Treating Comorbid Insomnia in Patients Receiving Transdiagnostic Internet-Delivered Cognitive Behaviour Therapy for Anxiety and Depression: A Randomized Controlled Trial

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Michael Robert Edmonds, candidate for the degree of Doctor of Philosophy in Clinical Psychology, has presented a thesis titled, Treating comorbid insomnia in patients receiving transdiagnostic Internet-delivered Cognitive Behaviour Therapy for anxiety and depression: A randomized controlled trial, in an oral examination held on June 12, 2023. The following committee members have found the thesis acceptable in form and content, and that the candidate demonstrated satisfactory knowledge of the subject material.

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Abstract

Studies have demonstrated that transdiagnostic Internet-delivered Cognitive Behavioural Therapy (ICBT) programs for patients experiencing anxiety and depression can produce large improvements in symptoms. Comorbid insomnia is common among individuals seeking treatment for anxiety and depression, yet transdiagnostic ICBT programs rarely target insomnia and many ICBT patients report that symptoms of insomnia remain after treatment. The current trial was designed to explore the value of including a brief intervention for insomnia alongside an existing transdiagnostic program (Wellbeing Course). A new insomnia intervention was developed using a patient-oriented approach to maximize ease-of-understanding and overall acceptability to patients. Patients were randomly assigned to receive either the standard Wellbeing Course (n = 75) or the newly developed Sleep-Enhanced program (n = 142). The Standard Wellbeing program included basic sleep hygiene advice. The Sleep-Enhanced program included psychoeducation about insomnia and a brief introduction to sleep restriction and stimulus control, which are two key behavioural components of cognitive behavioural therapy for insomnia. Patients assigned to the Sleep-Enhanced program reported larger reductions in insomnia than patients in the Standard Wellbeing control condition (Cohen’s d = 0.67; p = 0.001). There were no statistically significant differences between the Standard Wellbeing Course and the Sleep-Enhanced program in terms of course completion rate ($\chi^2_{(1)} = 0.653; p = 0.419$) or mean reduction in symptoms of generalized anxiety ($F_{(1, 135)} = 1.10; p = 0.296$) or major depression ($F_{(1, 139)} = 3.62; p = 0.059$) symptoms. Patients who received the sleep-enhanced program who more frequently adhered to sleep restriction guidelines reported greater reductions in insomnia symptoms during the program ($p =$
0.031). Patient-reported adherence to stimulus control instructions was not associated with symptom change ($p = 0.836$). Patients reported several factors impacted their sleep during the program, the most commonly reported being anxiety ($n = 98/128; 77\%$), care responsibilities ($n = 75/128; 59\%$), and interruptions such as being woken by noises/external factors ($n = 71/128; 55\%$). The trial results demonstrate that including a brief intervention targeting insomnia can be beneficial for many patients seeking treatment primarily for symptoms related to anxiety and depression, while maintaining the effectiveness of the program for reducing symptoms of anxiety and depression.

*Keywords:* Insomnia, transdiagnostic, anxiety, depression, internet, CBT
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CHAPTER 1: Introduction

The Transdiagnostic Approach

Diagnosis is the medical application of the scientific process of classification and is known as psychiatric nosology when applied to mental illnesses (Jain, 2017). A standard of the diagnostic approach to psychopathology is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM), which defines several distinct disorders that fall into the general categories of anxiety, mood, and sleep disorders, among many others (American Psychiatric Association, 2013; Regier et al., 2013). Psychiatric nosology has had a longstanding and widespread influence on how mental illnesses are understood and treated, but diagnostic approaches also have limitations that have led researchers to explore other options such as transdiagnostic models (Fusar-Poli et al., 2019).

A main purpose of diagnoses is informing the selection of an appropriate therapeutic intervention (e.g., a patient diagnosed with Major Depression Disorder might be offered a psychotherapy program designed for depression). Alongside the development and refinement of the DSM as a diagnostic tool, a wide range of evidence-based treatment options have been developed and tested to treat individuals diagnosed with a given disorder. The result has been that numerous disorder-specific treatment manuals have been developed to treat each specific diagnosis. Many of the available treatments designed for specific DSM anxiety and mood-related diagnoses have become recognized as evidence-based treatments and now form standards of care in many treatment settings (Goodheart et al., 2006). Despite the evidence in support of disorder-specific treatment, the growing number of disorder-specific treatment manuals creates logistical problems in
the provisioning of care, such as increased training burden and curriculum development costs (Dalgleish et al., 2020).

The diagnostic model offered by the DSM suggests that there are numerous distinct disorders that are randomly distributed in the population and co-occurrence is expected based on high base rates of each individual condition (Hranov, 2007). One complication of the diagnostic model is that individuals are frequently assigned multiple diagnoses and comorbidity rates between disorders are often very high. In the case of anxiety and depression, for example, the World Health Organization World Mental Health Surveys found that 45.7% of people with major depressive disorder in their lifetime also met criteria for at least one comorbid anxiety disorder (Kessler et al., 2015). The diagnostic model can be adapted to allow for possible interactions between disorders; however, there is substantial evidence that many of the same etiological and maintenance processes underlie different diagnoses, leading researchers to argue that case conceptualization should instead focus on assessing important shared factors that may underlie several diagnoses (Dalgleish et al., 2020; Hranov, 2007). For example, conceptualizing distinct disorders within the categories of anxiety and depression does not align well with evidence from studies of genetic risk factors. In a large longitudinal twin study, researchers evidenced there is correlation among the genetic risk factors for anxiety and depression (Kendler et al., 2007), evidence which favours a shared factor model.

Diagnosis-driven clinical intervention has practical limitations in routine practice. First, the diagnostic approach relies on accurate diagnosis to match the patient with the most appropriate evidence-based treatment. Accurate diagnosis is challenging given that
there is a great deal of heterogeneity in symptom presentations within diagnoses and that the presentation of psychopathology is known to change throughout the lifespan and depends on developmental processes (Dalgleish et al., 2020). Second, even if accurate diagnosis was made easier, high comorbidity rates complicates intervention selection within the “diagnose and treat” model (e.g., if a patient is diagnosed with major depressive disorder and generalized anxiety disorder, should they be referred to a program for mood- or anxiety-related disorders?). Finally, the diagnostic approach may fail to adequately capture subthreshold symptoms that do not meet diagnostic criteria for a disorder but are nonetheless distressing for the individual (Hranov, 2007). These limitations have helped fuel interest in alternative models for understanding the relationship between depression and anxiety that better account for possible shared factors, such as the transdiagnostic approach to anxiety and depression (Craske, 2012; Dalgleish et al., 2020).

Unitary models of mood and anxiety have been posited to explain the high comorbidity in prevalence studies, overlap in symptoms, and shared genetic risk factors for these conditions in terms of shared underlying factors (Hranov, 2007). For example, based on psychometric analyses, the tripartite model of emotional disorders proposes that while high negative affect is a shared factor between these conditions, anhedonia is a second factor that characterizes depression, and high physiological arousal is a third factor that characterizes anxiety (Clark & Watson, 1991). The tripartite model uses shared factors to address the problematic overlap of symptom definitions for generalized anxiety disorder and major depressive disorder (i.e., difficulty concentrating, sleep disturbance, or fatigue are symptoms of both) (Clark & Watson, 1991). In the anxiety disorders, shared
factors are also evident in the content overlap between various anxiety disorder-specific treatment programs (Barrera et al., 2014). Transdiagnostic therapy protocols for anxiety and depression embrace the concept of shared factors and include therapeutic content to target the shared factors that are common to many anxiety and depression disorders, while also offering the flexibility to include therapeutic content for specific concerns as needed.

Transdiagnostic programs are often based on Cognitive Behavioural Therapy (CBT). CBT offers a shared framework for understanding psychopathology in terms of the interrelationships between emotions, thoughts, behaviours, and physical sensations, providing an adaptable toolset for treating many conditions and therefore an ideal theoretical framework for a transdiagnostic protocol (Barlow et al., 2016). In CBT, the therapy process focuses on helping clients to correct problematic patterns of thinking and behaving. Face-to-face CBT has a substantial evidence base supporting its use for treating several specific conditions and a growing number of meta-analyses have revealed it is capable of producing large effect sizes for reductions in symptoms among those suffering from unipolar depression, generalized anxiety disorder, panic disorder, social anxiety disorder, and posttraumatic stress disorder (Butler et al., 2006; Cuijpers et al., 2013, 2014). Transdiagnostic CBT programs for anxiety and depression have also been shown to produce large overall effects on symptoms of these conditions, medium sized improvements in quality of life measures and greater reductions in depression among comorbid anxiety (McEvoy et al., 2009; Newby et al., 2016). Transdiagnostic approaches are evidenced and have advantages for practical terms of delivery (e.g., simplifying referral decisions, reducing the number of programs clinicians need training for) and
addressing comorbidity (Craske, 2012); accordingly, transdiagnostic approaches have increased in popularity and adoption for diverse therapy modalities, such as internet-delivered psychotherapy (Kazdin, 2015).

**Internet-delivered Psychotherapy**

Researchers who have been motivated by the possibility of providing the benefits of CBT-based psychotherapy on a wider scale and at lower cost have developed numerous Internet-delivered CBT (ICBT) programs and randomized trials have found that ICBT is effective for several conditions (Andersson, Carlbring, et al., 2019; Andersson, Titov, et al., 2019; Carlbring et al., 2018). Notably, a review of studies that directly compared ICBT to traditional face-to-face programs found evidence that ICBT can achieve similar outcomes for patients compared to face-to-face options while also sidestepping barriers to treatment (Andersson et al., 2014). Substantial evidence now supports the use of transdiagnostic ICBT for treating anxiety and depression, with large reductions in anxiety and depression symptoms reported in both large meta-analyses (Newby et al., 2016) and studies of ICBT routine care programs in the local Canadian context (Hadjistavropoulos, Nugent, et al., 2016).

The debate about whether to use transdiagnostic or disorder-specific approaches for the treatment of anxiety and depression has also been of interest to researchers who develop ICBT programs. An Australian ICBT research group conducted a study to directly compare the effectiveness of the transdiagnostic Wellbeing Course for anxiety and depression to a disorder-specific program for patients reporting high symptoms of generalized anxiety. The authors found that reductions in anxiety symptoms are not significantly different between patients who received the transdiagnostic and anxiety-
specific programs (Dear et al., 2015). In a set of similar studies, the authors found that the transdiagnostic program also produced similar effects to disorder-specific programs for panic disorder (Fogliati et al., 2016), social anxiety disorder (Dear et al., 2016), and major depression (Titov et al., 2015). A review of 19 ICBT studies found that transdiagnostic ICBT programs and disorder-specific programs for anxiety did not significantly differ in how much they reduced anxiety symptoms, but transdiagnostic ICBT programs did have an advantage in reducing comorbid symptoms of depression (Păsărelu et al., 2016). Similarly, meta-analysis of 83 treatment conditions collected largely from anxiety studies replicated the finding that disorder-specific and transdiagnostic programs produced similar effects and noted that those with comorbid anxiety and depression benefitted more from the transdiagnostic program (Pearl & Norton, 2017). Transdiagnostic ICBT programs for anxiety and depression therefore represent a promising treatment option and a great deal of research over the last decade has been devoted to improving the effectiveness and patient acceptability of these programs (Titov et al., 2019), including the present research which ultimately aims to improve outcomes by incorporating elements of CBT for insomnia.

Transdiagnostic ICBT typically involves the use of a website or app to deliver a standard set of content (e.g., text, images, and diagrams) to patients. The program teaches the patient skills for resolving problematic patterns of thinking and behaving based on CBT principles. Transdiagnostic ICBT programs include the key elements from face-to-face transdiagnostic anxiety and depression treatments and typically begins with psychoeducation about anxiety and depression and the cycle of symptoms. The CBT model is introduced to clients and used as a framework to guide them through later
lessons that include thought and behaviour monitoring, cognitive restructuring techniques (e.g., thought challenging), exposure therapy, and arousal regulation strategies (e.g., behavioural activation, relaxation techniques).

Transdiagnostic ICBT produces large reductions in mean symptom levels, but not every patient who receives the intervention benefits equally and some patients leave treatment early or report deterioration or nonresponse (Edmonds et al., 2018). For example, in a sample of 1201 patients who received transdiagnostic ICBT for anxiety and depression, approximately one quarter of patients did not access all five lessons of the program and only about half reported a reduction in either depression or anxiety symptoms larger than the required score to indicate a reliable change on symptom measures (Edmonds et al., 2018). Evidence suggests patients who start with higher symptoms stand to benefit most and younger people are at slightly higher risk of leaving the program early, but few other demographic factors are clearly related to patient outcomes (Edmonds et al., 2018; Hedman et al., 2014). Nonresponse to psychotherapy for depression is a concern for both ICBT and traditional face-to-face therapy; improving treatments for depression to decrease nonresponse continues to be an area of great research interest (Cuijpers, 2018). Given that no strong negative prognostic factors for transdiagnostic ICBT have been identified, the approach of improving outcomes by improving screening for treatment appropriateness has taken second seat to attempts to optimize outcomes by improving treatment content and processes.

