawn. Despite several difficulties with the implementation study, the managers of the SCS remained positive regarding the potential of iCBT for this population, and the intervention is considered to hold promise as an alternative to face-to-face treatment.

Introduction

Studies I and II of the present thesis provided preliminary evidence for the efficacy and acceptability of therapist and self-guided versions of the *UniWellbeing Course*. This evidence indicates it has potential for broader dissemination within a SCS. However, at the time of planning this thesis, a review of the literature found no evidence of iCBT treatments being offered within a SCS. Moreover, many treatments developed in research settings are not

successfully implemented into clinical settings (Haynes & Haines, 1998; National Institute of Mental Health, 2007; National Institutes of Health, 2010). Low levels of successful dissemination in clinical practice are considered a significant problem (for a review see McHugh & Barlow, 2008), and research that promotes understanding of how to best integrate evidence-based health interventions is a growing field (Fixsen et al., 2005; Greenhalgh et al., 2004; Grol & Wensing, 2009).

There is no consensus in the literature for the design, planning and deployment of implementation studies. For example, a review of 205 implementation studies published between 1995 and 2011 identified 68 various implementation strategies and definitions of implementation (Powell et al., 2012). The authors concluded that the use of inconsistent terminology, poorly defined strategies, and wide variations in the descriptions of key processes hinder implementation research (for a review see Michie et al., 2009). However, Damschroder et al., (2009), who reviewed a large number of implementation theories, proposed that many of the frameworks, theories and conceptual models have considerable overlap (Fixsen et al., 2005; Greenhalgh et al., 2004; Kitson et al., 2008). Drawing from evidence based theories, Damschroder and colleagues developed the Consolidated Framework for Implementation Research (CFIR: Damschroder et al., 2009). The CFIR is designed to allow researchers to capture and organise findings from implementation studies using consistent terminology. This provides a foundation for retrospective evaluation, which can be used to inform future dissemination and implementation efforts. For example, this format has been used to systematically review implementation efforts in alcohol interventions (Williams et al., 2011), and in the implementation of a family based schizophrenia intervention (Ruffalo & Capobianco, 2012).

Whilst there appears to be no widely used measure of barriers to implementation in the psychotherapy literature, the CFIR identifies the *characteristics of individuals*, and the *inner setting* of organisations as two of five domains to consider (Damschroder et al., 2009). This is consistent with research which has found attitudes toward evidence based treatments (Aarons, 2004; Nelson & Steele, 2007) and organisational readiness to change (Gotham, 2004) to be potential barriers. For example, evidence suggests that acceptance of online treatments may be associated with theoretical orientation, with those from a cognitive-behavioural background more likely to find it acceptable (Wangberg, Gammon, & Spitznogle, 2007). Several UK and Norwegian surveys have found attitudes toward computerised CBT interventions to be generally positive or neutral (Keeley, Shapiro, & Williams, 2002; MacLeod, Martinez, & Williams, 2009; Nordgreen & Havik, 2011; Whitfield & Williams,

2004). In comparison, an Australian survey of 456 self-selecting health professionals found 29% of respondents rated internet treatments as potentially acceptable, and only 38% considered they would use an internet based-treatment in the future (Gun, Titov, & Andrews, 2011).

The third domain of the five domains of the CFIR (Damschroder et al., 2009) is the *process of implementation*. The literature suggests that to create any change in clinician practice, didactic training is insufficient (Oxman, Thomson, Davis, & Haynes, 1995) and that competence training strategies which use supervision and coaching are critical (Crits-Christoph et al., 1998; Miller, Yahne, Moyers, Martinez, & Pirritano, 2004). The remaining two domains of the CFIR (Damschroder et al., 2009) pertain to the needs of consumers, and to the evaluation of the intervention. Consistent with this model Study III was designed as a pilot implementation study, which evaluated the integration of the *UniWellbeing Course* as part of a stepped care model within a SCS.

The primary aims of the present study were to evaluate the efficacy of the *UniWellbeing Course* for student consumers of a SCS, and to evaluate the acceptability of the treatment for student consumers, clinicians and managers of a SCS. A further and equally important aim was to evaluate the implementation of the intervention in the SCS using the CFIR framework developed by Damschroder et al. (2009).

Method

Design. The design comprised two components. First, an open trial design evaluated the efficacy and acceptability of the *UniWellbeing Course* for student consumers, clinicians and managers of a SCS. Second, evaluation of the implementation of the *UniWellbeing Course* within the triage service of a SCS was achieved by concurrently identifying and recording factors which influenced implementation using the CFIR framework. Ethical approval for the trial was provided by the Human Research Ethics Committee of Macquarie University, protocol HREC 5201200552. The trial was registered on the ANZCTR trial registry as ACTRN12612000955819.

Hypotheses. The hypotheses were that: 1) Significant improvements will be found at post-treatment and at 3-month follow-up on the primary outcome measures of depression and anxiety, the PHQ-9 and GAD-7, and the secondary measures of psychological distress and disability, the K-10 and SDS, respectively; 2) Participants, clinicians, and managers will rate

the treatment as acceptable. As this was an exploratory study, no hypotheses were formulated in regards to the factors which would influence implementation.

Sample size. A sample size of up to 50 participants was proposed for the open trial. Power calculations indicated this would allow detection of change with a high level of power based on an alpha of 0.05 and power of 0.90.

Participants, clinicians, managers and recruitment. The SCS, part of Campus Wellbeing Services at Macquarie University (MQ) was approached by the research team, and following a number of meetings exploring the feasibility of the proposed trial, the managers of MQ Campus Wellbeing Services became co-researchers on the study. The managers reported they were motivated to explore options for reducing student waiting lists and times in the SCS, and were eager to explore online interventions as a strategy for achieving this. Following multiple planning sessions, and presentations to staff at the SCS, it was agreed to offer the *UniWellbeing Course* (the 5 week iCBT intervention described in Study I) as an alternative treatment option to students presenting to the SCS triage team during the first weeks of Semester 2, September 2012. A high level of demand for treatment was anticipated, as this period was identified as a traditionally high demand period for the service, when students seeking treatment may have to wait for treatment due to service constraints.

The triage service within MQ SCS is an essential part of the MQ SCS stepped care model, where students seeking assistance are able to access a same day 30 minute appointment. The triage appointment allows the MQ SCS clinicians (clinicians) to assess risk, to identify needs and treatment requirements, and to refer the student to an appropriate service provider. Depending on the nature of the problem, students may be referred for face-to-face psychotherapy, to another provider within MQ Campus Wellbeing Services (e.g. student welfare services or disability services), or be referred externally to a specialist provider. Recruitment of participants and weekly contact was provided by three clinicians, who conducted triage appointments as a part of their role. These clinicians received support from the Candidate, and received clinical supervision by the managers. Following the triage assessment, each clinician was able to refer students who presented with anxiety and/or depression to the *UniWellbeing Course* instead of face-to-face psychotherapy. It was agreed with the managers that suitable students would be offered the next available of 3 start dates in September 2012, selected to avoid exam periods as suggested in feedback received from participants in Studies I and II. The clinicians were selected by the managers as individuals

interested in the aims of the study, and they received training in the delivery of the *UniWellbeing Course* during August, 2012. Eligible students presenting to the triage service who were referred to the *UniWellbeing Course* were followed from pre-treatment through to 2-month follow-up.

Training. Four training sessions were delivered prior to the trial starting. Training included content that described trial protocols, ethical standards, and the *UniWellbeing Course* content. These sessions were designed to build familiarity with the *UniWellbeing Course* content, structure and delivery. This included recruitment processes; gaining informed consent; using automated and manual emails; using the secure text based messaging system; posting announcements that appear when participants logged in; working with participants online, and accessing and tracking results online. A mixture of didactic and practical training was used to build skills in efficiently using the intervention. This included using a demonstration site which allowed clinicians to familiarise themselves with the course content and the way the system worked, and also included role playing how the intervention could be introduced to a potential participant. A detailed *UniWellbeing Course* training manual was developed by the candidate and provided to each clinician as a resource. This contained each lesson and resource of the course in paper form for ease of clinician reference, ethical guidelines and the research protocol, FAQ's for clinicians, and a section providing suggestions to assist in managing participants based on the experiences of the research team.

Procedure. In September 2012, information about the *UniWellbeing Course* and A1 sized posters were placed in the reception area of MQ SCS. Clinicians were encouraged to provide information about the *UniWellbeing Course* to eligible students, and invite them to participate as an alternative to face-to-face counselling. Students who wished to participate completed a paper based PHQ-9 and GAD-7 as part of the triage assessment. Participants were required to meet the following inclusion criteria: (1) Enrolled as a student at Macquarie University; (ii) Currently living in Australia; (iii) 18+ years of age; (iv) Have access to a computer, the internet, and use of a printer; (v) Not currently participating in CBT; (vi) Not currently experiencing a psychotic mental illness or severe symptoms of depression (defined as a total score ≥23 or responding >2 to question 9 (suicidal ideation) on the Patient Health Questionnaire-9 item (PHQ-9; Kroenke, Spitzer, & Williams, 2001); (vii) If taking medication (people taking benzodiazepines were excluded), had been taking the same dose for at least 1 month and did not intend to change that dose during the course of the course; (viii) Provided informed consent. The first names and emails addresses of participating students

were provided to the candidate by the clinicians. These were used to create login names and passwords for the *UniWellbeing Course* which were emailed to the participants (the *welcome email*). The clinicians then monitored the students as they completed the treatment, providing weekly telephone contact.

Five participants were referred over the initial recruitment period, 3rd to 24th September 2012, however no participants commenced the *UniWellbeing Course* due to difficulties in the application process which prevented them receiving the welcome email. These difficulties were resolved in October, 2012, and the recruitment period was then repeatedly extended until late November 2012, with a further 4 start dates offered. No participants were referred during this period. Feedback between clinicians, the managers and the research team led to 3 meetings being held to consider how best to overcome recruitment issues. Following these meetings, in January 2013, advertising of the *UniWellbeing Course* was increased. Information about the *UniWellbeing Course* was added to the SCS website, and to social media sites including the MQ and the SCS Facebook pages, and to the web pages of MQ's main website and library. The managers agreed an email would be sent to all students seeking an appointment with the SCS containing information about the *UniWellbeing Course.* The managers also encouraged all staff in the counselling service to learn about the *UniWellbeing Course* (using a demonstration website provided by the researchers), and to refer to the course. In addition, the candidate distributed over 2000 flyers at orientation week, and placed over 50 A1 sized glossy posters in the reception area of the SCS and around campus.

Despite these measures, significant recruitment issues continued and were not overcome in the limited time available for completion of this research. Recruitment was repeatedly extended and ran until May 2013. Three courses began (in February, March, and May, 2013) with less than 3 participants in each course. Participant flow is shown in Figure 6.