Researchers have attempted to optimize the effectiveness and cost-effectiveness of transdiagnostic ICBT programs by focusing on the amount of therapist contact. Transdiagnostic ICBT programs can be self-guided or they can include therapist
assistance, which typically takes place via secure internet message or over the telephone, and the optimal amount and timing of therapist contact is the subject of ongoing research (e.g., Hadjistavropoulos et al., 2019). Self-guided ICBT programs could potentially lower the cost of delivering ICBT interventions and large meta-analyses have demonstrated that self-guided programs can be effective in reducing depressive symptoms (Karyotaki et al., 2017). Research into whether therapist assistance is needed to attain therapeutic benefit has also been investigated in a trial of a disorder specific program designed to target depressive symptoms, which found that both self-guided ICBT programs to therapist-assisted ICBT programs produced significant improvement in depressive symptoms compared to wait lists; however, the group who received therapist-assisted ICBT reported a modestly larger reduction in symptoms compared to the self-guided group (Berger et al., 2011). ICBT is a lot of work for the patient and an important part of the therapist’s role is to encourage the patient to continue with the treatment and to help apply the principles to their life (Hadjistavropoulos, Pugh, et al., 2016). Studies have found improved treatment completion rates when even an automated email message reminds patients to continue working on the course (Titov et al., 2014). Researchers continue to look for other ways to maximize completion rates and patient outcomes in transdiagnostic ICBT programs, and persuasive design elements, such as increased interaction with a counselor, more frequent updates, and dialogue support, continue to be investigated and used to increase patient engagement (Kelders et al., 2012).

The present research continues with efforts to improve the effectiveness of transdiagnostic ICBT programs by providing patients with therapeutic content to help them simultaneously address sleep problems. In the DSM, sleep disruption is a symptom
listed in the criteria for both major depressive episodes and generalized anxiety disorder (American Psychiatric Association, 2013) and insomnia can be conceptualized as an important shared factor within a transdiagnostic model alongside anxiety and depression (A. G. Harvey et al., 2011). The current trial will prioritize the treatment of comorbid insomnia using a new sleep-enhanced transdiagnostic protocol.

**Insomnia**

The term insomnia comes from the Greek word *somnus* for sleep and is used diversely in the scientific literature and popular media. Insomnia is often defined simply by self-reported sleep difficulties operationalized as responses to questions like, “Do you have difficulty falling asleep or staying asleep?” (Roth, 2007). Insomnia is also operationalized in some medical studies as the presence of disturbed sleep patterns as measured using polysomnography (Roth, 2007). In clinical psychology practice, the term insomnia typically refers to the diagnostic criteria for Insomnia Disorder as defined in the DSM. Insomnia Disorder criteria in the DSM include unhappiness with the quality or quantity of sleep (e.g., difficulty falling asleep, difficulty staying asleep, or waking too early) that results in substantial distress, or impaired functioning, with a frequency of at least three times a week for a period of three months (American Psychiatric Association & Association, 2014).

Insomnia prevalence estimates vary widely and depend on the definition and the population being sampled (Roth, 2007). A large telephone survey of national health plan subscribers in the United States estimated insomnia prevalence at 23.2% (Kessler et al., 2011). In Quebec, a telephone survey of 2001 adults found that 29.9% reported insomnia symptoms and 9.5% met full DSM-IV criteria for insomnia disorder (Morin et al., 2006).
The same trial also investigated the determinants of what causes patients to seek treatment for insomnia, finding that daytime fatigue (48%), psychological distress (40%), and physical discomfort (22%) were the main determinants of treatment-seeking behaviour (Morin et al., 2006). Older individuals and women appear at higher risk for developing insomnia ("National Institutes of Health State of the Science Conference Statement: Manifestations and Management of Chronic Insomnia in Adults June 13-15, 2005," 2005). A longitudinal study of patients with chronic health issues found that patients who also had insomnia were at higher risk of developing affective disorders, cardiac morbidity, or musculoskeletal problems like back pain or hip impairment (Katz & McHorney, 1998). Insomnia is extremely common and is a risk-factor for several mental and physical health problems.

People with insomnia often report impairment in functioning in multiple domains (e.g., work, social, personal) and economic costs that result from this impairment has been studied in several countries and contexts. The authors of a study from Quebec, Canada categorized 948 randomly selected individuals as either having insomnia syndrome, insomnia symptoms, or as good sleepers based on their responses to questions about sleep (Roizen, 2010). Respondents also answered questions about missed work, reduced productivity, overall health, and use of health-care services and products, allowing the authors to estimate the direct and indirect costs of insomnia, including health-care related costs (e.g., visits to the doctor, prescriptions) and lost-productivity costs (e.g., work absenteeism). The average annualized per-person cost was $5,010 for individuals meeting criteria for insomnia syndrome, compared to $421 for good sleepers. Using extrapolation based on these results, the authors estimated the total economic cost
of insomnia to the province of Quebec at a staggering $6.6 billion (Roizen, 2010). Another study in France analyzed data from health insurance and employers to compare the cost of absenteeism between matched groups of employees with and without significant insomnia concerns. The study found that the employees with insomnia had significantly higher rates of absenteeism than their good sleeper counterparts and also noted that the vast majority of the resulting economic cost (88%) was borne by the employer (Godet-Cayré et al., 2006). In Australia, the direct and indirect costs of insomnia have been estimated at 0.8% of the country’s gross domestic product, which represents 1.8% of the Australia’s total disease burden (Hillman et al., 2006). An American study of health insurance records similarly found that patients with insomnia had significantly higher health care costs than matched non-insomniacs, which totaled an extra $1,253 per patient in individuals with insomnia (Ozminkowski et al., 2007). Another study in America highlighted that insomnia’s main effect on work productivity may not be through absenteeism but through reduced productivity while attending work, finding that having insomnia was associated with the average loss of 7.8 days of work productivity annually (Kessler et al., 2011). The substantial economic costs related to insomnia mean that effective interventions for insomnia have incredible potential as public-health measures, especially if the intervention could be delivered in a cost-effective and patient-acceptable medium.

**Insomnia and depression**

In the DSM-5, disruption of normal sleep is one of the criterion symptoms for Major Depression Disorder. Although insomnia is often thought of as a symptom of depression, many individuals report that their sleep problems precede the onset of
depression and persist after depression is successfully treated (Vargas & Perlis, 2020). A meta-analysis reviewed the question of whether the presence of insomnia might predict the development of depression and found that non-depressed individuals experiencing insomnia were twice as likely to develop depression compared to normal-sleeping individuals (Baglioni et al., 2011). Some evidence suggests the relationship between insomnia and depression may be even stronger in some specific populations, such as one study of elderly patients in general practice that found that patients with insomnia were 3.7 times more likely to be depressed than patients without sleep problems (Almeida & Pfaff, 2005). In light of such evidence, insomnia has moved from being thought of as a symptom of depression to being thought of as an important risk factor for depression (Vargas & Perlis, 2020).

Current thinking is that a number of neurobiological factors may mediate or moderate the relationship between insomnia and depression (Vargas & Perlis, 2020). For example, one study measured insomnia as well as chronotype (one’s preference for morning vs. evening) in patients and found that while insomnia was a significant risk factor for the development of depression, an evening chronotype was an even stronger risk factor, suggesting that processes related to circadian rhythm may have particular importance in how sleep disruption contributes to the development of depression (Chan et al., 2014). Circadian rhythm disruption has been implicated in the insomnia-depression relationship (Germain & Kupfer, 2008). Gender differences in rates of insomnia develop during adolescence, with rates of insomnia among females rising during this time, suggest the possibility of an important hormonal role in the development of insomnia (Marver & McGlinchey, 2020). In general, although the causal relationship between
circadian disruption and the development of depression has not been completely clarified (Wittmann et al., 2018), evidence seems to generally align with a transdiagnostic model where sleep is considered a shared factor for depression and other disorders.

The conceptualization of insomnia as playing a role in the development and maintenance of depression rather than as a symptom of depression is also consistent with evidence from treatment trials. For example, patients with comorbid insomnia and depression who received CBT for insomnia reported reductions in symptoms of both depression and insomnia (Taylor et al., 2007). A randomized trial using internet-delivered therapy found that among patients with comorbid insomnia and depression, those who were assigned to receive a CBT-based intervention for insomnia had better outcomes overall compared to those who were assigned to receive an intervention for depression (Blom et al., 2015). Another study of patients with comorbid depression and insomnia who were receiving escitalopram for their depression found that patients reported larger reductions in both insomnia and depression symptoms when escitalopram was supplemented with CBT for insomnia (Paul L. Enright et al., 1996). Among depressed patients who received interpersonal psychotherapy, a disrupted EEG sleep profile predicted a worse clinical outcome following the intervention (Thase et al., 1997). The evidence suggests that the early and effective treatment of insomnia can significantly decrease the risk that non-depressed individuals will develop depression, while also improving long term outcomes for depressed patients.

**Insomnia and anxiety**

Significant insomnia is also reported by many people living with anxiety disorders. A meta-analysis of studies reporting symptoms of insomnia and anxiety
revealed that the presence of anxiety was related to large increases in subjective sleep disturbance \( (g = 2.16) \) and medium sized decreases in total sleep time \( (g = -0.40) \) (Cox & Olatunji, 2020). The nature of the relationship between insomnia and anxiety has been studied using several methods. A longitudinal study that followed 1420 children and adolescents sought to determine whether sleep problems were present in individuals before they developed a psychiatric disorder (e.g., major depression, anxiety disorders), or whether sleep problems began after the onset of another psychiatric condition (Shanahan et al., 2014). The results showed that insomnia predicted the later development of generalized anxiety disorder and higher symptoms of anxiety and depression, but also showed that the presence of anxiety symptoms predicted the later development of insomnia, suggesting a bidirectional causal relationship between insomnia and anxiety, as well as further evidencing a relationship between insomnia and depression (Shanahan et al., 2014). Results from clinical interviews with 1014 youth, who were asked to report the approximate age of onset of any psychiatric symptoms they endorsed, showed moderate lifetime associations between insomnia and both anxiety and depression (Johnson et al., 2006). Johnson et. al., (2006) also found that the presence of any anxiety disorder significantly predicted the later development of insomnia, while the presence of insomnia significantly predicted the later development of depression. For individuals with anxiety disorders, there is some evidence that insomnia may attenuate psychotherapeutic treatment effects for anxiety, yet there is no impediment to providing insomnia treatments to individuals with anxiety (Carney & Edinger, 2010).
Insomnia Treatments

CBT also has a strong evidence base supporting its use for insomnia (Trauer et al., 2015). CBT protocols for insomnia generally include cognitive therapy, stimulus control, sleep restriction, sleep hygiene, and relaxation (Edinger & Carney, 2014; Trauer et al., 2015). Stimulus control involves asking the patient to avoid all non-sleep activities (excepting sex) in the bedroom and is thought to work by removing the behavioural association between the bedroom and high arousal states invoked by behaviours such as eating, working, or watching television in bed (Edinger & Carney, 2014). Sleep restriction involves sleeping on a strict schedule (e.g., avoiding napping and sleeping in) and begins with mild sleep deprivation to help the patient restore their circadian rhythm and sleep more easily during the night (Edinger & Carney, 2014). Sleep hygiene is simply a name for some psychoeducation about sleep (e.g., tips like keeping the bedroom dark and cool during sleep) and produces modest effects at best (Edinger & Carney, 2014).

The CBT elements for insomnia that fall into the categories of cognitive therapy (e.g., examining beliefs about sleep) and relaxation techniques (e.g., controlled breathing) are nearly identical to those of CBT for anxiety, and designed to combat physiological over-arousal (Carney & Edinger, 2010; Edinger & Carney, 2014). CBT for insomnia is an effective treatment overall that shares many therapeutic elements with CBT for depression and anxiety, making the integration of these therapies easy to contemplate.

Internet-delivered versions of CBT for insomnia have been tested extensively and a recent meta-analysis found that ICBT for insomnia produced effect sizes similar to face-to-face therapy (Zachariae et al., 2016). Within this meta-analysis, evidence was also found that longer treatment duration and more therapist support were related to improved
outcomes (Zachariae et al., 2016). ICBT for insomnia has also been tested among depressed patients, with one study finding that among patients with comorbid insomnia and depression, those who received an ICBT program for insomnia experienced greater reductions in symptoms of both insomnia and depression than patients who received an ICBT program for depression (Blom et al., 2017). There is also evidence for the importance of a strong therapeutic alliance in ICBT for insomnia, with more contact with a therapist being related to greater symptom reductions (Kaldo et al., 2015). An individually-tailored ICBT program has shown that sleep restriction and stimulus control are the most important components, and patient compliance with treatment components targeting insomnia also impacts symptoms of depression (Kraepelien et al., 2019).

Including some key components of CBT for insomnia within a transdiagnostic program for anxiety and depression has great potential to improve patient outcomes. The present research was designed to address a gap in the existing literature in two respects. First, the current trial is the first to specifically investigate whether simultaneously treating insomnia among patients of transdiagnostic can improve patient outcomes. Second, the current trial investigated the differential effect of patient engagement in stimulus control and sleep restriction, which could help to identify the critical components of an effective transdiagnostic ICBT program.

**Purpose and Hypotheses**

The current trial was designed to determine whether an established transdiagnostic ICBT program for depression and anxiety can be improved by offering patients with comorbid insomnia additional materials based on ICBT for insomnia. The initial development and pilot testing of a new Sleep-Enhanced version of the Wellbeing
Course began in 2019. The current randomized controlled trial compared the effect of the new Sleep-Enhanced program to the standard ICBT program. To compare outcomes between conditions, patients completed a battery of questionnaires at screening, at completion of the 8-week program, and then again at 20-week follow-up from post-treatment.

Questionnaires included measures of symptoms (e.g., depression, anxiety, insomnia, panic, social anxiety), distress and impairment, and satisfaction with treatment, as well as questions to elicit feedback about the new materials. The Sleep-Enhanced ICBT program was expected to help patients and lead to a reduction in comorbid insomnia symptoms. Specific research questions and related hypotheses are outlined below. The research questions were generated with input from our patient-oriented research steering committee (PORSC). The PORSC was formed to include and engage several stakeholders in the development and evaluation of an insomnia intervention, including patient-partners (i.e., individuals with lived experience in accessing similar mental health resources), clinicians, and health care decision makers. Patient-oriented research methods have developed because of knowledge translation efforts that seek to maximize the public health benefit of interventions by including several stakeholders – especially patients – to maximize the patient-acceptability of the new intervention (Sunderji et al., 2019). Consideration was also taken to make sure the research questions were directly relevant to the practice of the Online Therapy Unit, so that the results provide maximum benefit to the residents of Saskatchewan and Canada, who have funded this ongoing research program. Accordingly, Online Therapy Unit staff have
provided ongoing advice to ensure the newly developed Sleep-Enhanced program will function within the Online Therapy Unit’s routine care practices.

**Research Question #1: Effect of the Sleep-Enhanced Program on Symptoms**

Does providing ICBT for insomnia materials to patients of the Wellbeing Course produce an effect on symptoms above and beyond the standard program? We know that patients receiving transdiagnostic therapy for anxiety and depression are likely to experience distressing and impairing insomnia, and many patients report that sleep problems remain even after taking the course. The current trial investigates whether including components of ICBT for insomnia as part of a transdiagnostic program for anxiety and depression can produce further reductions in symptoms of insomnia, anxiety, and depression. Patients admitted to this trial completed the Insomnia Severity Index at pre-treatment and at post-treatment to assess for insomnia symptom changes. It was hypothesized *a priori* that patients assigned to the Sleep-Enhanced condition would report greater reductions in insomnia symptoms than the control group and that these differences would be statistically significant.

**Research Question #2: Differential Effect of Sleep Restriction and Stimulus Control**

The newly developed Sleep-Enhanced program includes two key behavioural components that are common for CBT protocols for insomnia and considered important for optimal for insomnia psychotherapy; specifically, sleep restriction (i.e., sleeping on a strict schedule) and stimulus control (i.e., reserving bed for sleep and sex only). During the 8-week ICBT program, patients who received the Sleep-Enhanced program were asked to report how many days over the last week they engaged in sleep restriction and
how many days they engaged in stimulus control. Weekly sleep questionnaires allowed for estimating patient participation in the two therapeutic practices. Patients also completed weekly measures of anxiety (Appendix H) and depression (Appendix G), as well as subjective and objective questions related to sleep quality and quantity (Appendix M). It was hypothesized a priori that patient reports of more frequent engagement in sleep restriction and stimulus control would be statistically significantly correlated with patient-reported change in insomnia symptoms between pre-treatment and post-treatment.

**Research Question #3: Treatment Acceptability and Satisfaction**

Are sleep restriction and stimulus control acceptable treatments within ICBT provided to persons with anxiety and depression? Patient responses to a treatment satisfaction questionnaire were analyzed to test the hypothesis that there will be no statistically significant difference in treatment satisfaction between the Sleep-Enhanced and Standard Wellbeing conditions. Patients who participated in the new Sleep-Enhanced version of the course were asked to complete questionnaires assessing the understandability and utility of the content (See Appendix K – Treatment Satisfaction). Patients were expected to find the information helpful and were expected to provide feedback on the materials. Patient feedback was analyzed using a qualitative content analysis approach to understand any possible challenges patients faced with the program and to identify opportunities for improvements.
CHAPTER 2: Method

Trial Design

The present trial received ethics approval through the University of Regina Research Ethics Board on February 10, 2020 (Appendix A). The trial was registered through ClinicalTrials.gov (#NCT04512768) and follows up a brief pilot of the new materials \((n = 25)\) with a randomized controlled trial designed to test the relative effect of the Sleep-Enhanced program against the standard Wellbeing Course. Patients with symptoms of insomnia were randomly assigned to either receive the Standard Wellbeing program for anxiety and depression or to receive the Sleep-Enhanced program. The target sample size \((n=200)\) was based on a meta-analysis of eight randomized controlled trials wherein ICBT programs for insomnia produced reductions in insomnia severity and improvements in subjective sleep quality with an average hedge’s g effect size of 0.49 (Zachariae et al., 2016). Assuming the new brief intervention can achieve similar reductions in this intervention, a power analysis estimate using 0.8 power and 0.05 significance level indicated two groups of 66 patients would be needed to detect the effect of the intervention against the control. Allocation to the intervention group was doubled to an estimated 123 to increase the power to detect the effects of adherence to sleep restriction and stimulus control (i.e., Research Question #2). The randomization scheme is displayed in Figure 1 and is discussed further below. The randomized trial was registered in advance per CONSORT recommendations. A change to the trial that occurred after registration was that the Working Alliance Inventory was not administered to patients during the trial. The Working Alliance Inventory was planned for inclusion to assess for associations between therapist-patient connection and symptom change;
however, feedback from patients and clinicians during the program pilot suggested the
questionnaires were too long and the 12-item Working Alliance Inventory was identified
as tangential and removed.

**Patient Participants**

Patients who signed up for the Wellbeing Course during the trial period were
asked to complete the Insomnia Severity Index (Appendix L) and those who endorsed
significant symptoms of insomnia (i.e., scores over 10) were offered the opportunity to
participate in this research by receiving the new sleep materials. Patient were recruited
using the same procedures as the existing Wellbeing Course offered by the Online
Therapy Unit (Hadjistavropoulos, Nugent, et al., 2016).

Inclusion criteria require applicants to be 18 years old, residents of Saskatchewan,
to report having access to a computer and sufficient time for the 8-week program and 20-
week follow-up measures, as well as the endorsement of significant symptoms of either
anxiety or depression. No diagnosis is required for this free program and patients arrive
to the program through several referral sources including referral from a family doctor,
referral from another health practitioner, referral from a friend, or self-referral because of
internet-searching. Patients also had to provide an emergency medical contact and must
consent to the use of their responses in the trial results. Patients who endorsed primary
concerns about psychosis or substance abuse, or who are considered high risk for suicide
are referred out to other more appropriate services and were excluded from the trial.
Patients with other sleep concerns, including sleep apnea, restless leg syndrome, extreme
nightmares, and shift work, for which sleep restriction and stimulus control are not the
recommended treatment were screened out of the new sleep program using screening
questions designed for this purpose from the Sleep-50 (Spoormaker et al., 2005) and follow-up assessment of any endorsed items that took place during the screening phone call prior to admission (Appendix E). Treatment consent was obtained from those patients admitted to the trial (Appendix F).

Program

Program Content

The existing Wellbeing Course was originally developed by Macquarie University and has since been adapted for use in Canada (Hadjistavropoulos, Nugent, et al., 2016; Titov et al., 2011). The course consists of five lessons that are designed to be completed over an 8-week period with the assistance of an e-therapist. The e-therapist checks in with the client each week during the program to provide encouragement, answer questions, and guide the patient through the course.

Lesson 1 focuses on psychoeducation about anxiety and depression, including introducing the CBT model. Lesson 2 deals with cognitive symptoms of anxiety and depression and introduces thought challenging as a technique for adjusting problematic negative thinking patterns. Lesson 3 addresses the physiological effects of anxiety and depression, with patients learning how to use activity planning and relaxation/breathing techniques to manage their physiological arousal level. Lesson 4 focuses on the behavioural consequences of anxiety and depression, including safety behaviours and avoidance, and introduces patients to graded exposure as a tool for correcting problematic patterns of avoidance. Lesson 5 consolidates learning and helps patients create a plan to prevent relapse in the long term. More details about the Wellbeing Course are available in the original publication from the Macquarie University research team (Titov et al., 2011).
The Wellbeing Course also includes several “additional resources” that are made available to patients. These include resources about structured problem solving, assertive communication, managing panic, managing worry, and, notably, a brief resource about sleep concerns. The existing additional resource on sleep consists mainly of sleep hygiene advice (e.g., keep your bedroom dark, cool, quiet) and is notably different than the newly developed materials in that it does not emphasize sleep restriction or stimulus control strategies.

The new sleep materials that were developed for use in the current trial were based on existing CBT programs for insomnia which emphasize the importance of sleep restriction and stimulus control (Edinger & Carney, 2014; L. Harvey et al., 2002). The components were written to be brief and easily understood. The new materials were developed in consultation with patient partners (volunteers with related lived experience) who agreed to help provide feedback on wording, understandability, and general acceptability. The new Sleep-Enhanced program materials underwent four rounds of revision based on feedback from the PORSC before a pilot study was conducted and two more rounds of further review were conducted before the materials were considered ready for the current trial. Figure 1 provides an overview of the main components in the new sleep materials, divided into 1) psychoeducational components designed to increase patient knowledge on the topic; and 2) behavioural strategies designed to guide patients towards activities that are helpful for improving sleep patterns.
Figure 1. Overview of main components included in the brief insomnia intervention provided to patients randomly assigned to the Sleep-Enhanced condition.

### Behavioural Strategies

**Sleep Restriction.** Instruct the patient on how to increase nighttime sleepiness by only sleeping during a consistent sleep window that is slightly shorter than their present average daily sleep. Introduces simple behavioural rules including avoiding napping, going to bed at a set time and using an alarm to wake at a consistent time.

**Stimulus Control.** Describe how engaging in stimulating activities in bed contributes to alertness at night and encourage patient to avoid doing things like using a smartphone, watching tv, eating, gaming etc. in bed, as well as the instruction to get up and do something relaxing if in bed unable to sleep for longer than 20 minutes.

### Psychoeducational Components

**Circadian Rhythm.** Describe the system that govern the body's natural clock and what happens when this system becomes disrupted.

**Anxiety and Insomnia.** Explain how anxiety increases alertness at night which interferes with sleep and how lack of sleep can increase anxiety.

**Depression and Insomnia.** Discuss how low mood leads to disrupted sleep and how lack of sleep leads to fatigue and missing out on previously enjoyed activities.

**Beliefs about Insomnia.** Encourage reflection on how beliefs about sleep (e.g., that everyone should be getting a perfect 8-hour sleep each night) can make symptoms of insomnia worse.
The newly developed sleep lesson was designed to be offered at the beginning of treatment, offering maximum time for the therapist to provide support to the client, which is known to be important for the success of sleep restriction and stimulus control (Edinger & Carney, 2014). Each week patients were asked to complete a weekly sleep questionnaire (Appendix M) that reinforced sleep restriction and stimulus control. Following each of the core wellbeing lessons the week’s lesson was briefly related to sleep (e.g., how to apply cognitive strategies to beliefs about sleep or how to use relaxation techniques to help with sleep).

**Therapist Support**

Patients were contacted each week by their e-therapist during the 8-week program. The e-therapist provided support and encouragement each week either by secure message or telephone. The e-therapist assigned to a patient typically spends about 20 minutes each week sending a message to the client and may choose to contact patients via telephone who 1) reported a meaningful elevation in symptoms; 2) reported suicidality; 3) have not logged in for the last week; or 4) requested to speak with the therapist by phone. E-therapists follow guidelines for what to include in messages (e.g., encouragement, direction about the course, psychoeducation, answering questions) (Hadjistavropoulos et al., 2018). For patients in the Sleep-Enhanced program, the e-therapists also provided guidance and support specifically related to integrating sleep restriction and stimulus control into their lives.