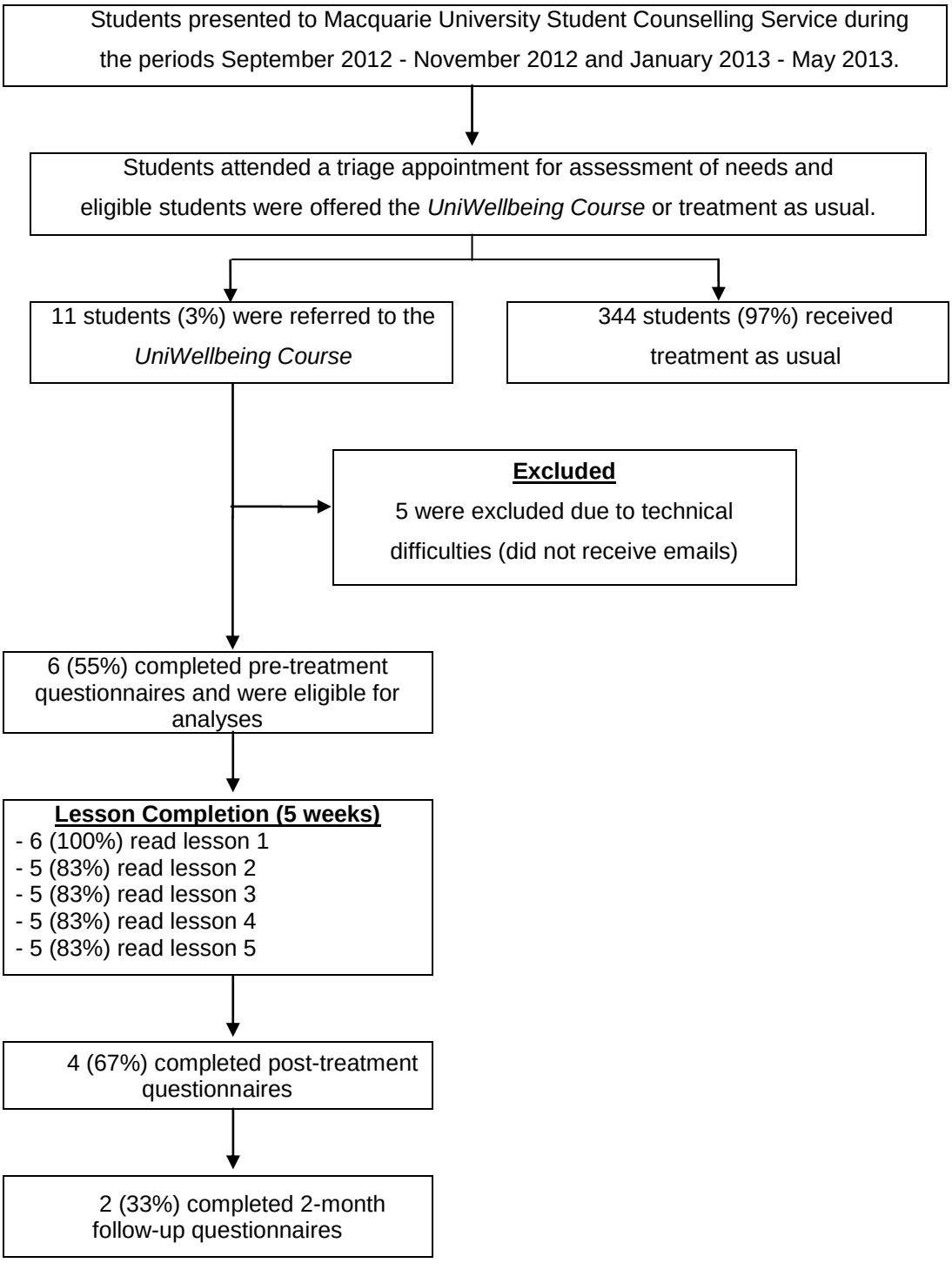

Figure 6. Implementation trial flow chart. Illustrates participant flow from presentation to the triage service to 2-month follow-up.

Evaluation of the Open Trial

Open trial measures.

The same primary and secondary outcome measures were used in the open trial as used in Study I and Study II of this thesis. However, due to the limited sample size, estimates of internal consistency were not calculated in this Study.

Primary outcome measures.

Patient Health Questionnaire - Nine Item (PHQ-9: Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a nine-item measure of the symptoms and severity of major depressive disorder based on the DSM-IV criteria for depression. A total score of 10 on the PHQ-9 has been identified as an important threshold for identifying DSM-IV congruent depression, and increasing scores indicate greater symptom severity (Kroenke et al., 2001). Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) with a maximum score of 27. Scores ranges represent *mild* (5-9); *moderate* (10-14); *moderately severe* (15-19), and *severe* (20-27) levels of depression. Psychometric studies indicate a high internal consistency of .86-.89 (Kroenke et al., 2001) and the measure is sensitive to change (Kroenke et al., 2010) with a drop of at 5 points or more considered a clinically significant response (Kroenke & Spitzer, 2002).

Generalized Anxiety Disorder - 7 Item Scale (GAD-7: Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 comprises 7 items measuring symptoms and severity of GAD based on the DSM-IV diagnostic criteria for GAD. Items are scored on a 4-point scale from 0 (not at all) to 3 (nearly every day) and severity ranges are described as: 5 - 9 *mild;* 10 - 14 *moderate*; and 15-21 *severe* anxiety (Löwe et al., 2008). The GAD-7 has high internal consistency (.89), a test retest correlation of 0.83, correlates highly when administered as self-report or via a clinician, and has good convergent validity with other anxiety scales (Kroenke et al., 2010, Spitzer et al., 2006). Evidence indicates the GAD-7 is sensitive to DSM-IV congruent GAD, social phobia, and panic disorder with increasing scores indicating greater severity of symptoms (Löwe et al., 2008). The GAD-7 is increasingly used in research and in large scale dissemination studies as a generic measure of change in anxiety symptoms (Clark et al., 2009; Richards & Suckling, 2009).

Secondary outcome measures.

Sheehan Disability Scales (SDS: Sheehan, 1983). The SDS comprises five items with a maximum score of 50 with higher scores indicating greater disability. Scores range from 0 (*not at all*), 1-3 (*mildly*), 4-6 (*moderately*), 7-9 (*markedly*) to 10 (*extremely*). Items enquire about disability in psychosocial functioning across three domains including work/study, family, and social domains. The SDS has high internal consistency (Cronbach's $\alpha = .89$; Leon et al., 1997), a sensitivity of 83% and a specificity of 69% (Leon et al., 1997).

Kessler-10 item (K-10: Kessler et al, 2002). The K-10 is a 10 item measure of psychological distress, with strong evidence supporting the relationship between the K-10 and a diagnosis of anxiety and depressive disorders (Andrews & Slade, 2001). Items are scored on a 5-point scale from 0 (*none of the time*) to 5 (*all of the time*) with a maximum score of 50. Higher scores reflect increased symptoms. The K-10 has been reported as having excellent internal consistency, even with ethnically diverse populations (Fassaert et al., 2009).

Administration of outcome measures. At application, paper versions of the PHQ-9 and GAD-7 were administered to participants by clinicians in the SCS. Primary and secondary outcome measures were administered over the internet at pre-treatment, post-treatment and at 2-month follow-up. Primary outcome measures were also administered weekly over the internet to monitor participant wellbeing. Additional questions regarding treatment satisfaction were administered to participants and clinicians at post-treatment over the internet. Research indicates that the online administration of self-report questionnaires is reliable and equivalent to pen and paper versions of self-report questionnaires (Carlbring et al., 2007; Donker et al., 2010; Hedman et al., 2010).

Intervention. Clinicians treated students remotely using the *UniWellbeing Course* with weekly clinical contact, instead of face-to-face treatment as usual. Participants received access to the *UniWellbeing Course*, which contained all the content described in Study I, including automated emails, and was administered over 5 weeks. In addition, the contact information and the logo for MQ SCS was added to the material, and two extra slides were added at the beginning of lesson 1 to introduce the researchers and management team of the SCS. (Figures 8 and 9). Participants in each course were monitored on a daily basis by the candidate for the duration of the course to ensure the integrity of the material, and to resolve any participant issues with access.

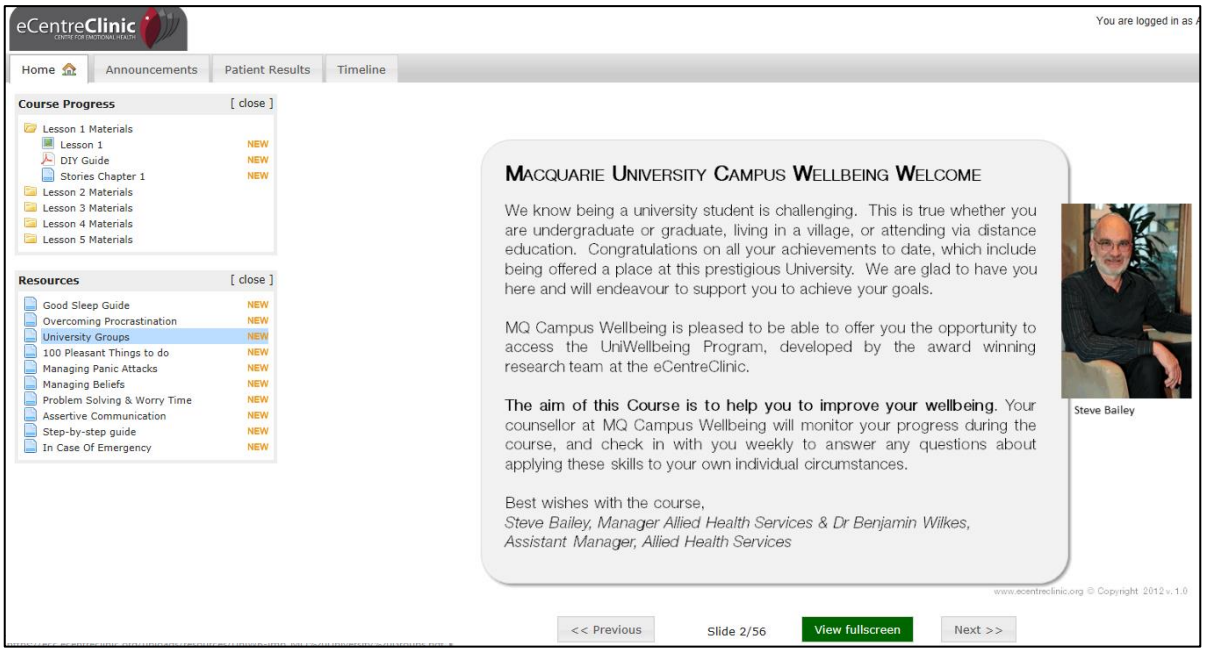

Figure 7. Welcome by the Student Counselling Service. Illustrates how the *UniWellbeing Course* was introduced in the lesson slides.

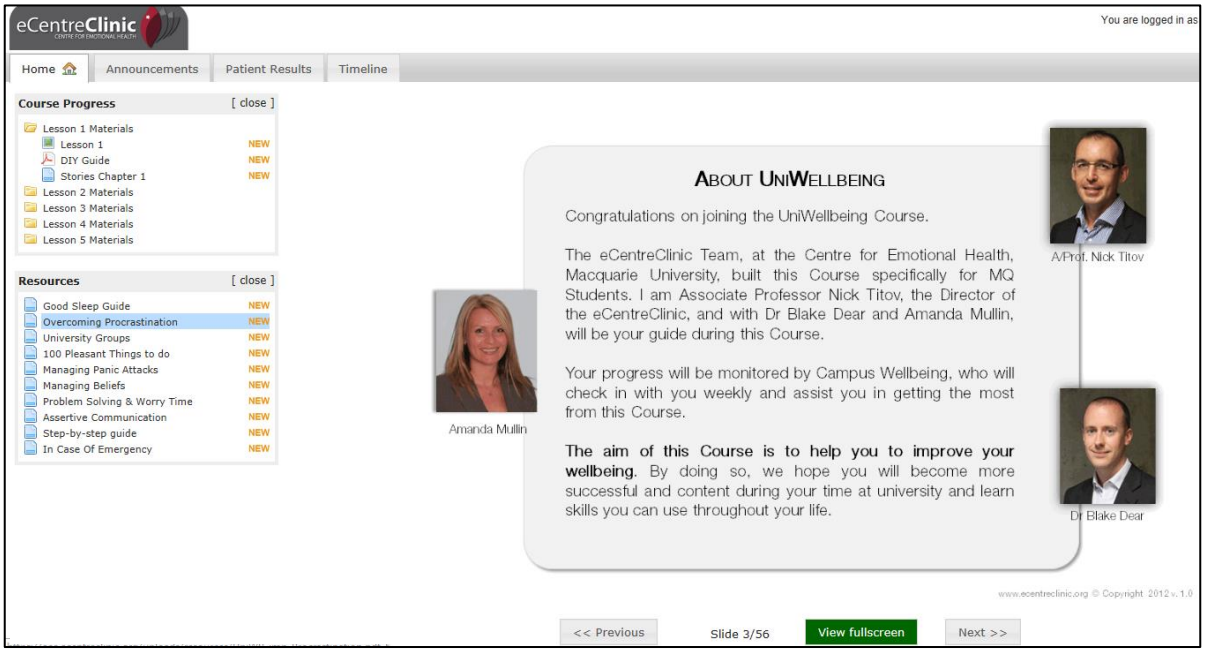

Figure 8. Welcome by the eCentreClinic. Illustrates how the eCentreClinic was introduced in the lesson slides.

Clinician contact. Clinician contact was provided by three staff members at the SCS, with supervision from two managers and support from the candidate. The clinicians telephoned participants once per week at a pre-arranged time. At 2-month follow-up, clinicians telephoned participants to encourage completion of the questionnaires, and to determine whether participants required any further assistance from the SCS.

Feedback about the implementation. Feedback was collected from email communications, records of meetings and informal communications in addition to formally administered measures.

Safety. Participants responses to the PHQ-9 were automatically monitored. Those whose PHQ-9 total scores increased during the course from pre-treatment by more than 5 points, and who also had a total score ≥15, indicating the presence of moderately severe depression, were contacted by the clinician via an email providing instructions about how to contact crisis services in the event of a mental health emergency. However, those with PHQ-9 scores of 20 or more, indicating severe depression, or scoring '3' to question 9 of the PHQ-9 indicating suicidal ideation, were telephoned by the clinician who carried out a risk assessment and implemented a safety management plan.

Negative outcomes. The number of times safety protocols were triggered because of elevated PHQ-9 scores, and the proportion of participants with significant deterioration in PHQ-9 or GAD-7 scores were recorded. The latter was calculated based on a completer analysis and defined as an increase in PHQ-9 or GAD-7 scores of 5 or more points from pre-treatment. This was based on the classification suggested by Kroenke and Spitzer (2002).

Statistical analysis. A mixed-models approach with an autoregressive covariance structured and using maximum likelihood estimation was identified as the best way to handle missing data at post-treatment and two-month follow-up. Differences in questionnaire scores were compared from pre-treatment to 2-month follow-up using pairwise comparisons. Effect sizes (Cohen's *d*) and 95% effect size confidence intervals were calculated using the estimated marginal means for within and between-group changes, based on the pooled standard deviation with an effect size of 0.2 to 0.5 described as small, between 0.5 to < 0.8 as medium, and 0.8 ≥ as large (Cohen, 1988). All analyses were performed using SPSS version 21.0.

Evaluation of the Implementation Trial.

An adapted version of the CFIR (Damschroder et al., 2009), was used to evaluate the overall success of the implementation trial. Use of the CFIR enables researchers to systematically capture and organise findings across five domains, thereby separating information gathered about the implementation into discrete areas for evaluation. The five domains are:

(1) The *characteristics of the intervention,*

(2) The *outer setting*, or needs of student consumers,

(3) The *inner setting*, which broadly consists of the organisational culture of the SCS and its readiness for change,

(4) The *characteristics of individuals* within the SCS, such as clinician attitudes towards the intervention and,

(5) The *process of implementation*.

These five domains are comprised of 39 constructs, of which researchers are advised to select and operationalise the constructs most salient to the specific implementation (Damschroeder et al., 2009). In this study, careful consideration was given by the Candidate to which constructs would be most useful to future research in implementing iCBT, and which could be effectively measured within the limitations of this study. This resulted in the selection of 9 constructs for evaluation, which are articulated in Table 7.

Table 7

Constructs and Measures for Evaluation of the Implementation.*

Construct	Description (that is, what is measured)	Measurement data (that is, how it is measured)
(1) Intervention Characteristics		
Evidence Strength & Quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	Feedback from managers and clinicians, quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *strong evidence (5)* to (1) *no evidence.*
Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus treatment as usual.	Feedback from managers and clinicians, quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *highly advantageous* to (1) *no advantage*.
Complexity	Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.	Feedback from managers and clinicians; quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *very complex* to (1) *very simple*.
(2) Outer Setting		
Patient Needs & Resources	The extent to which students needs are met.	Feedback from managers, clinicians and participants, quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *very much met needs* to (1) *very poorly met needs.*
(3) Inner Setting		
Compatibility	The degree of tangible fit with existing workflows and systems.	Feedback from managers and clinicians, quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *very highly compatible* to (1) *very poor compatibility*.
Readiness for Implementation	Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.	Feedback from managers following implementation. Evaluated using a 5 point scale from (5) *very highly* ready to (1) *not at all* ready.
(4) Characteristics of individuals		
Knowledge & Beliefs	Clinicians' attitudes toward and value placed on the intervention as well as familiarity with facts, and principles related to the intervention.	Feedback from managers and clinicians, quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *very positive* to (1) *very negative* attitudes.
(5) Process		
Planning	The degree to which the implementation plan is developed in advance and the quality of engagement.	Evaluated by time spent in planning, clarity of goals and communication. Evaluated using a 5 point scale from (5) *very well planned* to (1) *very poorly planned*.
Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, training, and other similar activities.	Evaluated by number of referrals to the treatment; feedback from managers, clinicians, and participants; quantitative data from satisfaction questionnaires. Evaluated using a 5 point scale from (5) *very good engagement* to (1) *very poorly engagement*.

*Adapted from the Consolidated Framework for Implementation Research (Damschroder et al., 2009).

Results of the Open Trial.

Adherence and attrition. Eleven participants met all inclusion criteria and were allocated to the trial. Five participants were formally excluded due to technical problems which prevented participants receiving emails and from logging in to complete questionnaires. Six participants completed the pre-treatment questionnaires, began the lessons and were eligible for analysis. Post-treatment data was collected from 4 participants (67%) and 2-month follow-up data was collected from 2 participants (33%).

Lesson completion. 100% of participants (n = 6) began Lesson 1. Five participants (83%) completed all 5 lessons within the allocated time, and the mean number of completed lessons was 4.3 (SD = 1.63).

Primary and secondary outcome measures. The results of primary and secondary outcome measures are shown in Table 8. Estimated means for primary outcome measures are shown in Figure 9.

PHQ-9. The mixed-models analyses examining PHQ-9 scores revealed no significant main effect for Time ($F_{6,\ 22.77}$ = 1.64, p = .181) from pre-treatment to 2-month follow-up.

GAD-7. The mixed-models analyses examining GAD-7 scores revealed no significant main effect for Time ($F_{6,\ 21.26}$ = 2.23, p = .080) from pre-treatment to 2-month follow-up.

K-10. The mixed-models analyses examining K-10 scores revealed no significant effect for Time ($F_{2\ 9.12}$ = 1.16, p = .357) from pre-treatment to 2-month follow-up.

SDS. The mixed-models analyses examining SDS scores revealed a significant effect for Time ($F_{2\ 6.10}$ = 144.21, p < .001). Pairwise comparisons revealed a significant improvement from pre-treatment to post-treatment (p >.001), but this improvement was not sustained, with no significant improvement from pre-treatment to 2-month follow-up (p = .846).

Effect sizes. Table 8 shows the effect sizes for primary and secondary measures. A large pre-treatment to post-treatment effect size (*Cohen's d*=1.91) was found for the SDS, but this was not sustained at follow-up. No other outcomes were statistically significant; therefore the effect sizes for the other measures cannot be reliably interpreted.

Table 8

Results of Outcome Measures.

Measure	Observed Means			Estimated means			Effect Sizes (Based on estimated means)	
	Pre	Post	Follow-up	Pre	Post	Follow-up	Pre-post	Pre-Follow-Up
PHQ-9	12.17 (5.38)	10.00 (5.76)	11.17 (5.53)	13.29 (3.09)	10.43 (3.71)	11.50 (5.29)	0.84 (-0.40 to 1.95)*	0.41 (-0.76 to 1.52)*
GAD-7	12.33 (4.84)	10.83 (6.27)	11.00 (4.29)	13.41 (3.72)	11.89 (4.49)	10.13 (6.57)	0.37(-0.80 to 1.48)*	0.61 (-0.59 to 1.72)*
K-10	32.00 (7.62)	27.83 (10.55)	31.33 (9.11)	33.83 (6.54)	27.45 (7.83)	31.61 (11.37)	0.88 (-0.36 to 1.99)*	0.24 (-0,91 to 1.36)*
SDS	21.17 (12.56)	14.33 (9.27)	21.33 (7.03)	22.23 (5.31)	12.02 (5.37)	23.11 (5.40)	1.91 (0.43 to 3.10)	0.16 (-1.28 to 0.98)*

Note: For observed means, an intention to treat model was employed with pre-treatment data being carried forward where post-treatment or follow-up data was not available. Estimated means were obtained using the mixed model analyses. Standard deviations and confidence intervals are shown in parentheses. Pre: Pre-Treatment; Post: Post Treatment; Follow-up: 3-month follow-up; PHQ-9: Patient Health Questionnaire 9-Item; GAD-7: Generalized Anxiety Disorder 7-Item; K-10: Kessler 10-Item; SDS: Sheehan Disability Scales.