**Screening Questionnaires**

Potential patients interested in the Wellbeing Course gave their consent (Appendix B) before completing a short online screening questionnaire to determine their
eligibility (Appendix C). Demographic information was collected at this time, including age, gender, education, employment status, relationship status, and whether they lived in a city or a rural area (Appendix D). Potential patients also completed short symptom questionnaires at screening for the purpose of determining eligibility, including established measures of depression, anxiety, and insomnia.

Patients admitted to the program were then asked to complete a battery of pre-treatment questionnaires, which included established symptom measures of symptoms of depression, anxiety, insomnia, panic, social anxiety, and posttraumatic stress disorder. In addition to completing measures at pre-treatment, patients also completed brief measures each week during lessons 2-5, and the full battery again upon finishing the course (post-treatment), and at 3-months after course completion. There were also additional measures administered as part of routine practice at the Online Therapy Unit that were secondary to the current trial (e.g., medical service usage, disability, general distress). Consistent with intent-to-treat, e-therapists were instructed to contact patients in the final week to encourage them to complete post-treatment measures. OTU staff followed up with any patients who did not complete follow-up measures to encourage them to complete the questionnaires. All measures are included in the appendices, but only measures analyzed as part of the current trial have been detailed below.

**Primary Symptom Measures**

*The Patient Health Questionnaire 9-Item Scale* (Kroenke et al., 2001). The PHQ-9 includes nine items related to common symptoms of depression. Respondents answer each item on a scale ranging from 0 (not at all) to 3 (nearly every day), producing a total score between 0 and 27. Studies on the psychometric properties of the PHQ-9 have
demonstrated good reliability and validity (Kroenke et al., 2010) and a cut-off score of 10 or above appears optimal for diagnosing major depression (Manea et al., 2012). A six-point change on the PHQ-9 represents a reliable change in symptoms (Gyani et al., 2013).

**Generalized Anxiety Disorder 7-Item Scale** (Spitzer et al., 2006). The GAD-7 includes nine items related to common symptoms of anxiety. Respondents answer each item on a scale ranging from 0 (not at all) to 3 (nearly every day), producing a total score between 0 and 21. Studies on the psychometric properties of the GAD-7 have demonstrated good reliability and validity (Bandelow & Brasser, 2009) and a cut-off score of 10 or greater appears optimal for the diagnosis of generalized anxiety disorder (Spitzer et al., 2006). A four-point change on the GAD-7 represents a reliable change in symptoms (Gyani et al., 2013).

**Insomnia Severity Index**

The ISI includes seven items that ask about symptoms related to insomnia. It includes questions about difficulties falling asleep, staying asleep, and waking too early, which respondents answer on a scale from 0 (None) to 4 (Very Severe), as well as the impact of these symptoms on functioning and distress which respondents answer on a scale from 0 (Not at All) to 4 (Very Much). The questionnaire produces a total score with a minimum of 0 and a maximum of 28. The ISI has been found to have good reliability and validity, and a cut-off score of 10 or above appears optimal for detecting cases of insomnia (Morin et al., 2011).

**Secondary Measures**

**Panic Disorder Severity Scale – Self Report** (Houck et al., 2002) The PDSS-SR (Appendix I) includes seven items related to common symptoms of panic disorder.
Respondents answer each item on a 0-4 scale, producing a total score between 0 and 28. Studies on the psychometric properties of the PDSS-SR have demonstrated good internal and test-retest reliability (Houck et al., 2002) and a cut-off score of 8 or above appears optimal for the diagnosis of panic disorder (Allen et al., 2016).

**Social Interaction Anxiety Scale and Social Phobia Scale – Short Form** (Peters et al., 2012). The SIAS-6/SPS-6 (Appendix J) includes 12 items related to common symptoms of anxiety that are summed to create a total score. Respondents answer each item on a scale from 0 (not at all characteristic) to 4 (extremely characteristic). Cutoff scores of 7 and above on the SIAS-6, or 2 and above on the SPS-6 appears optimal for detecting individuals with social anxiety disorder (Peters et al., 2012). Research into the psychometric properties of the combined measure has shown that summing all 12 items creates a single reliable and valid measure of social anxiety (Peters et al., 2012).

**Treatment satisfaction**

After completing the final lesson, patients also completed a treatment satisfaction questionnaire that includes questions about their opinion of the program and the working alliance they developed with their therapist. Patients were also asked whether they would recommend the treatment to others.

**Inclusion Criteria and Randomization Plan**

All patients began the program by completing an online screening questionnaire which assessed the client for basic eligibility criteria, including age over 18, willingness to provide their doctor’s contact information, sufficient time, computer with access to internet, and significant symptoms of anxiety or depression, as well as a score on the Insomnia Severity Index of 10 or above (i.e., indicating the possibility of clinically-
significant concerns related to insomnia). A telephone screening call was used to further assess patient fit for the program, including assessing for exclusion criteria such as high risk of suicide, symptoms of a different serious mental illness for which referral is more appropriate (e.g., psychosis), a primary concern related to addictions, or a high likelihood that a person’s sleep concerns are related to a different sleep disorder or health condition for which sleep restriction may be contraindicated (e.g., Sleep Apnea, Restless Leg Syndrome).

Patients who were admitted to the trial following the screening process were randomly assigned to a treatment condition by the staff member who conducted their telephone screening at the conclusion of the call. The staff member conducting the screening was kept blind to the randomization sequence until the conclusion of the screening call and the patient was then assigned to the treatment condition. A computer-generated randomization function that is available as part of the REDCap study management software package was used to assign the patients to their condition and the screener then assigned the patient to an e-therapist and the appropriate program (REDCap, n.d.). Twice as many patients were intentionally assigned to receive the Sleep-Enhanced intervention for two reasons: 1) in order to investigate the possible mediating role that engaging in sleep restriction and stimulus control could have on symptom trajectories a larger sample was needed in the intervention group; and 2) the Online Therapy Unit has years of baseline user data against which the control group can be compared and assessed as “typical”, and against which the intervention group can be compared. E-therapists were not blinded to the trial condition as those e-therapists providing care in the Sleep-Enhanced condition were provided specific instructions on
providing support to the patient related to implementing sleep restriction and stimulus control.

**Analytical Plan**

The number of patients who completed the online and telephone screening were tabulated to characterize the sample. Reasons for patient exclusion were tabulated and include referrals to a more appropriate service (e.g., elevated suicide risk) and the presence of a sleep condition which is not likely to respond to CBT for insomnia (i.e., sleep apnea, restless leg syndrome, shift work, severe nightmares suggestive of PTSD, sleep walking). Descriptive statistics were calculated for recorded patient demographic variables (e.g., age, gender, employment status, disability status, and education history). Successful randomization of patients was assessed with independent t-tests to compare patient demographics across the two conditions. A p value of 0.01 was chosen as the threshold for determining statistical significance. Independent t-tests were also used to compare pre-treatment symptom scores as an added assurance that randomization was successful.

Completion rates for each lesson of the course were tabulated for the Sleep-Enhanced and control conditions. Missing data due to patient attrition is expected in trials of internet-delivered therapy programs and chi-square tests were conducted to assess for differences in the proportions of patients who completed all five lessons across the two conditions. Logistic regression was used to assess relationships between symptom scores, demographic factors, course completion, and missing data. Logistic regressions were also used to investigate whether there were any statistically significant relationships between demographic factors or symptom scores collected from patients at pre-treatment and
course completion. In the first regression model, symptom scores at pre-treatment were entered stepwise using $p = 0.01$ as a cutoff value for inclusion in a model predicting course completion. A second logistic regression was used to examine whether demographic variables can significantly predict course completion, with demographic variables entered using a stepwise procedure and a threshold for inclusion in the model of $p = 0.01$.

To test the first hypothesis (i.e., patients assigned to the Sleep-Enhanced condition will report reductions in symptoms that are statistically significantly greater than the Standard Wellbeing condition), patient responses to symptom questionnaires at screening and at post-treatment were analyzed. Mean symptom changes on primary symptom measures (i.e., insomnia, anxiety, depression) were calculated and reported for both groups of patients at pre-treatment, post-treatment, and 20-week follow-up. An ANCOVA was used to assess for statistically significant ($p < .01$) between-group differences in symptoms by entering condition as the independent variable, initial symptom scores as covariates, and post-treatment scores as the dependent variables. A recent review of common statistical approaches to analyzing pre-post treatment data in clinical research found that “ANCOVA models have the smallest variance, highest power, and nominal 95% confidence interval coverage compared to ANOVA using post treatment scores as dependent variable, ANOVA using symptom change scores as dependent variables, and linear mixed models” (O’Connell et al., 2017). In addition to being a well-validated approach to analyzing pre-post data, the ANCOVA approach also offers easily interpretable results. A conservative p-value of 0.01 to determine statistical significance was again selected.
To test the second hypothesis (i.e., the frequency of therapy-related behaviours reported by patients, including sleep restriction and stimulus control, will be statistically significantly correlated with the magnitude of patient-reported reductions in insomnia symptoms at post-treatment), the average number of days per week the patient reported engaging in sleep restriction and stimulus control was calculated. Few patients were expected to complete every weekly sleep measure and the total number of days patients report engaging in sleep restriction and stimulus control was therefore divided by the number of weekly sleep questionnaires that each patient completed. A hierarchical regression model predicting ISI scores at post-treatment was created and pre-treatment ISI score was entered into the first block. The average number of days patients reported that they spent each week engaged in sleep restriction and stimulus control were entered into the second block. Parameters were considered statistically significant if they passed a threshold probability of $p < 0.05$.

Patients were also asked whether a range of different factors had affected their sleep each week. For each patient, a ratio was calculated of the number of weeks a factor was reported as impacting their sleep relative to the number of weekly sleep measures completed. The proportion of patients who reported experiencing the factor at least once between pre-treatment and post-treatment was calculated for each factor. Hierarchical regressions were then used to assess relationships between the frequency that patients reported experiencing different factors impacting sleep and changes in insomnia symptoms from pre-treatment and post-treatment. Factors affecting sleep were considered statistically significant if they achieved a cut-off probability of $p < 0.05$. 
To test the third hypothesis (i.e., no statistically significant differences in treatment satisfaction will be reported by patients who received the Standard Wellbeing and Sleep-Enhanced conditions) about patient acceptability, patient responses to the treatment satisfaction questionnaire were analyzed. Mean ratings reported by patients were calculated for treatment satisfaction, website satisfaction, confidence in recommending the program to a friend, and the percentage of patients who reported the course was worth their time. An ANOVA was used to assess whether satisfaction ratings were statistically significantly different \((p < .01)\) between the Standard Wellbeing and Sleep-Enhanced groups.

Finally, a qualitative analysis of the responses provided by patients who answered an open-ended question designed to elicit feedback about the sleep resource was conducted. Patients were asked “Do you have any feedback about the sleep materials you received?” and patient responses to this question were coded using an open qualitative content analysis approach (Hsieh & Shannon, 2005). During the coding process, a research assistant (A.W.) experienced with conducting thematic analysis for the Online Therapy Unit conducted the first round of coding and then continued until saturation was reached (defined as finding no new themes in ten patient responses). The author (M.E.) then recoded the responses using the identified themes as a quality assurance check and to ensure no important themes had been missed. Identified themes were then discussed with our patient-oriented research steering committee before being described and the relative frequency of each theme tabulated in the results section. Furthermore, patient responses to a question asking, “Can you give us an example of how a skill or strategy from the Wellbeing Course made a difference in your life?” were similarly coded and the
frequency of responses that mention skills related to the new sleep resource was calculated.
CHAPTER 3: Results

Patient Recruitment

The enrolment period for this trial began on September 9, 2020, and closed on December 17, 2020, during which time 607 individuals completed the online screening for the Wellbeing Course. Potential patients \((n = 467)\) had scores on the ISI of 10 or above and most \((n = 391)\) completed the telephone interview as scheduled. After the telephone screening, some patients \((n = 62)\) were referred out to a more appropriate service, typically for elevated suicide risk \((n = 19)\). Other potential patients \((n = 109)\) were excluded due to probable presence of one or more conditions determined \textit{a priori} to cause sleep difficulties, but for which CBT for insomnia is likely unhelpful, including sleep apnea \((n = 51)\), restless leg syndrome \((n = 38)\), shift work \((n = 33)\), severe nightmares suggestive of PTSD \((n = 29)\), or sleep walking \((n = 3)\). Following the planned 2:1 randomization strategy, patients were assigned to the Sleep-Enhanced group \((n = 142)\) or the Standard Wellbeing group \((n = 75)\). Figure 2 provides a flow chart that details randomization and patient flow throughout the stages of screening, accessing the program, and completing post-treatment and 20-week follow-up measures in each group.
607 patients completed the online screening for the Wellbeing Course (September 9, 2020 – December 29, 2020)

Excluded from trial due to minimal presence of insomnia symptoms; ISI score < 10 (n = 140)

Met Initial Inclusion Criteria (n = 467; 76.9%)