*Mixed models analyses indicated that these outcomes were not statistically significant and cannot be reliably interpreted.

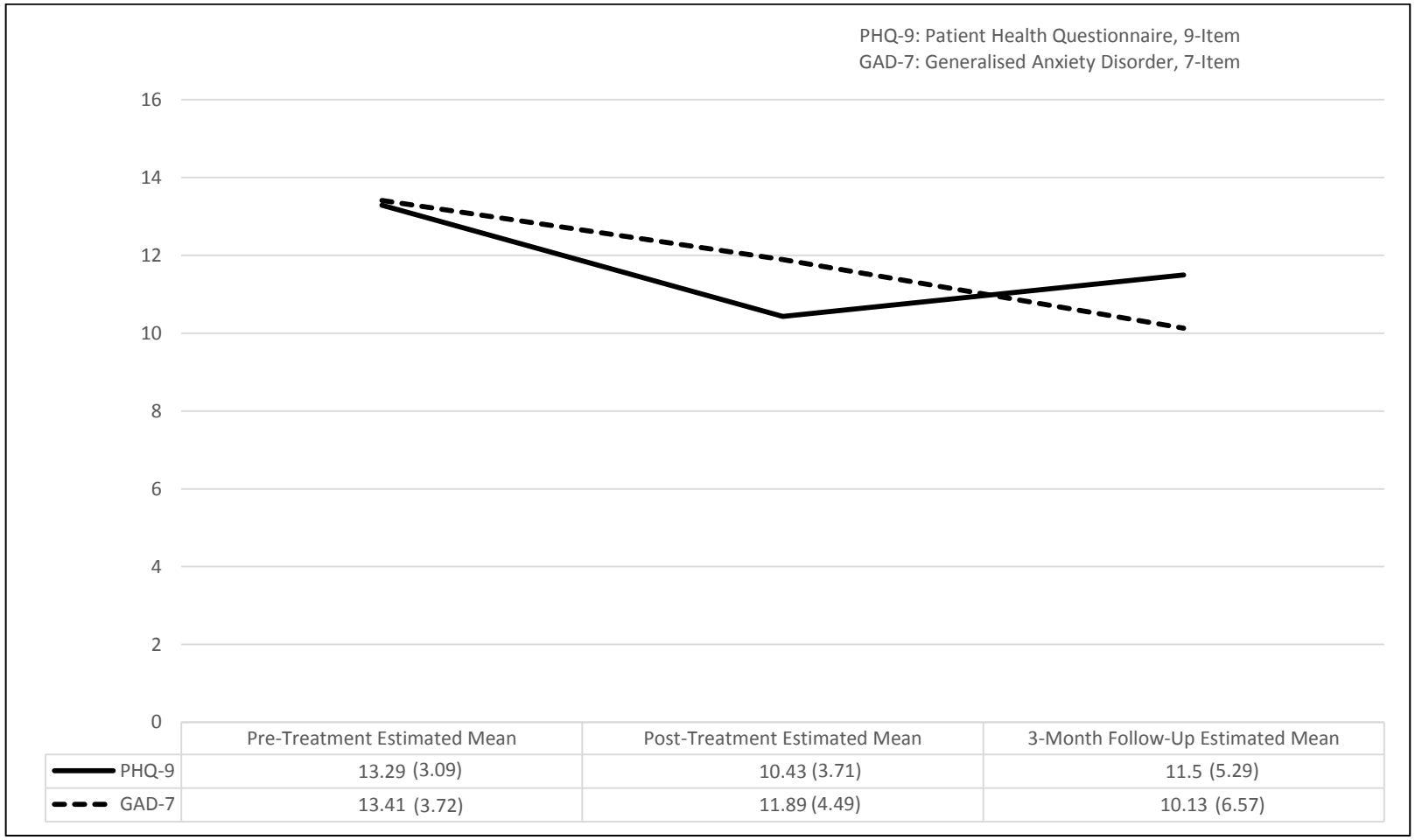

Figure 9. Pre-treatment, post-treatment and 3-month follow-up observed means and standard deviations. Describes the observed means for the primary outcome measures (Patient Health Questionnaire, 9-Item, and Generalized Anxiety Disorder, 7-Item).

Clinical significance. The small sample size and missing data at post-treatment and 2-month follow-up precluded any reliable statistical analyses assessing recovery or remission.

Participant satisfaction. At post-treatment, 3/6 participants (50%) completed the satisfaction questionnaire. Using a five-point scale ranging from *very satisfied* to *very dissatisfied*, 2 participants (67%) reported being *very satisfied* with the course and 1 participant (33%) reported their satisfaction as *neutral*. Using a five point scale, 2 participants (67%) reported the *UniWellbeing Course* had *increased their confidence* that they can learn to manage symptoms of stress, anxiety and low mood, and 1 participant (33%) reported *no change in their confidence*. All 3 respondents (100%) reported it was *worth their time doing the course*, and that they *would recommend the course to a friend*. Participants were generally positive in their feedback comments about the intervention. Examples of such comments included "*I would recommend this course to everyone, it was very helpful in managing my symptoms of stress and anxiety. although I am not completely healed, I have learned to manage my symptoms and ensure I have the skills at hand in case there is a relapse."*

Clinician Satisfaction. At post treatment, 2 of the 3 clinicians (67%) completed post-treatment satisfaction questionnaires. Using 5 point scales ranging from *very satisfied* to *very dissatisfied*, both clinicians reported being *mostly* or *very satisfied* with the course in delivering helpful education to students, and *very satisfied* with the quality of training and support provided. One clinician reported that their *confidence had increased* in delivering iCBT to students, whereas the other clinician reported *no change in confidence*. Both clinicians reported that it was *worth their time delivering the course* and both clinicians reported that they *would recommend it to a colleague*.

Service Satisfaction. At the end of the study, two SCS managers (100%) completed satisfaction and feedback questionnaires. In addition to providing qualitative feedback, both reported that they would recommend iCBT to another University Wellbeing Service, and using 5 point scales, reported being *very satisfied* with the quality and design of the intervention ($M = 5$, $SD = 0.00$) and that the *UniWellbeing Course* was *somewhat effective* or *highly effective* ($M = 4.5$, $SD = 0.71$) in meeting the needs of students seeking help from the service.

Safety and negative outcomes. There were no instances of PHQ-9 scores elevating during the course, and no clinically significant deterioration was observed from pre-treatment to post-treatment or pre-treatment to 2-month follow-up. However, missing data at post-treatment and at follow-up limits conclusions about negative outcomes.

Results of the Implementation Evaluation

This section describes the outcomes of the evaluation of the implementation according to the five components of the CFIR model. This section also describes the ratings relevant to each domain, using measurements articulated in Table 7 (see Methods Section, Page 89).

(1) Characteristics of the intervention.

Evidence strength and quality. Overall rating = 4/5, indicating "*moderately strong evidence"*. Feedback during planning from the managers was that iCBT had good credibility and high levels of potential adaptability. The managers demonstrated good knowledge and understanding of stepped care models and iCBT. All therapists at the SCS were invited to attend an information session presented by the researchers, that outlined the purpose, features and benefits of iCBT. However, informal feedback generally reflected a degree of scepticism that an online system would be able to manage the individual needs of students. Several staff members were concerned with risk management, one commented that students required more assistance then "basic CBT", and one commented that the level of technical skill required would be too high for many students or clinicians. In an effort to address many of these issues, all SCS therapists were provided with access to, and invited to trial a version of the *UniWellbeing Course* developed specifically for this purpose. Due to system limitations, it was not possible to ascertain how many staff accessed the course, however, no feedback or follow-up questions were received.

Relative advantage. Overall rating = 3/5, indicating "*neutral relative advantage"*. The overall costs of the implementation were low, as the *UniWellbeing Course* was offered to the SCS at no cost other than the management time to plan and supervise the implementation and the training time for clinicians. Additionally, iCBT is a cost effective model of treatment, with Study I indicating evidence of significantly reduced clinician time when compared to face-to-face CBT. The intervention was able to be tested on a small scale within the SCS, minimising risks and affording key stakeholders the opportunity to gain experience with iCBT. At the planning stage, the managers repeatedly highlighted potential advantages for the service, clinicians and consumers in using iCBT. However feedback at planning and at post-

implementation indicated that some clinicians in the SCS had concerns that treatment as usual may be more effective, particularly for students with complex needs.

***Complexity*.** Overall rating = 4/5, indicating "*moderate complexity"*. Although complexity was assumed to be low by the research team and managers during the planning stage, a number of unexpected barriers arose. At post-implementation, complexity was rated as *fairly simple* (2/5) by the overall manager of the SCS and as *somewhat complex* (4/5) by the manager who had supervised the clinicians. Several characteristics of the intervention were identified as barriers to implementation. These included the degree of complexity in the application process, and a lack of flexibility in adapting the intervention when a design flaw was identified, due to the need to meet conditions of ethical approval. For example, the study design required participants to be allocated a newly created and unique Gmail account, from which they were advised to login and set up a mail forwarding service to an email of their choice. This process caused considerable frustration for participants and clinicians and led to the first five participants being excluded for technical reasons. Additionally, these complexities were noted to result in clinician frustration and anecdotal feedback suggested it may have led to clinician disengagement with the implementation in the early stages.

(2) The outer setting.

***Student needs and resources*.** Overall rating = 4/5, indicating "*needs moderately met*". All of the student consumers who used the intervention and gave feedback said they would recommend it to a friend. Clinician feedback was that students accessing treatment had a strong preference for face-to-face treatment and were unwilling to be "stepped-down" to iCBT, and this was consistent with feedback from the managers of the SCS, with the following an example of manager feedback:

> *"At the most recent Heads of Counselling meeting for Universities in UNSW/ACT, I discussed our issues with recruitment and several colleagues who had been referring to "MyCompass" and other online interventions and came to the same conclusion... those people seeking online treatments directly are different to those that would be referred post a face-to-face assessment. The transition from face to face to online seems to be a big one (particularly for students)"* (B. Wilkes, personal communication, November 7, 2012).

The timing of the research trial also appeared to be important, with feedback that the nature of appointments changed during the examinations provision period. During those weeks, the managers advised that there appeared to be few cases that would be referral

possibilities for the course, as the majority of the triage appointments were for past service users or those previously registered with disabilities.

(3) The inner setting.

***Compatibility*.** Overall rating = 2/5, indicating "*low compatibility*". A lack of time to explain treatment options to consumers was reported to be a significant barrier by clinicians during the study. Although the triage appointment time was increased from 30 to 60 minutes this did not improve recruitment. The clinicians who used the intervention and provided feedback reported being *mostly* and *very satisfied* with the iCBT treatment. One of the managers suggested that intervention compatibility may be increased by directing suitable students to the treatment at an earlier time point, for example, from the SCS webpage, rather than offering a choice between online or face-to-face therapy, and then stepping-up as required.

Readiness for implementation. Overall rating = 3/5, indicating "*somewhat ready for implementation"*. Tangible indicators of organisational commitment included the management team meeting regularly with the researchers, and the managerial patience demonstrated through the allocation of extra time to the triage session following clinician feedback. At review, the managers reported being *somewhat ready* for this type of intervention, noting culture change and a review of administration processes would be important to increase service readiness.

(4) Characteristics of the individuals involved.

Knowledge and beliefs about the intervention. Overall rating = 3/5, indicating "*neutral knowledge and beliefs"*. Knowledge and skill for clinicians using the intervention was provided by both didactic and competency based practical training, which included using the demonstration site, and role playing introducing the intervention to a potential participant. Four training sessions of 60 minute duration were provided, and engagement with training was variable. Although it was encouraged, two of the clinicians had not logged in to the *UniWellbeing Course* demonstration website prior to the first training session, citing lack of available time as the reason. One of the clinicians was unable to attend the initial training session, which prevented some didactic training being delivered to this clinician. The online system was considered simple and easy for clinicians to use, and overall, knowledge of the intervention was considered as low-moderate. Individual characteristics of the clinicians, for example, familiarity with software systems or learning styles, were not evaluated.

(5) The implementation process.

***Planning*.** Overall rating = 3/5, indicating "*neutral planning*". Monthly planning meetings were held for this project with multiple stakeholders' needs and perspectives considered. Strategies were tailored for the implementation to be undertaken within the triage population of SCS, and appropriate communication channels were identified and used. Consideration was given to barriers created by norms and values (how they do things) within the organisational structure, and clinician beliefs about how best to treat students. However, an assumption by the managers and the research team during the planning stages that the implementation would be simple reduced contingency planning. This meant that study designs which would have captured important information (e.g. the number of students offered iCBT) were not adequately considered during planning.

***Engaging*.** Overall rating 3/5, indicating "*neutral engagement*". The managers gave feedback that online treatments appeared confronting for a number of staff, and that attitudes varied from "hostility" to "championing the treatment". The managers reported the attitudes of the clinicians involved in the intervention were generally positive. Although clinician attitudes may have played a role in the small number of referrals, feedback suggested that even the clinician who championed the intervention was unable to overcome the barrier of students' expectations of face-to-face therapy.

Discussion

Main findings of the open trial. This pilot study explored the implementation of the *UniWellbeing Course* in a SCS. Disappointingly, the open trial had a very small number of participants (n = 6). Mixed models analyses revealed no statistically significant changes over time on the GAD-7 or the PHQ-9 which were the primary outcome measures. In terms of the secondary outcome measures, no statistically significant improvements were obtained for the K-10. Although, a statistically significant large effect size (d = 1.91) was revealed for the pre-treatment to post-treatment scores on the SDS, this was not sustained at 2-month follow-up. The findings, together with the small sample size prevent conclusions being drawn about the effectiveness of the course in this setting.

It was also hypothesised that participants, clinicians and managers would rate the treatment as acceptable, and this hypothesis was supported. Despite extensive difficulties with recruitment, 5 out of the 6 participants (83%) completed all lessons, indicating good adherence in this small sample. In addition, participants and clinicians who completed the satisfaction questionnaires indicated a high level of satisfaction with the treatment protocol,

and 100% (5/5) reported they would recommend the treatment to friends and colleagues. The managers of the service also reported high levels of satisfaction and that they would recommend the *UniWellbeing Course* to other SCSs.

These high acceptability ratings suggest that therapist-guided iCBT treatments may be acceptable in SCSs, and could be extended to increase student access to evidence based treatment. However, despite good acceptability ratings from those who used the intervention and gave feedback, substantial recruitment difficulties raise a number of concerns about how to best to implement such courses.

Main findings of the implementation evaluation. As this was an exploratory study, no hypotheses were formulated in regards to the factors which would influence implementation. Instead, factors were identified and evaluated using an adapted version of the CFIR, which allowed quantitative information and qualitative feedback to be grouped meaningfully, adding value to the research. Using this framework, it was noted that the perceptions of relative advantage in adopting iCBT appeared to vary by position within the SCS, with the highest level of support for iCBT at the top of the organisation. Consistent with this, managers reported that staff attitudes varied from championing the treatment to mild hostility, and informal feedback suggested some staff members perceived iCBT as a potential threat to their role, or as less effective than face-to-face therapy. This appears consistent with a survey of attitudes towards iCBT, which reported 29% of Australian health professionals rated internet treatments as potentially acceptable, and 38% considered they would use an internet delivered treatment in the future (Gun et al., 2011). Future research could explore whether providing more extensive training and support would mitigate concerns regarding the validity and suitability of iCBT. Evidence suggests that it is not enough to train staff in a new treatment (Sholomskas et al., 2005), but that they must be onside for effective implementation to occur.

The implementation evaluation identified low contingency planning, and low compatibility of the intervention for existing triage workflows as barriers in this study. One of the most influential barriers was considered to be the complexity of the intervention in the early stages of implementation. The process used to protect the anonymity of students was a significant design flaw and appeared to lead to disengagement for both students and clinicians involved in the study. Initially, students had to set up a mail forwarding service rather than use a personal email address (as it contained identifying information). This was an ethical research practice that was unsustainable in a real-world setting. The requirement for ethical approval is standard for research trials, and may be considered a potential barrier as it forces

rigid adherence to protocols developed in the planning stage, reducing flexibility and the ability to adapt quickly to local demands. In this instance, the email forwarding process caused significant frustration for five participants and for the clinicians. Ultimately, it resulted in the exclusion of these participants who were unable to receive emails.

Clinician attitudes are considered to be a significant factor in implementing evidence based treatments (Aarons, 2004; Nelson & Steele, 2007), and models of work performance would suggest that for effective change, clinicians may need to be adaptive and proactive when a novel work practice is introduced (Griffin, Neal, & Parker, 2007). These factors may have been influenced by disengagement, which was suggested by the reduction in referrals to the *UniWellbeing Course*. In the first four weeks of implementation 9% of students (5/55) were referred to the *UniWellbeing Course,* whereas, in comparison, only 2% of students (6/289) were referred over the following 6 months. The clinicians reported that during the 30 minute triage appointments they often ran out of time to discuss or offer iCBT, however, extending the triage session to 60 minutes did not overcome recruitment issues. In comparison, a previous study reported 38% (6/16 students) attending a SCS accepted an invitation to participate in CCBT (Mitchell & Dunn, 2007). It was not possible to compare student uptake in this study as it was unclear how many students were offered iCBT as an option.

These recruitment difficulties were not anticipated, reflecting the assumption held by the researchers and managers during the planning stage that the implementation would be relatively simple. Consistent with this, feedback from the SCS managers following the study indicated they remained enthusiastic about the potential of iCBT, but regarded the SCS was only *somewhat ready* for the implementation of this intervention. The head of the SCS reported that increased managerial influence would be essential for future implementation success. This influence could potentially include conducting a review of administration processes to increase readiness, and creating systems which made referral to iCBT an expected outcome, unless clinical considerations warranted face-to-face treatment.

The CFIR framework also prompted an evaluation of how well the intervention met the needs of student consumers. Satisfaction ratings indicated the majority (67%) of students who participated and provided feedback were *very satisfied*, with 100% reporting they *would recommend the UniWellbeing Course* to a friend. However, extensive difficulties in recruitment were a feature of this study. Clinician feedback indicated students attending the triage service had a strong preference for face-to-face treatment which they were unable to

overcome, which was consistent with anecdotal feedback from the managers regarding other SCSs who had attempted to use an iCBT course.

Implications. Clinician attitudes, including disengagement with the intervention may have significantly influenced recruitment, and it was a significant limitation of the study that the reasons for recruitment difficulties could not be accurately determined. Intervention fidelity is necessary to allow accurate interpretations of outcomes (Perepletchikova & Kazdin, 2005), and recording the proportion of students attending the triage appointment who were seeking help for anxiety and depression would have been advantageous. The acceptability ratings from this study suggest that iCBT treatments may hold significant and as yet unrealised potential for SCS and for students. Feedback regarding student expectations for face-to-face treatment and the difficulties in "stepping-down" suggests that the way treatment options are offered and marketed may facilitate future attempts at implementation. Future implementation attempts may benefit from increased consideration of ways to increase the acceptability of the treatment and to reduce the resistance of stakeholders. This could include providing immediate online access to Lesson 1 materials following assessment; offering technical support; creating a pilot virtual service within the SCS or recruiting therapists with positive attitudes towards iCBT.

Limitations. This study was exploratory in nature; however, there were a number of significant limitations identified. These included the small sample size, which precludes reliable conclusions about treatment outcomes and satisfaction ratings. In addition, the study design had several weaknesses including reliance on qualitative measures. The inclusion of robust, quantitative measures of clinician attitudes and participant preferences may have increased the validity of conclusions. Further, no evaluation was conducted of training outcomes of clinicians, and further research may benefit from the inclusion of competence benchmarks for completion of training. Data regarding clinician time per participant, and participant feedback regarding clinician contact was not collected, and future research would benefit from the inclusion of such measures. Finally, evaluation of the implementation was conducted by the candidate and may have led to bias in the interpretation of data. Future research would benefit from using independent and blind reviewers to evaluate the data.

Conclusions. Significant recruitment issues were a feature of this study and a significant barrier in exploring the efficacy of the *UniWellbeing Course* in treating anxiety and

depression in this setting. There were no statistically significant outcomes on the primary measures of anxiety and depression, and the findings, together with the small sample size prevent conclusions being drawn about the effectiveness of the course in this setting.

Use of the CFIR was found beneficial in the organisation of information to allow evaluation of the success of the implementation. The most significant barriers were found to be the assumption by the researchers and managers of the SCS that the intervention would be relatively simple, which led to poor contingency planning and study design flaws, and the high complexity of the research model in the early stages when used in a real-world setting. These precluded reliable conclusions being drawn about the influence of clinician attitudes on outcomes. However, despite the implementation having limited success, the intervention was rated as acceptable by clinicians and students who used it. Importantly, those students, as well as the clinicians and the management team at the SCS who were involved in the implementation study would recommend the intervention to other students, clinicians and University Wellbeing Services, respectively. This suggests that despite implementation difficulties, therapist-guided iCBT treatments may hold promise as an alternative to face-to-face treatment for university students with depression and anxiety. It is hoped this study will promote understanding of how to implement evidence-based interventions for the student population.