Did not complete telephone interview (n = 77)

Completed Telephone Interview (n = 390; 64.4%)

Excluded from trial after telephone screening and offered standard Wellbeing Course (n = 108)
Probable presence of one or more sleep-related conditions for which CBT for insomnia is not appropriate
- Sleep Apnea (n = 51)
- Restless Leg Syndrome (n = 37)
- Shift Work (n = 33)
- Nightmares (n = 29)
- Sleep Walking (n = 3)

Patients who were eligible to be randomized but did not receive the correct condition due to administrative error (n = 2)

Referred out after telephone screening (n = 63)
- Elevated suicide risk (n = 19)
- Alcohol use primary (n = 11)
- Recent hospitalization suggests client’s mental health is not sufficiently stable for ICBT (n = 10)
- Drug use primary (n = 9)
- Client no longer met basic age and provincial residence requirements (n = 3)
- Symptoms of bipolar/mania (n = 3)
- Concerns about online format (n = 2)
- Minimal symptoms anxiety and depression (n = 2)
- Currently receiving mental health treatment more than twice a month (n = 1)
- Symptoms of psychosis (n = 1)
- Symptoms of mental health condition other than anxiety or depression (n = 1)
- An interfering medical condition is present (n = 1)

Randomized Patients (n = 217)

Sleep-Enhanced Wellbeing (n = 142; 100%)

Standard Wellbeing (n = 75; 100%)

Did Not Start Course (n = 7/142; 4.9%)

Did Not Start Course (n = 6/75; 7.9%)

Logged in to Course (n = 135/142; 95.1%)

Logged in to Course (n = 70/75; 92.1%)

Formally Withdrew from Course (n = 23/142; 16.2%)

Formally Withdrew from Course (n = 13/75; 18.6%)

Patients who completed 8-week follow-up (n = 89/142; 62.7%)

Patients who completed 8-week follow-up (n = 44/75; 57.8%)

Patients who completed 3-month follow-up (n = 85/142; 59.9%)

Patients who completed 3-month follow-up (n = 46/75; 60.5%)

Figure 2. Flow chart of patient randomization and completion rates.
Sample Characteristics

Demographic data collected from patients \((n = 217)\) is displayed in Table 1. Patients were predominantly white \((89.5\%; n = 194)\) and female \((75.6\%; n = 64)\). Approximately half of patients \((53.9\%; n = 117)\) reported having paid work while approximately 1 in 5 \((20.3\%; n = 44)\) selected that childcare or homemaker best described their employment status. Patient demographic proportions were reasonably consistent with the Saskatchewan population; specifically, approximately half \((50.7\%; n = 110)\) lived in a large city, with others living in a rural area or small town \((20.3\%; n = 44)\), or a medium town or small city \((29.0\%; n = 63)\). Most patients reported at least some post-secondary education \((77.4\%; n = 68)\) and a minority \((1.8\%, n = 4)\) reported not graduating high school. Many patients \((63.6\%, n = 138)\) reported learning about the program from a health care professional \((e.g., a doctor or other mental health professional)\), with others learned about the program from a friend or family \((17.5\%, n = 38)\) or online sources \((8.8\%, n = 19)\).
Table 1. *Sample characteristics.*

<table>
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<th>Variable</th>
<th>Standard Wellbeing $(n = 75)$</th>
<th>Sleep-Enhanced $(n = 142)$</th>
<th>All Patients $(n = 217)$</th>
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<td>194 (89.4%)</td>
</tr>
<tr>
<td>Indigenous</td>
<td>3 (4.0%)</td>
<td>6 (4.2%)</td>
<td>9 (4.1%)</td>
</tr>
<tr>
<td>Asian</td>
<td>3 (4.0%)</td>
<td>1 (0.7%)</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>South Asian</td>
<td>0 (0.0%)</td>
<td>4 (2.8%)</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>Other/Prefer not to answer</td>
<td>3 (4.0%)</td>
<td>3 (2.1%)</td>
<td>6 (2.8%)</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paid work</td>
<td>44 (58.7%)</td>
<td>73 (51.4%)</td>
<td>117 (53.9%)</td>
</tr>
<tr>
<td>Homemaker and/or childcare</td>
<td>10 (13.3%)</td>
<td>34 (23.9%)</td>
<td>44 (20.3%)</td>
</tr>
<tr>
<td>Retired</td>
<td>4 (5.3%)</td>
<td>9 (6.3%)</td>
<td>13 (6.0%)</td>
</tr>
<tr>
<td>Student</td>
<td>3 (4.0%)</td>
<td>3 (2.1%)</td>
<td>6 (2.8%)</td>
</tr>
<tr>
<td>Unfit for work due to health problems</td>
<td>6 (8.0%)</td>
<td>15 (10.6%)</td>
<td>21 (9.7%)</td>
</tr>
<tr>
<td>Unemployed for other reasons (e.g., involuntary unemployment or volunteer work)</td>
<td>8 (10.7%)</td>
<td>8 (5.6%)</td>
<td>16 (7.4%)</td>
</tr>
</tbody>
</table>
Table 1. *Sample characteristics.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standard Wellbeing <em>(n = 75)</em></th>
<th>Sleep-Enhanced <em>(n = 142)</em></th>
<th>All Patients <em>(n = 217)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Location</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural Area or Small Town (&lt;7,000 citizens)</td>
<td>15 (20.0%)</td>
<td>29 (20.4%)</td>
<td>44 (20.3%)</td>
</tr>
<tr>
<td>Medium Town/Small City (7,000-200,000 citizens)</td>
<td>29 (38.7%)</td>
<td>34 (23.9%)</td>
<td>63 (29.0%)</td>
</tr>
<tr>
<td>Large City (&gt;200,000 citizens)</td>
<td>31 (41.3%)</td>
<td>79 (55.6%)</td>
<td>110 (50.7%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>0 (0.0%)</td>
<td>4 (2.8%)</td>
<td>4 (1.8%)</td>
</tr>
<tr>
<td>High school diploma</td>
<td>13 (17.3%)</td>
<td>32 (22.5%)</td>
<td>45 (20.7%)</td>
</tr>
<tr>
<td>Any post-secondary education</td>
<td>62 (82.7%)</td>
<td>106 (74.6%)</td>
<td>168 (77.4%)</td>
</tr>
<tr>
<td><strong>Referral Source</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printed Poster</td>
<td>2 (2.7%)</td>
<td>0 (0.0%)</td>
<td>2 (0.9%)</td>
</tr>
<tr>
<td>Online Source</td>
<td>9 (12.0%)</td>
<td>10 (7.0%)</td>
<td>19 (8.8%)</td>
</tr>
<tr>
<td>Friend or family</td>
<td>10 (13.3%)</td>
<td>28 (19.7%)</td>
<td>38 (17.5%)</td>
</tr>
<tr>
<td>Employer, union, or professional assoc.</td>
<td>2 (2.7%)</td>
<td>5 (3.5%)</td>
<td>7 (3.2%)</td>
</tr>
<tr>
<td>Physician or other medical health Professional</td>
<td>50 (66.7%)</td>
<td>88 (62.0%)</td>
<td>138 (63.6%)</td>
</tr>
<tr>
<td>Other</td>
<td>2 (2.7%)</td>
<td>11 (7.7%)</td>
<td>13 (6.0%)</td>
</tr>
</tbody>
</table>
Results of independent t-tests showed that patient demographic characteristics were not significantly different between patients assigned to the Sleep-Enhanced and Standard Wellbeing groups, suggesting successful randomization, and providing some assurance that the treatment and control groups were not statistically significantly different. According to independent t-tests, pre-treatment symptom scores (i.e., ISI, PHQ-9, GAD-7, PDSS, and SIAS-6/SPS-6 scores) were also not significantly different between the Sleep-Enhanced and Standard Wellbeing groups.

**Completion Rate and Missing Data**

Table 2 provides an overview of patient engagement with the program. Many patients ($n = 125$; 57.6%) accessed the final lesson in the 8-week program. A chi-square test revealed that the proportion of patients who accessed Lesson 5 was similar for the Sleep-Enhanced and Standard Wellbeing groups ($\chi^2 (1) = 0.653; p = 0.419$).

There was substantial patient attrition and resulting missing data at post-treatment and 20-week follow-up; as such, regression was used to test for relationships between attrition and patient demographics. None of the pre-treatment symptom scores were found to be significant predictors of missingness, however, pre-treatment SIAS-6/SPS-6 scores did approach the threshold for inclusion in the model ($p = 0.019$) as did PHQ-9 scores ($p = 0.025$), suggesting that a statistically significant relationship between SIAS-6/SPS-6 or PHQ-9 scores and attrition may be detectable in a larger sample. Consistent with previous research (Edmonds et al., 2018) younger patients were more likely to attrition ($p = 0.018$), but age explained a relatively small portion of the variance in course completion (i.e., 3.6%).
Table 2. Proportion of clients completing each lesson in the Standard Wellbeing and Sleep-Enhanced conditions.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Admitted n</th>
<th>Access 1 n (%)</th>
<th>Accessed Lesson 1 n (%)</th>
<th>Accessed Lesson 2 n (%)</th>
<th>Accessed Lesson 3 n (%)</th>
<th>Accessed Lesson 4 n (%)</th>
<th>Accessed Lesson 5 n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Wellbeing</td>
<td>75</td>
<td>69 (92.0%)</td>
<td>65 (86.7%)</td>
<td>53 (70.7%)</td>
<td>49 (65.3%)</td>
<td>46 (61.3%)</td>
<td></td>
</tr>
<tr>
<td>Sleep-Enhanced</td>
<td>142</td>
<td>135 (95.1%)</td>
<td>124 (87.3%)</td>
<td>106 (74.6%)</td>
<td>92 (64.8%)</td>
<td>79 (55.6%)</td>
<td></td>
</tr>
<tr>
<td>All Patients</td>
<td>217</td>
<td>204 (94.0%)</td>
<td>189 (87.1%)</td>
<td>159 (73.3%)</td>
<td>141 (65.0%)</td>
<td>125 (57.6%)</td>
<td></td>
</tr>
</tbody>
</table>
Symptom Measures

Table 3 presents the mean symptom scores at pre-treatment, post-treatment, and 20-week follow-up. Consistent with previous Wellbeing Course research (e.g., Hadjistavropoulos et al., 2022), large reductions in symptoms of anxiety and depression were observed at post-treatment and maintained at 20-week follow-up. Large reductions in insomnia symptom scores and symptoms of panic disorder were also observed at post-treatment and were maintained at 20-week follow-up. Reductions in social anxiety scores were moderate at post-treatment and were maintained at 20-week follow-up.

The Sleep-Enhanced group demonstrated a greater reduction in ISI scores ($F_{(1, 139)} = 11.75; p = 0.001$) at post-treatment. Other symptom measures were not statistically significantly different between the Sleep-Enhanced and Standard Wellbeing groups, including depression symptoms (i.e., PHQ-9; $F_{(1, 139)} = 3.62; p = 0.059$), anxiety symptoms (i.e., GAD-7; $F_{(1, 135)} = 1.10; p = 0.296$; PDSS-SR; $F_{(1, 138)} = 0.171; p = 0.679$), and social anxiety symptoms (i.e., SIAS-6/SPS-6; $F_{(1, 137)} = 1.32; p = 0.253$).
Table 3. Patient symptom questionnaire scores at screening, post-treatment, and 20-week follow-up, divided by treatment group.