CHAPTER FIVE

General Discussion

Anxiety and depression are common and often co-morbid disorders (Slade et al., 2009). Although clinically effective psychological treatments such as CBT are available, multiple barriers to treatment exist, and consequently many people do not receive evidence-based interventions. This appears especially true for the university student population who report increased levels of psychological distress compared to age-matched controls (Stallman, 2010). Despite this, the utilisation rates for university counselling services are very low, with between 2 to 4% of students accessing services (Raunic et al., 2008). Several barriers to treatment have been identified in student populations. These include low mental health literacy, attitudes and stigma (Rickwood et al., 2007) and a preference for obtaining health information online, or from informal sources, rather than from a professional (Hodges et al., 2007; Ryan et al, 2010). They also include the limited resources of university counselling services, who report increases in the numbers of students presenting with serious psychological problems (Gallagher, 2009). These barriers suggest innovative, online, evidence based treatments may offer some potential to reduce the treatment gap.

The efficacy of iCBT interventions has been well documented, and there are emerging effectiveness studies demonstrating good outcomes for adult population samples (for a review, see Andersson et al., 2013) with a great deal of research currently being conducted, particularly by teams in Sweden, the Netherlands, Switzerland and Australia. These studies indicate iCBT has considerable potential to overcome many of the barriers described above. Additionally, the few studies which have specifically examined the use of CCBT, or CCBT delivered as iCBT for university students with anxiety or depression as a primary group of interest, have indicated the preliminary efficacy of this treatment (Day et al., 2013; Kenardy et al., 2003; Mitchell & Gordon, 2007).

Therefore, the primary aims of this thesis were to develop and evaluate a transdiagnostic iCBT treatment for anxiety and depression for university students, and to explore the implementation of the treatment in a SCS as an alternative to face-to-face treatment. The studies reported in this thesis aimed to evaluate the efficacy and acceptability of the *UniWellbeing Course*, a brief transdiagnostic iCBT treatment for anxiety and depression specifically tailored to university students in: (a) A therapist-guided format; (b) A self-guided format, and; (c) To identify real-world barriers in moving the treatment from a research clinic

to a service provider. The latter aim was achieved by evaluating the implementation of the *UniWellbeing Course* as a treatment option within a SCS.

Main Findings

Efficacy. Based on reviews (Andersson & Cuijpers, 2009; Andrews et al., 2010; Coull & Morris, 2011; Spek et al., 2007) and previous research using a similar intervention (Titov et al., 2013), it was hypothesised that participation in a therapist-guided or a self-guided version of the *UniWellbeing Course* would result in significant reductions in symptoms of anxiety and depression, as measured by the GAD-7 and PHQ-9 respectively. The results of Studies I and II, which are summarised in Table 9, supported this hypothesis. In Study I, a RCT design was used to evaluate a therapist-guided version of the *UniWellbeing Course* compared to a waitlist control condition. Mixed-models analyses revealed statistically significant reductions in symptoms of anxiety and depression for the treatment group (n = 29), relative to the control group (n = 23). Consistent with this, the treatment group obtained large within-group effect sizes on the PHQ-9 (*Cohen's d* = 1.13) and GAD-7 (d = 0.96) at post-treatment, which were sustained at 3-month follow-up. In Study II, participants from the waitlist-control group of Study I (n = 16) were provided access to a self-guided version of the *UniWellbeing Course*. Outcomes on the PHQ-9 and GAD-7 in Study II were consistent with those obtained in Study I. In addition to the pattern of improvements in symptoms of anxiety and depression observed in Study I, results also indicated reductions in the prevalence of DSM-IV anxiety disorders and depression at 3-month follow-up. In addition, statistically significant improvements in secondary measures of psychological distress (K-10) and disability (SDS) were observed in Study 1, with medium to large effect sizes at post-treatment, which were sustained at follow-up. Similar outcomes were observed in Study II for the SDS, and although outcomes for the K-10 at post-treatment were not significant, a significant improvement was noted at 3-month follow-up.

Overall, these outcomes provided preliminary evidence that both a therapist-guided and a self-guided version of the *UniWellbeing Course* may be efficacious in treating anxiety and symptoms of depression in this population. However, the conclusion of preliminary efficacy was curtailed by the results of the open trial within the implementation study (Study III), which failed to replicate these outcomes. The results of this Study are also summarised in Table 9. No statistically significant change was found on the primary measures in Study III, and although this may have been affected by the small sample size in that study (n = 6), these results limit the conclusions of efficacy that can be made about the *UniWellbeing Course*.

Table 9

Outcomes of Studies I, II and III.

Study	Design	Outcome Measures	Within-Group Effect Size Pre-Post (Cohens'*d*)	Completion Rate	Rated satisfaction as *very* or *mostly satisfied*	Would recommend to a friend/peer
I	**RCT** Treatment (*n* = 29) vs. Control Group (*n* = 23)	PHQ-9 GAD-7 K-10 SDS	1.13 (0.56 to 1.67) 0.96 (0.41 to 1.49) 0.79 (0.24 to 1.31) 0.77 (0.23 to 1.29)	55%	88%	94%
II	**Open Trial** Waitlisted-control group from Study 1 (*n* = 16)	PHQ-9 GAD-7 K-10 SDS	0.71 (-0.02 to 1.41) 1.08 (0.31 to 1.79) 0.62 (-0.10 to 1.31) 1.08 (0.32 to 1.79)	65%	86%	100%
III	**Open Trial** Implementation study (*n* = 6)	PHQ-9 GAD-7 K-10 SDS	0.84 (-0.40 to 1.95)* 0.71 (-0.80 to 1.48)* 0.88 (-0.36 to 1.99)* 1.91 (0.43 to 3.10)	83%	Participants = 67% Clinicians = 100% Managers = 100%	100%

Note: 95% confidence intervals are shown in parentheses. Pre: Pre-Treatment; Post: Post Treatment; PHQ-9: Patient Health Questionnaire, 9-Item; GAD-7: Generalized Anxiety Disorder, 7-Item; K-10: Kessler 10-Item; SDS: Sheehan Disability Scales.

*Mixed models analyses indicated that these outcomes were not statistically significant.

Currently, results from meta-analyses have indicated that self-guided internet treatments may be less effective than therapist-guided internet treatments (Andersson & Cuijpers, 2009; Spek et al., 2007), however Studies I and II demonstrated good outcomes for both therapist-guided and self-guided courses. This is consistent with two other investigations which directly compared self-guided to therapist-guided iCBT for depression (Berger, Hämmerli, Gubser, Andersson, & Caspar, 2011) and social anxiety (Berger, Caspar, Richardson, Kneubuhler, Stuuer & Andersson, 2011) in the general population. These studies found no significant difference between the therapist-guided or self-guided courses on the primary outcome measures of depression or social anxiety, respectively. The moderate to large effect sizes obtained in Studies I and II are consistent with those reported in the general literature, and add to the growing body of evidence documenting the effectiveness of minimal-help or self-help internet interventions (Andersson & Cuijpers, 2009; Andrews et al., 2010; Coull & Morris, 2011; Spek et al., 2007). The outcomes for this transdiagnostic intervention are also consistent with those reported in the most recent trial of the *Wellbeing Course* (Titov et al., 2013), a transdiagnostic iCBT intervention targeting people with anxiety disorders or depression. In that study which explored the efficacy of an entirely self-guided intervention, large effect sizes (PHQ-9 ES=.96; GAD-7 ES=1.08) were reported at post-treatment, with further improvements at 3-month follow-up.

Importantly, findings from Studies I and II extend the literature on iCBT for the student population, with outcomes consistent with a transdiagnostic iCBT program developed specifically for students (Day et al., 2013). In that RCT, which had a sample of 66 university students recruited by advertisements, medium effect sizes for anxiety and depression were found on the Depression Anxiety Stress Scale (DASS: Lovibond & Lovibond, 1995) following 5 sessions of therapist-guided iCBT compared to a waitlist-control. The results of the study by Day and colleagues (2013), and the results of the present study provide preliminary support for the efficacy of a transdiagnostic treatment protocol for this population.

The present results are not consistent with the findings of Coull and Morris (2011) who reported that effect sizes often diminish at follow-up. In Studies I and II of the present thesis, increased effect sizes were obtained at follow-up on the primary outcome measures, which is consistent with studies evaluating the *Wellbeing Course* (Titov et al., 2012, 2013), on which the *UniWellbeing Course* was based. The sustained gains or improvements may reflect the benefits of transdiagnostic content which allows participants with co-morbid anxiety or depression to learn strategies that target core symptoms relevant to multiple diagnoses, rather

than having to participate in several disorder-specific protocols (Boisseau et al., 2010; Wilamowska et al., 2010). The clinically and statistically significant reductions in the mean number of cases of anxiety disorders and depression in Study I add support to this argument. However, it is important to note that future research would benefit from a longer follow-up period to explore the sustainability of these gains.

Completion rates and acceptability. Based on several lines of research including reports that websites are a preferred source for seeking advice for mental health problems (Escoffrey et al., 2004; Ryan et al., 2010), that 47% of Australian students surveyed considered they would use an online intervention (Ryan et al., 2010), and from the high satisfaction ratings observed in the *Wellbeing* body of work (Titov et al., 2011; Titov et al., 2013), it was hypothesised that participants would rate the *UniWellbeing Course* as highly acceptable. This was supported, with 97% of participants who gave feedback reporting it was worth their time doing the *UniWellbeing Course*, and that they would recommend it to a friend. However, satisfaction data was not received from participants who did not complete the course, and completion rates were variable across the studies, ranging from 55% in the therapist-guided course, to 65% in the entirely self-guided course, to 83% in the therapist-guided implementation study. Non-completion of internet-based self-help is common (Melville, Casey, & Kavanagh, 2010), with completion rates for online self help interventions such as *MoodGYM*, reported to be as low as 2% (Christensen et al., 2006). Providing an end date and an interview at the end of therapy may improve adherence and completion rates (Nordin, Carlbring, Cuijpers, & Andersson, 2010) and both strategies were used in these studies. However, overall, the completion rates were less than those consistently reported (81%) for a similar transdiagnostic *Wellbeing Course* used with the general population (N. Titov, personal communication, August 20, 2013). In addition, completion rates were also generally less than those reported (71%) in a large effectiveness study of iCBT in a Dutch online mental health clinic (Ruwaard, Lange, Schrieken, Dolan, & Emmelkamp, 2012).