<table>
<thead>
<tr>
<th>Symptom Domain (Measure)</th>
<th>Pre-treatment</th>
<th>Post-treatment</th>
<th>20-week follow-up</th>
<th>Pre-Post Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>M</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td>Insomnia (i.e., ISI)(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>75</td>
<td>15.81</td>
<td>4.07</td>
<td>48</td>
</tr>
<tr>
<td>Sleep-Enhanced</td>
<td>142</td>
<td>16.37</td>
<td>4.56</td>
<td>92</td>
</tr>
<tr>
<td>All Patients</td>
<td>217</td>
<td>16.18</td>
<td>4.40</td>
<td>140</td>
</tr>
<tr>
<td>Depression (i.e., PHQ-9)(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>75</td>
<td>13.87</td>
<td>5.76</td>
<td>48</td>
</tr>
<tr>
<td>Sleep-Enhanced</td>
<td>142</td>
<td>14.20</td>
<td>5.39</td>
<td>92</td>
</tr>
<tr>
<td>All Patients</td>
<td>217</td>
<td>14.09</td>
<td>5.51</td>
<td>140</td>
</tr>
<tr>
<td>Anxiety (i.e., GAD-7)(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>75</td>
<td>12.59</td>
<td>4.95</td>
<td>47</td>
</tr>
<tr>
<td>Sleep-Enhanced</td>
<td>142</td>
<td>13.17</td>
<td>4.91</td>
<td>89</td>
</tr>
<tr>
<td>All Patients</td>
<td>217</td>
<td>12.97</td>
<td>4.92</td>
<td>136</td>
</tr>
<tr>
<td>Panic (i.e., PDSS-SR)(^2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>75</td>
<td>7.76</td>
<td>6.06</td>
<td>47</td>
</tr>
<tr>
<td>Sleep-Enhanced</td>
<td>142</td>
<td>8.49</td>
<td>5.78</td>
<td>92</td>
</tr>
<tr>
<td>All Patients</td>
<td>217</td>
<td>8.24</td>
<td>5.87</td>
<td>139</td>
</tr>
</tbody>
</table>
Social Anxiety (i.e., SIAS-6/SPS-6)$^2$

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Wellbeing</th>
<th>Sleep-Enhanced</th>
<th>All Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard</td>
<td>75</td>
<td>13.51</td>
<td>10.36</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note.</td>
<td>ISI = Insomnia Severity Index; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7; PDSS-SR = Panic Disorder Severity Scale; SIAS-6/SPS-6 = Social Interaction Anxiety Scale / Social Phobia Scale</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^1$ Primary Symptom Measure

$^2$ Secondary Symptom Measure
Sleep Behaviour Analyses

Table 4 presents results from the weekly brief sleep measure completed by patients who received the Sleep-Enhanced program. Most patients who were admitted to the Sleep-Enhanced program completed at least one weekly sleep measure (90%; $n=128$), which were administered from the second week of the program onward, and the mean number of weekly sleep measures completed by each patient was 4.94 ($SD = 2.01$) out of a possible seven. Patients reported a full range of therapy-related sleep behaviours, with some patients reporting that they adhered to the instructions in the Sleep-Enhanced program with respect to sleep restriction, stimulus control, and avoiding napping on every day of the week, whereas other patients did not report engaging in the behaviours on any days.

In a hierarchical regression model predicting post-treatment ISI score based on pre-treatment ISI score (block 1) and the average number of days of sleep restriction and stimulus control reported by patients over the treatment period (block 2), only the number of days of sleep restriction was found to be statistically significantly associated with the reductions in ISI scores ($\beta = -0.705, p = 0.031$), while the number of days of stimulus control was not a significant predictor of post-treatment ISI scores ($\beta = -0.07, p = 0.836$). The resulting model explained about 18.2% of the variance in ISI change scores ($R^2 = 0.182$; $F_{(2,88)} = 6.521; p < 0.001$), and inclusion of sleep restriction and stimulus control parameters contributed about 6.5% of this explanatory power ($R^2$ change).
Table 4. *Average number of sleep-related behaviours reported by patients in weekly sleep questionnaire during treatment period (n = 128).*

<table>
<thead>
<tr>
<th>Sleep Behaviour</th>
<th>M</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average days of sleep restriction per week</td>
<td>3.24</td>
<td>1.87</td>
</tr>
<tr>
<td>Average days of stimulus control per week</td>
<td>4.32</td>
<td>1.87</td>
</tr>
<tr>
<td>Average number of naps per week</td>
<td>1.09</td>
<td>1.33</td>
</tr>
</tbody>
</table>
Factors Affecting Sleep

Table 5 presents the mean ratio of reports for each factor (i.e., the proportion of weeks patients endorsed each factor). Table 5 also presents the proportion of patients who reported each type of sleep problem at least once during the 8-week program. A hierarchical regression model predicting ISI scores at post-treatment found that, of all the factors affecting sleep that patients were asked to report about each week (see Table 5), more frequent reports of medications affecting sleep ($\beta = 4.429; p = 0.020$) and other factors affecting sleep ($\beta = 6.041; p = 0.019$) were the only factors that were statistically significant predictors of relatively higher post-treatment ISI scores. The model including initial ISI scores and factors affecting sleep explains approximately 32.8% of the variance in ISI scores at post-treatment ($R^2 = 0.395; F_{(9, 82)} = 5.942; p < 0.001$).
Table 5. *Average proportion of weeks during the program that clients reported various factors they believed affected their sleep* (n = 128).

<table>
<thead>
<tr>
<th>Factors Affecting Sleep</th>
<th>M</th>
<th>SD</th>
<th>n (%) of patients who reported at least once</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interruptions (e.g., being woken up by noises, external factors)</td>
<td>0.30</td>
<td>0.36</td>
<td>71 (55%)</td>
</tr>
<tr>
<td>Care responsibilities (e.g., young children or other individuals who need care in the night)</td>
<td>0.35</td>
<td>0.38</td>
<td>75 (59%)</td>
</tr>
<tr>
<td>Medications</td>
<td>0.12</td>
<td>0.27</td>
<td>32 (25%)</td>
</tr>
<tr>
<td>Alcohol usage</td>
<td>0.03</td>
<td>0.12</td>
<td>11 (8.6%)</td>
</tr>
<tr>
<td>Drugs</td>
<td>0.02</td>
<td>0.09</td>
<td>5 (3.9%)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.44</td>
<td>0.36</td>
<td>98 (77%)</td>
</tr>
<tr>
<td>Low mood</td>
<td>0.26</td>
<td>0.34</td>
<td>66 (52%)</td>
</tr>
<tr>
<td>Other factors affected sleep</td>
<td>0.15</td>
<td>0.25</td>
<td>48 (38%)</td>
</tr>
</tbody>
</table>
Treatment Satisfaction

Table 6 presents the treatment satisfaction results. Patients who received the Standard Wellbeing program and the Sleep-Enhanced program reported high levels of satisfaction overall and no statistically significant differences were found between the Standard Wellbeing and Sleep-Enhanced groups on any of the treatment satisfaction questions. Patients who completed the course reported being either satisfied or very satisfied with the course (77.4%; \( n = 106 \)), and only one patient (0.5%) reported being very dissatisfied. Nearly all patients (97.1%; \( n = 133 \)) reported that they thought the course was worth their time and that they would recommend it to a friend.
Table 6. Summary of patient responses to the treatment satisfaction questionnaire for Standard Wellbeing and Sleep-Enhanced conditions.

<table>
<thead>
<tr>
<th>Question</th>
<th>Standard Wellbeing ((n = 47))</th>
<th>Sleep-Enhanced ((n = 90))</th>
<th>All Patients ((n = 137))</th>
<th>F-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall, how satisfied were you with treatment? *Mean (SD)</td>
<td>4.13 (0.90)</td>
<td>4.02 (0.83)</td>
<td>4.06 (0.86)</td>
<td>(F_{(1, 135)} = 0.467) (p = 0.50)</td>
</tr>
<tr>
<td>Overall, how satisfied were you with using the Online Therapy Unit website? * Mean (SD)</td>
<td>4.40 (0.77)</td>
<td>4.26 (0.82)</td>
<td>4.31 (0.80)</td>
<td>(F_{(1, 135)} = 1.066) (p = 0.30)</td>
</tr>
<tr>
<td>Would you feel confident recommending this treatment to a friend? n (%)</td>
<td>96%</td>
<td>98%</td>
<td>97%</td>
<td>(F_{(1, 135)} = 0.445) (p = 0.51)</td>
</tr>
<tr>
<td>Was it worth your time doing this course? n (%)</td>
<td>96%</td>
<td>97%</td>
<td>96%</td>
<td>(F_{(1, 135)} = 0.074) (p = 0.79)</td>
</tr>
</tbody>
</table>

*Note.* * Patients selected a response on a 5-point scale ranging from Very Dissatisfied (1) to Very Satisfied (5)
Feedback on Sleep Resource

Table 7 presents the patient acceptability results. Most patients who completed the feedback questionnaire reported being at least somewhat satisfied (i.e., a rating of 5 or higher) with the materials they received regarding sleep concerns (79.8%; n = 71). Several patients reported they were very satisfied (i.e., a rating of 7) with the sleep materials (32.6%; n = 29). Most patients (82.0%; n = 73) reported they would be at least somewhat likely to recommend the sleep materials to a friend (i.e., a rating of 5 or higher). A minority of patients (7.8%, n = 7) indicated they would not recommend the resource to a friend (i.e., a rating of 3 or lower). When asked about ease of understanding, no patients selected that the sleep materials were very difficult to understand (i.e., a rating of 1) and the majority of patients (93.2%, n = 82) who answered this question said that the materials were at least somewhat easy to understand (i.e., a rating of 5 or higher). Most respondents (70.8%; n = 63) indicated that the sleep materials were at least somewhat helpful at addressing their concerns (i.e., a rating of 5 or higher), while fewer were neutral (7.7%; n = 11; a rating of 4) or reported that the sleep resource was somewhat to very unhelpful (16.9%; n = 15; a rating of 3 or lower). When asked how much they felt their knowledge of sleep concerns had changed, the majority of patients (79.8%; n = 71) reported that they felt their knowledge of sleep had at least somewhat increased (a rating of 5 or higher), while only 4 patients (2.8%) felt their knowledge had not increased at all (a rating of 1). Finally, when patients were asked to report how much they felt their sleep-related behaviours had changed because of reading the sleep materials, the majority (73.0%; n = 65) endorsed that they felt their behaviours had at
least somewhat changed (a rating of 5), while only a few patients (5.6%; n = 8) reported that their sleep-related behaviours had not changed at all (a rating of 1).
Table 7. Sleep material feedback questionnaire responses from patients who received the new Sleep-Enhanced program (n = 89).

<table>
<thead>
<tr>
<th>Question</th>
<th>M  (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How satisfied were you with the materials you received on sleep concerns? (1 – extremely unsatisfied to 7 – extremely satisfied)</td>
<td>5.45 (1.58)</td>
</tr>
<tr>
<td>How likely would you be to recommend the sleep materials to a friend experiencing sleep problems? (1 – extremely unlikely to 7 – extremely likely)</td>
<td>5.80 (1.52)</td>
</tr>
<tr>
<td>How easy was it to understand the materials on sleep concerns? (1 – extremely difficult to 7 – extremely easy)</td>
<td>6.20 (1.12)</td>
</tr>
<tr>
<td>How helpful have the materials on sleep concerns been for addressing your sleep concerns? (1 – extremely unhelpful to 7 – extremely helpful)</td>
<td>5.29 (1.77)</td>
</tr>
<tr>
<td>How much did your knowledge of sleep concerns change during the course? (1 – not much at all to 7 – very much)</td>
<td>5.10 (1.83)</td>
</tr>
<tr>
<td>How much do you feel you’ve changed your sleep-related behaviours as a result of the course? (1 – not much at all to 7 – very much)</td>
<td>4.42 (1.86)</td>
</tr>
</tbody>
</table>
Qualitative Analysis of Patient Feedback

No new themes were identified after analyzing 59 responses (i.e., saturation was reached). Although the majority of patients chose to leave the open feedback response box blank (50.8%; \( n = 30 \)), those that responded (25.4%; \( n = 15 \)) provided generally positive statements. Several responses (18.6%; \( n = 11 \)) also specifically mentioned that the sleep information provided was important or useful. Some patients (8.5%; \( n = 5 \)) reported that the information and strategies presented in the sleep materials did not apply to their situation. A minority of patients (8.5%; \( n = 5 \)) expressed some degree of confusion about the instructions provided or difficulty applying them. Very few patients (6.8%; \( n = 4 \)) reported that the information provided was not new to them.

Themes were also identified in what patients said interfered with their being able to improve their sleep by using the strategies suggested in the sleep materials. These included difficulties managing sleep while caring for young children, difficulties sleeping with a partner who has their own sleep concerns (e.g., restlessness, nightmares, shiftwork), disruption of sleep schedule due to holidays/travel, late nights or other responsibilities, pets that cause nighttime waking, health issues (e.g., pain, headaches, enuresis, hormone issues), and medication side-effects. Notably, when patients were asked “Can you give us an example of how a skill or strategy from the Wellbeing Course made a difference in your life?”, several patients (12.5%, \( n = 9 \) of 72 responses) specifically wrote about sleep skills in their response.
CHAPTER 4: Discussion

The current trial is part of an ongoing program of research being undertaken by the OTU designed to improve the quality of internet-delivered psychotherapy. The OTU uses a learning health system model (Menear et al., 2019) that involves continually monitoring patient outcomes, evaluating feedback from patients and clinicians, and then making incremental improvements to the provided ICBT services. A patient-centered approach was used to conceptualize, design, and implement the current trial, with the hope that the results could lead to further improvements in the OTU’s most popular course, the Wellbeing Course, a transdiagnostic program for anxiety and depression. The process began with a qualitative review of symptoms reported by past patients of the Wellbeing Course, which found that insomnia was prevalent among people seeking ICBT for anxiety and depression (Edmonds et al., 2020). Previous research on ICBT for patients with comorbid insomnia and depression underscored the importance of addressing insomnia symptoms (Blom et al., 2015). The OTU convened a patient-oriented research committee, including patient-partners, clinicians, health managers, and researchers, to investigate whether the transdiagnostic Wellbeing Course should put greater emphasis on insomnia than the brief discussion of sleep hygiene that was part of the original Wellbeing Course. Feedback from patient-partners during this process was notable for steering the final product toward containing clearer phrasing, better emphasizing important behavioural takeaways, and increasing the relatability and patient-acceptability of content (e.g., careful consideration of how phrasing or elements of design may be perceived by different groups). The current trial was designed to evaluate the product of the patient-oriented research committee’s work – a new brief intervention for
Insomnia which could be offered to patients alongside the Wellbeing Course – and the patient-oriented research committee helped formulate the research questions about the acceptability and effectiveness of the new sleep materials investigated in the current trial. The current trial’s results are expected to inform future OTU practices, as well as ICBT research and practice in other contexts. The patient-oriented research committee participated in knowledge translation activities following the trial, resulting in plain language summaries of the study findings being shared with the public via website and social media channels.