These reduced completion rates may reflect important characteristics of student samples. For example, a completion rate of only 61% was reported for therapist-guided iCBT with a student population (Day et al., 2013). Moreover, other reports indicate that students typically attend between 1 to 6 sessions of face-to-face counselling (Draper, Jennings, Baron, Erdur, & Shankar, 2002; Lambert Hansen, & Finch, 2001), and that close to 50% drop out of therapy prematurely (Hatchett, 2004). In addition, although there are few studies which have focused on student populations, the reported completion rates for iCBT and CCBT in this population

are highly variable, even using the same intervention. For example, two studies which used the CCBT intervention *Beating the Blue*s with a student population reported completion rates of 83% (Mitchell & Dunn, 2007) and 26% (Richards et al., 2013) respectively. The reason for these differences is unclear, but may be related to the level of therapist support, although this variable is also related to inconsistent results. Investigations which have directly compared self-guided to therapist-guided iCBT for depression in an adult population (Berger et al., 2011a) have found completion rates to be lower for a self-guided (36%) course in comparison to a therapist-guided (56%) course, however, a similar study of iCBT for social anxiety in an adult population (Berger et al., 2011b), found no difference in the completion rates (72%) between the therapist-guided and self-guided groups. In comparison, studies with students indicate that adherence is generally lower and some researchers have suggested that this reflects problems with site useability, low attractiveness and low relevance to the student population (Ellis et al., 2011; Sethi et al., 2010). However, as the *UniWellbeing Course* had high satisfaction ratings, with 85% of participants rating satisfaction as *mostly/very satisfied*, this indicates that other factors relating specifically to students may have affected adherence. For example, participants consistently reported the competing priority of exam stress and *lack of time* as a reason for not logging in to complete lessons, and one significant limitation of this study was that it was unable to assess the impact of examination distress on outcomes.

Future research would greatly benefit from exploring the variable of examination distress as a covariate, as psychological distress appears to change in point prevalence across the academic year (Stallman, 2008). Staging a treatment intervention during stressful periods such as the examination period, when the skills are most needed, but least likely to be learned, is likely to confer little advantage to these students. Potentially, this may make them more likely to drop out of treatment, or miss lessons, as well as more likely to fail to practice tasks, resulting in poorer outcomes. Therefore timing of interventions may be a key consideration for future research and dissemination with this population. This issue is discussed further below.

Factors influencing implementation. The CIFR framework (Damschroder et al., 2009) was used in Study III to structure information and to identify factors which may be relevant to future dissemination efforts with the student population. Factors explored included consumer preferences for face-to-face treatment, clinician attitudes towards iCBT, and issues relating to the constraints of research protocols.

Although it was not possible to evaluate the individual characteristics or backgrounds of clinicians who participated in the implementation trial, clinician attitudes are acknowledged as a potential barrier in the wide-scale dissemination of treatments (Aarons, 2004; Nelson & Steele, 2007). A recent Australian survey found only 29% of self-selecting health professionals rated internet treatments as potentially acceptable (Gun et al., 2011) suggesting further evidence of the benefits of iCBT within a SCS may be required before therapists are more accepting of them. In this study, the head of the SCS reported that attitudes towards the *UniWellbeing Course* varied from "*championing the treatment*" to "*hostility*". Such concerns appear consistent with the literature, which suggests online treatments may be more acceptable for those with a cognitive-behavioural background (Wangberg et al., 2007), and that more students may receive psychodynamic or integrative therapy than receive CBT at a SCS (Connell et al., 2008). This was consistent with anecdotal feedback gathered during the implementation study which indicated several staff in the SCS had reservations about the *UniWellbeing Course* as a treatment option. Generally, there appeared to be some reluctance to engage with this treatment approach. For example, several staff raised concerns that therapeutic alliance would be compromised, that client needs were too complex for online treatment, or that face-to-face treatment was more effective.

Feedback from managers and clinicians of the SCS who attempted to implement the *UniWellbeing Course* suggested that the students presenting to the triage service had a strong preference for face-to-face support, and that this was very difficult to overcome. This finding is consistent with a previous study which reported that only 6 of 16 students (38%) attending a SCS accepted an invitation to participate in CCBT (Mitchell & Dunn, 2007). Clinician attitudes towards iCBT, the way the treatment was offered to consumers, and the numbers of students offered iCBT in the implementation study were not measured, and this missing information precludes reliable conclusions. However, although clinician attitudes may have played a role in the small number of referrals, feedback suggests that even the clinician who championed the intervention was unable to overcome the barrier of students' preferences for face-to-face therapy. Therefore, it may be that participants who chose this intervention, either from their own initiative, or through the recommendation of a clinician, prefer self-help. This appears consistent with an earlier study (Mitchell & Dunn, 2007), which found that several students reported they would not consider face-to-face counselling.

Overall, studies which have evaluated iCBT with students (Day et al., 2013; Mitchell & Dunn, 2007) indicate that students who apply directly to participate in iCBT, or who chose it as a treatment option, find it moderately or highly acceptable. Future research may benefit by

directing suitable students to the treatment at an earlier time point, for example, from the SCS webpage, rather than offering a choice between online or face-to-face therapy at triage assessment. This research could then also explore the potential benefits of stepping-up students who do not respond to iCBT to face-to-face or more intense models of service delivery as required.

Treatment expectations are an important consideration, and it cannot be concluded that students who chose to participate in the *UniWellbeing Course* are representative of the student population seeking help. For example, it has been reported that over 60% of students attending student counselling services want 20 or more sessions (Owen, Smith, & Rodolfa, 2009), and as yet, the expectations of students using an online intervention are unknown. Demand for services is a problem, as currently, university counselling services do not have an alternative to face-to-face counselling for students, and around 12% of university counselling services use a triage system similar to the one at MQ to manage caseloads (Gallagher, 2010), which means that students with mild symptoms may have to wait for treatment. CCBT and iCBT interventions may offer a useful role as a preliminary treatment (Schmidt, 2003), as being placed on a waitlist after a triage appointment may lead to attrition (DiMino & Blau, 2012). However feedback in the implementation study suggested that any iCBT intervention would need to be integrated into the routine structure of SCS to both enforce use by clinicians and to create positive expectations for clients. This is consistent with findings from previous research, which has found that organisational readiness to change can be a significant barrier (Gotham, 2004). In Study III of the present study, despite the managers of the SCS reporting they were keen to be early adopters of innovative, evidence based treatments, and having good knowledge and understanding of both stepped care models and iCBT, at review, the managers considered they were only *somewhat ready* for this type of intervention. For any future implementation, it is likely that culture change and a review of administration processes will be essential targets to increase readiness. This is consistent with the literature on organisational change, which suggests that for successful implementation to take place, employee in-role behaviours must change (Hornung & Rousseau, 2007). Models of work performance (Griffin et al., 2007) indicate that the ability of clinicians and managers to adapt to new demands (such as integrating a new treatment) and be proactive (i.e. taking self-directed action to initiate change) may be important considerations in the dissemination of iCBT.

Overall, recruitment difficulties were one of the most significant features of this study. Despite the use of iPads as incentives in the RCT, the use of social media, and a substantial

advertising campaign, only small samples were recruited for the studies in this thesis. Finding the optimum recruitment to attract students to iCBT interventions is important but this issue has not yet been systematically explored in the literature. Some studies which have reported large participant numbers have recruited students who received credit for participation (Kenardy et al., 2003), although others (Day et al., 2013) appear to have successfully recruited participants using a similar advertising process to the one used in the RCT. Interestingly, feedback from many students who participated in the RCT was that advertising for the RCT was not evident. However, the recommendations made by these students to improve promotion of the trial, such as advertising on the University website homepage, library website and putting up posters across Campus were actually utilised in the initial advertising campaign. The issue of optimum strategy for promotions is a major barrier to the potential dissemination of this treatment and is an important target for further research. Many students have concerns about stigma, and it may be that the marketing of the *UniWellbeing Course*, which (for ethical purposes) clearly described the course as a treatment for students with anxiety and depression may have affected recruitment, however, this cannot be confirmed. The marketing of iCBT as an educational course to increase quality of life and academic outcomes, rather than as a clinical treatment to reduce anxiety and depression may be of value in engaging a population who typically avoid revealing any mental health issues.

Despite the difficulties described above, it is important to note that in Study III of the present thesis, both managers of the SCS reported that they would recommend iCBT to another University Wellbeing Service. Both managers reported they were *very satisfied* with the quality and design of the intervention, and that they considered the *UniWellbeing Course* to be *somewhat effective* or *highly effective* in meeting the needs of students seeking help from the service. The considerable flexibility, managerial patience and enthusiasm by the managers of the SCS were considered overall positive influences in the implementation.

Limitations

Several limitations of the studies in this thesis need to be acknowledged. First, the sample size for Study III was very low, and although the sample sizes for Studies I and II were adequate, difficulties in recruitment resulted in a loss of statistical power. This limitation affects the conclusions that can be drawn about the results reported in this thesis, hence the reference to the outcomes as providing preliminary evidence of efficacy.

It should also be noted that the limitations of sample size in the studies of the present thesis reflect a broader challenge relevant to other studies in the field of transdiagnostic

treatment which typically require larger samples than studies of disorder-specific interventions (Johnston et al., 2011). For example, although there was sufficient power to detect overall differences between groups in Study 1 of the present thesis, that study was not designed to compare within groups based on principal diagnosis, or co-morbidity, and more expansive research in this area is required. The limited sample sizes also limit conclusions about treatment efficacy for specific disorders, particularly MDD, Pan/Ag, SP, OCD, and PTSD which were represented by very small samples.

The use of self-report outcome measures which were administered online may represent a second limitation, as many of the questionnaires were not developed for online administration. In particular, it appears no studies have compared online vs. paper and pencil administration of the PHQ-9 and GAD-7. However, previous research using other self-report measures of anxiety and depression have found high correlations between outcome measures administered online compared to when using paper and pencil (Carlbring et al., 2007; Donker et al., 2010; Hedman et al., 2010). These studies have suggested that online administration is unlikely to result in any significant differences from paper and pencil administration. A third limitation relates to whether the measures used in the studies in the present thesis were most appropriate. In the studies in this thesis brief measures were selected to reduce the burden on participants, but such measures may not be as sensitive to change as measures with more items. This issue has been previously identified in the broader field of transdiagnostic research (Titov, Dear, Johnston, & Terides, 2012), and future studies would benefit from broader discussion regarding questionnaire batteries to facilitate the comparison of results across population groups.

A fourth potential limitation relates to the absence of blinded assessors. Blinded diagnostic assessments were not possible given the requirement that, as part of this doctoral thesis, the candidate complete these assessments. The lack of blinding for diagnostic interviews, and the lack of follow-up interviews with the control group in Study I may have resulted in under-estimations of diagnostic symptoms in the treatment group at follow-up. The consistency and robustness of the effects found with the self-report questionnaires indicates that this potential threat to validity is small, assuaging some of this concern.

Another important limitation was the proportion of missing data at post-treatment and at follow-up. This was managed using mixed linear models, which have been identified as the best way to handle missing data at post-treatment and 3-month follow-up (Verbeke & Molenberghs, 2009).