**Insomnia Symptoms**

The current randomized-controlled trial was designed to investigate whether offering patients a brief lesson on insomnia before the well-established transdiagnostic program for anxiety and depression could produce greater benefits than the standard transdiagnostic program. The current results showed patients who were randomly assigned to the Sleep-Enhanced condition reported a 48.6% reduction in insomnia symptoms, which was statistically significantly greater than patients assigned to the standard condition who reported a 25.2% reduction in insomnia symptoms. Compared to patients who received the Standard Wellbeing Course, patients who received the Sleep-Enhanced version of the course reported reductions in their ISI scores that were 3.97 points greater than those in the control condition. The reduction in ISI scores is comparable to previous trial results assessing CBT-based interventions for insomnia. For example, a meta-analysis of 15 randomized control trials comparing ICBT to wait-list controls evidenced ICBT for insomnia resulted in a decrease in ISI scores from pre- to post-treatment of 4.3 points (95% CI: -7.1, -1.5; p = 0.017) more than wait-list control.
Previous research has found that a reduction of approximately 4.65 points on the ISI corresponded to a slight clinical global improvement as assessed by an external evaluator and a reduction of 8.39 points on the ISI corresponded to a moderate improvement (Morin et al., 2011), underscoring support for targeting insomnia as part of treating patients for anxiety and depression. Based on previous results (Hadjistavropoulos et al., 2022) the Standard Wellbeing Course was expected to produce a moderate reduction in insomnia symptoms through three possible mechanisms: 1) reducing alertness at night through the use of skills to manage anxiety; 2) increasing activity levels in the daytime through activity planning; and 3) encouraging basic sleep hygiene. The current results show that augmenting the Standard Wellbeing Course by adding more information about sleep problems and introducing basic behavioural strategies for addressing insomnia further reduced insomnia symptoms relative to the standard course.

Comparing to Transdiagnostic Research

Adding anything new to an already long transdiagnostic protocol could shift client attention away from other key aspects of the course. Tracking changes in anxiety and depression symptoms was important to assess how effective the new Sleep-Enhanced Wellbeing Course was for reducing symptoms of anxiety and depression. Data collected from patients over six years of offering the Wellbeing Course in routine care provides a comparator baseline evidencing large mean effect sizes, with anxiety symptoms from pre-treatment to post-treatment reducing by 50% ($g = 1.19$, 95% CI: 1.15-1.23) and depression symptoms by 47% ($g = 1.01$, 95% CI: 0.97-1.05) (Hadjistavropoulos et al., 2022). Only patients with prominent insomnia symptoms (i.e., having an ISI score of 10 or above) were included in the current trial; as such, higher mean anxiety and depression
symptom scores at screening were expected and observed. Patients in both current trial conditions demonstrated a 52.7% reduction in depression symptoms and a 51.1% reduction in anxiety symptoms, which is a slightly greater reduction than has been observed over the long history of the Wellbeing Course (Hadjistavropoulos et al., 2022). The relatively greater reduction can likely be attributed to the greater severity of patients eligible for the current trial. The current results compare favourably to a meta-analysis of 19 other CBT trials for anxiety and depression including a total of 2952 patients, which demonstrated medium to large effect sizes (anxiety: $g = 0.82$, 95% CI: 0.58-1.05, depression: $g = 0.79$, 95% CI: 0.59-1.00) (Păsărelu et al., 2016). Patients assigned to the Sleep-Enhanced condition reported slightly larger reductions in symptoms of depression (Sleep-Enhanced: 56.3%; Standard: 45.5%) and anxiety (Sleep-Enhanced: 54.1%; Standard: 45.1%), neither of which were statistically significant.

**Sleep-Related Behaviours**

The newly created sleep lesson introduced two behavioural strategies to patients for managing insomnia (i.e., sleep restriction, stimulus control). A secondary purpose of the current trial was exploring how patient use of the two strategies was related to symptom change. Patients were asked each week to estimate how many days they had used each of the two behavioural strategies. Patients who reported adhering to sleep restriction guidelines also reported greater insomnia symptom reductions at post-treatment. The number of days patients reported they engaged in stimulus control was not associated with insomnia change. The current results evidence that sleep restriction is a particularly valuable skill for patients with insomnia and comorbid anxiety and depression, which is consistent with previous research (Maurer et al., 2022).
restriction might be facilitated with a modified version of the technique known as sleep compression, which involves reducing time in bed slowly over a period of weeks. A recent trial comparing sleep restriction and sleep compression suggests that sleep compression may offer similar insomnia symptom reductions, but with increased patient adherence (Rosén et al., 2023). Engaging in stimulus control may still be a useful strategy; indeed, the current trial may have been insufficiently powered to evidence and effect, or patients may have already learned parts of stimulus control through exposure to ubiquitous sleep hygiene advice.

Patients were also asked at post-treatment to estimate how much they thought they had changed their behaviours related to sleep because of the course. The current results showed most patients (73.0%; n = 65/89) felt their behaviours had at least somewhat changed and only 8 (5.6%) reported that their sleep-related behaviours had not changed at all. Accordingly, the sleep materials appear generally beneficial and the results support advising patients to try sleep restriction and stimulus control. The current qualitative analytic results were consistent in that many patients were at least somewhat successful in changing their sleep behaviours. Patients reporting no changes in their sleep behaviours commonly reported already being familiar with the behavioural strategies presented. The benefits of engaging with the sleep intervention, and sleep restriction in particular, were consistent with previous ICBT for insomnia research results (Kraepelien, Blom, Jernelöv, et al., 2021); therefore, innovating ways to monitor and improve patient engagement in key aspects of therapy appears to represent a key conceptual direction to guide future research.
Factors Affecting Sleep

Feedback from patient-partners and clinicians emphasized the importance of the myriad factors that commonly affect people’s sleep. The current trial was designed to assess the frequency with which common factors were associated with sleep among those patients seeking online therapy for anxiety and depression. Patients indicated that anxiety impacted their sleep in 44% of the weekly sleep questionnaires completed during the course. Anxiety was the most frequently reported factor impacting sleep, which was expected given the Wellbeing Course is marketed for individuals with anxiety and depression. Patients reported that low mood was also a common factor impacting sleep, occurring in 26% of completed weekly sleep questionnaires. Patients who more frequently reported that medications and other factors interfered with their sleep during the course also reported more modest insomnia improvements at post-treatment.

Caring for young children or others who need care throughout the night was also a commonly reported factor impacting sleep, which was reported in 35% of weekly sleep reports. Caring for young children was also a theme identified in the qualitative analyses of patient feedback about the new sleep resource, with some patients describing the behavioural strategies as impractical. Feedback from clinicians providing care during the trial also included cases where patients felt instructions like avoiding daytime napping were inappropriate for them. The Wellbeing Course receives many referrals for mothers experiencing post-partum anxiety and depression. Past systematic reviews have evidenced sleep problems during pregnancy and post-partum as predicates for depression and recommended sleep interventions as potential treatments (Lawson et al., 2015). The new sleep materials will be amended to provide modified advice for caregivers (e.g.,
considering whether following strict sleep restriction instructions is appropriate). Reports of caregiving responsibilities interfering with sleep were not consistently associated with insomnia symptom change at post-treatment. A larger sample size may have allowed for an association between caregiving and insomnia symptom change to be detected; alternatively, many caregivers may have still benefited despite being unable to apply all of the strategies exactly as described in the new sleep resource.

Patient feedback also included evidence of uncertainty regarding using prescription and non-prescription sleep aides (e.g., cannabis, melatonin) alongside the new behavioural strategies. Medications were indicated as impacting sleep in 12% of patient weekly sleep questionnaires, suggesting many patients should be encouraged to discuss sleep concerns with a physician. Recent meta-analytic results from 19 studies comprising 1162 patients suggest that combining CBT for insomnia and pharmacotherapy can be effective (Zhang et al., 2022); therefore, future versions of the sleep resource will include the advice that patients consult their doctor about how to integrate their medication into their treatment. Patients only reported drug usage impacting their sleep in 2% of weekly sleep questionnaires and alcohol impacting their sleep in 3% of weekly sleep questionnaires. The relatively infrequent reports of drugs or alcohol impacting sleep could result from be patients with primary alcohol or drug concerns routinely being referred to addiction programs.

**Effect of the COVID-19 Pandemic**

Major stressful life events (e.g., wildfires, earthquakes) can cause sleep disturbances (Lavie, 2001). The current trial was conducted during the first year of the COVID-19 pandemic, which may have impacted patient experiences and the current
results. A large meta-analysis with data from 22,330 individuals in 13 countries over four continents from May to August 2020 (i.e., the months immediately before the current trial recruitment period began in September 2020) evidenced insomnia prevalence as variable and very high (20–35%) (Morin et al., 2021). A Canadian longitudinal study also measured insomnia prevalence in a cohort of adults who were previously surveyed in 2018 and found that, during the first wave of the pandemic (i.e., April to May 2020), incidence increased by 32.7% compared to an otherwise comparable pre-pandemic period (Morin et al., 2022). The available results suggest the current trial patients may have had higher than usual insomnia symptoms due to factors related to the pandemic. Higher initial symptoms necessarily allow for greater symptom reductions (Edmonds et al., 2018); as such, the higher initial symptoms among current trial patients may have increased the effect size for the Sleep-Enhanced version of the Wellbeing Course.

Using a learning health system model, such as the one employed at OTU provides the ability to monitor changing patient symptoms, patient needs, and program effectiveness over time in a large population of people seeking treatment for mental health concerns and respond appropriately to patients’ changing needs. The current results suggest that brief ICBT interventions targeting insomnia can be an important part of the public health response to wide-spread stressors such as the COVID-19 pandemic. People’s daily routines were disrupted during the pandemic and homeostatic pressure (duration of wakefulness) was reduced for a large portion of the population who were no longer waking using an alarm clock and showing up at work at a fixed time, and no longer engaging in social, self-care (e.g., eating, exercising), and leisure activities at relatively fixed times throughout the day (Morin et al., 2020). Daylight exposure, the
primary factor regulating the circadian timing system, was also disrupted during the pandemic isolation periods, which likely increased night-time wakefulness (Morin et al., 2020). Patients in the current trial who received the Sleep-Enhanced condition were provided with psychoeducation about circadian rhythm and sleep restriction, which would have encouraged them to counteract the effects of the pandemic on their sleep behaviours by encouraging them to keep a regular sleep schedule.

The Sleep-Enhanced condition also emphasizes the importance of good sleep; however, the control condition in the current trial also included basic information about the importance of sleep and basic sleep hygiene tips. Explaining that sleeping on a regular schedule is an important behavioural intervention for those suffering from insomnia during a pandemic is consistent with the current trial evidencing greater engagement with sleep restriction behaviours as associated with larger reductions in insomnia. Qualitative results from reviewing patient feedback included specific mentions of how sleep behaviours were worse during the pandemic and that the course had helped to improve sleep. Insomnia can have a lasting impact on a patient’s ability to manage sleep disruption in the context of life stressors and brief interventions have the potential to improve quality of life; a follow-up study of patients who previously completed an ICBT for insomnia in 2016-2017 found that ICBT for insomnia produced greater resilience during the COVID-19 pandemic compared to sleep education alone (Cheng et al., 2021). Further research could investigate whether a brief intervention for insomnia offered as part of a transdiagnostic course, as in the current trial, would be able to produce a similar prophylactic effect for patients who experience life stressors that increase risk for insomnia.
Patient Acceptability

Patient acceptability is an important concern for CBT-based interventions for insomnia as the behavioural strategies for changing sleep habits and improving insomnia can be difficult to explain to patients, to justify, and for the patient to follow through on. It was hoped that using a patient-oriented approach would result in materials that were maximally acceptable to the patient and the patient satisfaction questionnaire was designed to test whether this had been achieved. Most patients reported that they were satisfied overall with the sleep materials provided to them in post-treatment responses. Although patient-reported satisfaction is only a proxy for patient acceptability, the combination of patient ratings of overall satisfaction and positive symptom improvement certainly suggest that, at least for patients who completed the course, acceptability of the sleep materials was high.