Another important potential limitation concerns the generalisability of these findings to *very severely depressed* students, defined in the studies in this thesis as those with a total score ≥23 or responding >2 to question 9 which inquired about suicidal ideation. The six students with such elevated scores who applied to participate in Study 1 were excluded. Thus the results of Study I as well as Study II, which comprised the control group from Study I, do not provide information about how these results apply to very severely depressed students. The impact of this limitation is mitigated somewhat by the likelihood that people with very severely elevated symptoms of depression require urgent face-to-face assessment and support, and may be less appropriate for internet-delivered interventions.

Future research

Independent replication of these studies with larger samples is required to determine the reliability of the findings. In addition, there remain several important and outstanding research questions. For example, direct comparison of transdiagnostic iCBT with face-to-face treatment outcomes for student populations would begin to inform the debate around the relative utility of these approaches. Such studies would offer the potential to examine differences in outcomes related to presenting problems, primary diagnoses, co-morbidity, and the attitudes of both university students and clinicians towards treatment and clinical support. Further research is also required to assess the longer term clinical outcomes, including possible impact on academic outcomes. Such research should also explore the relative cost effectiveness of self-guided iCBT compared to traditional face-to-face treatment as usual. Finally, a replication and extension of the Study III, the implementation study, will help further determine the factors required for successful implementation of iCBT in SCSs. Such a replication would benefit from providing a link to allow students to apply directly from the SCS website, recording the numbers of students offered the iCBT intervention by clinicians, and making the intervention available to students with anxiety and/or depression who are already registered with the SCS.

Conclusions

Notwithstanding the limitations of the studies in this thesis as described above, the overall results provide promising data which adds to the emerging literature on the efficacy and possible implementation of self-guided and therapist-guided iCBT treatments in SCSs. These studies also provide information that partially addresses the gap in knowledge about the potential of iCBT for university students. Such research has important potential for increasing

the range of treatment options available to students. Such research also has the potential to increase the options in the delivery of services, which currently rely on face-to-face interventions, and are subject to traditional resource constraints such as number of clinicians, clinic space and funding. Overall, the results from the RCT (Study I) and the open trial (Study II) provide preliminary evidence that the 5 week *UniWellbeing Course* was efficacious in reducing anxiety and depression, with results sustained at 3-month follow-up.

However, the results of the open trial conducted as part of Study III, the implementation study, were not statistically significant. This indicates caution is warranted about drawing conclusions about the efficacy of iCBT for students or about the potential of implementation of iCBT. Importantly, all studies indicated students rated iCBT as moderately or highly acceptable, and high levels of acceptability were reported by the clinicians and managers of a SCS. One positive outcome was that the students, clinicians and managers in Study III reported they would recommend the intervention to friends, peers and other university counselling services respectively. Therefore, although this thesis provides a step forward in the understanding of possible new treatments for the university student population, key questions remain. These include questions about how best to disseminate treatment options to this population, and the optimum timing for administering such interventions to a student population. The answers to these questions have considerable implications not only for the clinical and cost-effectiveness of such interventions, but also how they can be best implemented and integrated. It is hoped that the learnings resulting from the studies in this thesis will contribute to the eventual and successful implementation of iCBT for student populations.

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APPENDIX A

Copies of Measures Used

Patient Health Questionnaire, 9-Item (PHQ-9)

This questionnaire will give your clinician more specialised information about your health. Instructions: Over the last 2 weeks, how often have you been bothered by any of the following problems? (Please choose the most appropriate answer)

1. Little interest or pleasure in doing things?
2. Feeling down, depressed, or hopeless?
3. Trouble falling or staying asleep, or sleeping too much?
4. Feeling tired or having little energy?
5. Poor appetite or overeating?
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down?
7. Trouble concentrating on things, such as reading the newspaper or watching television?
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?
9. Thoughts that you would be better off dead, or hurting yourself in some way?

Scoring

Not at all = 0

Several days = 1

More than half the days = 2

Nearly every day = 3

Generalised Anxiety Disorder, 7-Item (GAD-7)

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Please check the most appropriate box).

1. Feeling nervous, anxious, or on edge.
2. Not being able to stop or control worrying.
3. Worrying too much about different things.
4. Having trouble relaxing.
5. Being so restless that it is hard to sit still.
6. Becoming easily annoyed or irritable.
7. Feeling afraid as if something awful might happen.

Scoring

Not at all = 0

Several days = 1

More than half the days = 2

Nearly every day = 3

Sheehan Disability Scale (SDS)

The following question is about how much your symptoms interfere with your life.
The rating scale is as follows:
0 = Not at all
1-3 = Mildly
4-6 = Moderately
7-9 = Markedly
10 = Extremely

Questions 1-3 ask you to rate the extent your symptoms have disrupted your daily life over the past week.

1. Over the past week, to what extent have your symptoms disrupted your work / studies 0-10
2. Over the past week, to what extent have your symptoms disrupted your social life/ leisure activities 0-10
3. Over the past week, to what extent have your symptoms disrupted your family life/ home responsibilities 0-10

Questions 4-5 ask you to rate how many days your symptoms have disrupted your life over the past week.

4. On how many days in the last week did your symptoms cause you to miss school or work or leave you unable to carry out your normal daily activities? 0-7
5. On how many days in the last week did you feel so impaired by your symptoms, that even though you went to school or work, your productivity was reduced? 0-7

Scoring
0 = 0 to 10 = 10

Kessler 10-Item (K-10)

Instructions: For each question, please tick the most appropriate answer.

In the past 4 weeks:

1. How often did you feel worn out for no good reason?
2. How often did you feel nervous?
3. How often did you feel so nervous that nothing could calm you down?
4. How often did you feel hopeless?
5. How often did you feel restless or fidgety?
6. How often did you feel so restless you could not sit still?
7. How often did you feel depressed?
8. How often did you feel that everything was an effort?
9. How often did you feel so sad that nothing could cheer you up?
10. How often did you feel worthless?

Scoring

None of the time = 1

A little of the time = 2

Some of the time = 3

Most of the time = 4

All of the time = 5

Participant Acceptability Questionnaire

The following questions ask you about your satisfaction with the course. Additionally, we would be grateful if you would provide us with your feedback about the Course.

1. Overall, how satisfied were you with the Course?
   1 – Very Dissatisfied; 2- Somewhat Dissatisfied; 3-Neutral; 4- Mostly satisfied; 5- Very Satisfied

2. How has this Course affected your confidence that you can learn to manage symptoms of stress, anxiety and low mood?
   1 – Greatly reduced; 2- Reduced; 3-No change; 4- Increased; 5- Greatly Increased

3. What did you NOT LIKE about this Course? How would you suggest that we change or modify this Course for future participants? *(free text)*

4. What did you MOST LIKE about this Course? Is there anything we can do to make it more useful? *(free text)*

5. Was it worth your time doing this Course?
   1 – No; 2 – Yes

6. Would you feel confident in recommending this Course to a friend?
   1 – No; 2 – Yes

7. How would you rate the quality of the correspondence with Amanda Mullin?
   1 – Very Dissatisfied; 2- Somewhat Dissatisfied; 3- Neutral; 4- Mostly satisfied; 5- Very Satisfied

8. Your feedback is really valuable to us: do you have any other feedback that you would like to provide? *(Free Text)*

Clinician Satisfaction Questionnaire

The following questions ask you about your satisfaction with the UniWellbeing course. Additionally, we would be grateful if you would provide us with your feedback about the clinical procedures for administering it.

1. Overall, how satisfied were you with the Course in delivering helpful education to students?
   1 – Very Dissatisfied; 2- Somewhat Dissatisfied; 3-Neutral; 4- Mostly satisfied; 5- Very Satisfied

2. How has this Course affected your confidence in delivering brief iCBT to students?
   1 – Greatly reduced; 2- Reduced; 3-No change; 4- Increased; 5- Greatly Increased

3. What did you NOT LIKE about this Course? How would you suggest that we change or modify this Course for future participants or clinicians?*(free text)*

4. What did you MOST LIKE about this Course? Is there anything we can do to make it more useful? *(free text)*

5. Was it worth your time doing delivering this Course?
   1 – No; 2 – Yes

6. Would you feel confident in recommending this Course to a peer?
   1 – No; 2 – Yes

7. How would you rate the quality of the training and support from the eCC?
   1 – Very Dissatisfied; 2- Somewhat Dissatisfied; 3- Neutral; 4- Mostly satisfied; 5- Very Satisfied

8. Your feedback is really valuable to us: do you have any other feedback that you would like to provide?
   (Free Text)

Counselling Service Implementation Evaluation Questionnaire

The following questions ask you about your satisfaction with the *UniWellbeing* intervention. Additionally, we would be grateful if you would provide us with your feedback regarding the perceptions of the service in administering online CBT.

1. Prior to the implementation, what was your perception of the quality and validity of the evidence that the intervention would have desired outcomes?
   1 – Extremely strong; 2- Very strong; 3- Moderately strong; 4- Little evidence; 5- No evidence

2. Following this experience, what would you consider to be the biggest barrier for a University Counselling Service in providing this type of treatment option?
   (free text)

3. Would you recommend UniWellbeing to another University Wellbeing Service?
   1 – No; 2 – Yes
   Please comment on anything you would suggest doing differently *(free text)*

4. How complex did you find implementation? (I.e. The perceived difficulty of implementation, reflected by the duration; scope; radicalness; disruptiveness; intricacy and number of steps required to implement the intervention).
   1 – Very Complex; 2- Moderately Complex; 3- Somewhat complex; 4- Fairly Simple; 5- Simple

5. How satisfied were you with the quality and design of the intervention?
   1 – Very Dissatisfied; 2- Somewhat Dissatisfied; 3- Neutral; 4- Mostly satisfied; 5- Very Satisfied

6. How effective did you feel UniWellbeing was in meeting the needs of students seeking help from Campus Wellbeing for anxiety and depression?
   1 – Very effective; 2- Somewhat effective; 3- Neither effective nor ineffective; 4- Somewhat ineffective; 5- Not effective at all

7. How would you rate tension for change? I.e. the degree to which stakeholders in Campus Wellbeing perceived the need to offer treatments such as *UniWellbeing*?
   1 – Extremely high; 2- High; 3- Neutral; 4- Low; 5- Very low

8. How well do you consider UniWellbeing fitted with existing workflows and systems?
   1 – Extremely well; 2- Very well; 3- Moderately well; 4- Poorly; 5- Did not fit at all

9. Readiness for implementation: How ready did you consider Campus Wellbeing to be in terms of organisational commitment to implement an intervention?
   1 – Highly ready; 2- Somewhat ready; 3- Neutral; 4 - Somewhat unready; 5- Not at all ready

10. Engagement: How would you rate clinicians' attitudes (in general) at Campus Wellbeing towards the intervention and online CBT?
    1 – Positive; 2- Somewhat positive; 3- Neutral; 4- Somewhat negative; 5- Negative

Appendix B of this thesis has been removed as it may contain sensitive/confidential content