One goal of the new sleep materials was to provide psychoeducation about sleep to the patient. Most patients reported that the materials presented were easy to understand, helpful, and that their knowledge of sleep concerns had increased, while a minority reported the materials were somewhat to very unhelpful or that their knowledge had not increased. No patients reported the material was difficult to understand. These results suggest that the content that was presented to patients was chosen appropriately and presented effectively, as it was generally found to be helpful and informative.

High ratings of overall satisfaction, understandability, helpfulness, and increased knowledge, combined with most patients reporting that they changed their sleep-related behaviours suggests that patient acceptability for the new sleep materials was high. The finding that patient acceptability was high in the current trial is consistent with findings
of a recent network meta-analysis of research on CBT for insomnia, which showed that therapy delivered in digital formats had high acceptability that was comparable to individual and group in-person therapy formats (Gao et al., 2022) and superior to self-help interventions. Nonetheless, there remains room for improvement in these ratings of acceptability, especially if we assume that those patients who left treatment early might have provided lower ratings on at least some of the questions related to acceptability.

An ongoing concern related to patient acceptability in ICBT research is the burden that completing questionnaires places on patients. In the current trial, deciding what measures to administer to patients involved striking a balance between the need for rich data from patients for the purposes of research and the need to have patients spend as little time as possible completing questionnaires. For example, a detailed daily sleep diary might be considered the gold standard for tracking a patient’s sleep, but in the context of the current trial, having patients engage in such a time-consuming task may dissuade them from participating in the program, or it may take away patient time available for engaging in the cognitive and behavioural elements of the psychotherapy program that are thought to produce positive change. Given that further reducing the length of the questionnaires in this program represents one possible strategy for increasing patient acceptability, shorter measures should be considered wherever possible. Researchers who have sought to reduce the length of insomnia screening measures produced a two-item version of the Insomnia Severity Index which shows reasonably good sensitivity (Kraepelien, Blom, Forsell, et al., 2021), and the utility of such a brief measure in the context of transdiagnostic ICBT programs should be verified by future research.
Strengths and Limitations

This is, to our knowledge, the first trial to directly test whether including information based on CBT for insomnia can increase the effectiveness of a traditional transdiagnostic ICBT course for resolving insomnia symptoms. The current trial was designed to combine a randomized-controlled trial to test the main research question (i.e., does including an insomnia intervention in a transdiagnostic ICBT program improve patient outcomes?) with simultaneous exploratory research designed to better understand the experience of patients who received the new insomnia intervention. The current trial was designed with an unequal randomization strategy to boost the number of people in the treatment condition available for analysis. This increased sample size to facilitate exploration of how factors affecting sleep and adherence to therapeutic sleep behaviours are related to insomnia symptom change. The combination of quantitative and qualitative approaches employed by the current trial allows multiple avenues for understanding patient experiences and goes beyond demonstrating an effect size. Another strength of the current trial was the patient-oriented approach which was particularly valuable in developing the new sleep materials. Feedback indicated patients were satisfied with the sleep resource presented. Helpful suggestions about wording and images provided by the patient partners were incorporated into the new sleep resource. Integrating feedback from the patient partners and the rest of the patient-oriented research committee resulted in a new sleep resource that patients reported was helpful, and easy to understand. Striving for maximum patient acceptability means providing better patient experience and outcomes, which in turn meant that the current trial was more likely to detect an effect.
As is expected in research on ICBT programs, a limitation of the current trial is that there was considerable missing data at post-treatment and 20-week follow-up, and little is known about how patients who left the program prematurely eventually fared. Data completion rates were similar in both the Sleep-Enhanced and Standard Wellbeing (control) conditions, which suggests that whatever factors contribute to a patient leaving the course early were evenly distributed between the two randomly assigned treatment conditions. Sensitivity analyses were conducted to better understand what demographic or symptom-related factors might be related to attrition, although understanding the factors related to attrition was not a primary purpose of the current trial. As in previous studies, age was a weak predictor of program completion (e.g., M. Edmonds et al., 2018), but no other factors were related to program completion. This suggests that different demographic and symptom subgroups were well-represented in the post-treatment and 20-week follow-up data.

The current trial used weekly self-reports to track sleep behaviours and factors impacting sleep on a weekly basis. This choice likely limits the accuracy of the data relating to sleep habits. Although it may be considered a limitation of the current trial, this approach was chosen because it balances the need to provide reasonable estimate of patient behaviours with the perceived burden of reporting required of the patient. More accurate methods of measuring improvements in sleep efficiency would likely include logging daily sleep diary data or using alternative methods such as wearable devices. Daily sleep diaries require more effort and could potentially overburden the patient, while wearable devices require a level of funding that was not available for this research.
A final limitation of the current trial is that the results may not be generalizable to other settings. There are many transdiagnostic ICBT programs in use today that could likely benefit from a brief intervention targeting insomnia, however, transdiagnostic programs vary in the population they serve, the modality they are offered in (e.g., web, app, video) and myriad other factors (e.g., duration, amount of therapist support, cost). Many ICBT courses are based on a transdiagnostic model similar to the Wellbeing Course, however further research would be needed to verify the utility of an intervention like the Sleep-Enhanced program in other contexts. It is reasonable to expect, for example, that a replication study conducted during a period when patients are not enduring an active global pandemic could demonstrate a different effect size.

**Future Directions**

The current trial explored the relative importance of two key behavioural strategies (i.e., sleep restriction, stimulus control) for producing symptom change, and the results suggest that sleep restriction may be the more important of the two behavioural strategies. However, the observation is correlational only, as the current trial design was not sufficient to establish a causal relationship between engaging in sleep restriction and insomnia relief. Future studies could explore the relationship between engaging in sleep restriction and symptom change by randomly assigning patients to receive modified versions of the resource that either do or do not include sleep restriction instructions. Conducting dismantling trials in this way would provide valuable information about exactly which pieces of information presented and which behavioural strategies actually produced the improvements in insomnia symptoms observed in the current trial, thereby
informing what needs to be included or emphasized in future versions of the Sleep-Enhanced program materials.

Patients reported a wide variety of factors affecting their sleep, which also suggest lines for future research. Further improvements in the effectiveness of the newly developed sleep materials may be achieved if they include advice for coping with common factors affecting sleep (e.g., caregiving responsibilities, medications, and other external factors). Another exciting possibility for further improving patient acceptability and outcomes is individualizing instructions and psychoeducation based on each patient’s unique sleep concerns. Although addressing a wide range of sleep concerns would appear to serve the greatest number of patients, this should be balanced against the need to provide a resource that is succinct and digestible by patients. Future research should investigate whether an even briefer resource could be acceptable to a greater number of patients and compare the benefits of this approach to a longer resource that is more comprehensive.

The intervention developed for the current trial targets symptoms of insomnia; however, sleep concerns among the potential patients seeking treatment for insomnia and depression during this trial varied widely. The exclusion criteria for the current trial were developed so that patients with sleep concerns that were suggestive of a sleep problem other than insomnia (e.g., sleep apnea) would be excluded and directed instead to other more appropriate help for their sleep concerns. Although we expected that sleep apnea and other sleep conditions would be present in the population accessing the Wellbeing Course, a large number of patients were ultimately excluded from the trial because they reported sleep concerns that were not likely to improve as a result of participating in an
ICBT intervention targeting insomnia. Many patients were excluded from the current trial after reporting sleep apnea during their telephone interview because a more appropriate treatment for this condition is known. Similarly, reporting symptoms suggesting restless leg syndrome was another common reason that patients were excluded from the current trial. Future research investigating the types of education or behavioural interventions that could be included for individuals experiencing sleep apnea and restless leg syndrome could help improve outcomes for these individuals, should they engage with the Wellbeing Course. Another potential area of research for improving service to patients with sleep problems would be a collaboration with primary care physicians, so that, for example, patients can have health-related sleep problems addressed in a way that is consistent with their behavioural goals. Physicians are also well-positioned to provide patients with clarity about how sleep medication (both over the counter and prescription) fits with behavioural strategies for improving sleep patterns.

In addition to considering how to serve the subgroup of patients who had concerns about sleep but were screened out of the current trial, additional research is needed to investigate how to better help those patients who enrolled in the course but left before completing the whole course. Treatment completion rates in the current trial were somewhat lower than previous studies of the Wellbeing Course, which is likely due to the fact that only patients with elevated insomnia symptoms were admitted to this trial. Many mild severity patients who might be more likely to complete the course were excluded. Some of the patients who left the course before the end may have experienced symptom remission and some may have benefitted from the course despite not completing it; however, it is safe to assume that the outcome for some of those who did not complete
the course could be classified as treatment failure. Future research should consider factors that might increase treatment completion rates. Responding early when at-risk patients begin the course appears to be a promising method for improving treatment success rates (Forsell et al., 2019). Patients who are considered at increased risk for dropout can be given more therapist attention or receive other more intensive interventions. Existing research into the types of therapist behaviours that encourage engagement with the Wellbeing Course, such as the ICBT Therapist Rating Scale (Hadjistavropoulos et al., 2018), could be extended by examining what specific therapist behaviours support changes in patient sleep behaviours.

Additional research could further improve presentation of insomnia materials to patients. In the current trial, the new insomnia materials were provided to patients as a brief lesson before the standard course began, with brief reminder callbacks to the insomnia intervention after each of the subsequently presented modules of the Standard Wellbeing Course. The decision to present the materials before the existing course (as opposed to after the course or embedded throughout) was made after consideration of feedback provided by our patient-partners and other members of the PORSC. The PORSC thought that emphasizing the importance of addressing sleep concerns was best accomplished by placing the information at the beginning of the course. The Online Therapy Unit has also explored an alternative method of presenting the sleep materials. In this alternative approach, sleep materials are presented as an additional resource (i.e., “Good Sleep Guide”) that patients can optionally access (Peynenburg et al., 2022). This approach was intended to allow patients to decide for themselves about the appropriateness of an insomnia resource for their own sleep concerns thereby eliminating
the need to screen patients with elevated insomnia symptoms into a dedicated Sleep-Enhanced version of the Wellbeing Course. The study found that many patients did in fact choose to access the insomnia resource; however, accessing the insomnia resource was not significantly associated with the magnitude of change in insomnia symptoms (Peynenburg et al., 2022). One likely reason why a significant correlation between accessing the insomnia resource and insomnia symptom change was not found in the current trial could be that this sample included many patients with minimal or no insomnia symptoms – a notably different population than that which participated in the current trial. In the current trial, only patients with elevated insomnia symptoms were admitted, and the importance of sleep strategies was introduced early and made mandatory, which may have supported the relatively large effect size. Future research should therefore attempt to dismantle not only what the critical aspects of a brief insomnia intervention are, for relieving comorbid insomnia among patients seeking therapy for anxiety and depression, but also the most effective approach for presenting materials targeting insomnia. For example, a future trial might compare the overall effectiveness of an individualized approach to transdiagnostic ICBT that prioritizes the presentation of modules that relate to symptoms reported by the patient (e.g., the insomnia intervention created in the current trial being provided to patients with elevated insomnia) to a patient-led approach wherein patients are provided with access to a range of resources and can choose whatever they think is relevant.

Another important direction for new research involves the need to study the effectiveness of ICBT among diverse groups. The majority of patients in the current trial identified as white, and minority ethnic groups appear to be underrepresented when
compared to population demographics, similar to previous studies of the Wellbeing Course in Saskatchewan. Further improvements in patient acceptability of ICBT interventions may be achieved by gathering feedback from diverse groups of patients who can suggest ways to improve understandability and present information in a culturally appropriate way. Research into perceptions of ICBT among diverse groups would be valuable in marketing ICBT programming to underserved populations. In addition to researching how ICBT may be adapted to provide culturally sensitive service, research into how ICBT might be personalized for sub-groups based on other demographic variables, such as age, education or employment status, represents another avenue for potential further increases to patient acceptability.

The results of the present trial are consistent with a growing body of evidence that shows internet-delivered therapy is an effective tool for public health institutions to use in their response to mental health needs in the community (Andersson, 2018; Andersson, Carlbring, et al., 2019; Păsărelu et al., 2016). The results of this trial are expected to improve the quality of online therapy services offered in Saskatchewan and beyond, and continued interest in funding such research by government is likely to continue producing valuable findings in the future; however, the successful deployment of internet-based health services also depends on internet equity (i.e., fair access to internet-based services for all citizens) and internet literacy (i.e., citizens possessing sufficient computer skills to access services). Government funding should therefore not only be increased for the development, implementation, and improvement of online therapies, but also designated specifically for establishing equitable internet access and developing internet literacy programs. In the modern age, access to the internet provides not only access to
information and entertainment, but also the ability to access critical health services, such as those offered by the OTU. Efforts to improve digital literacy and internet equity should therefore be considered important components of continuing to provide internet-delivered public health services.

**Conclusions**

Transdiagnostic ICBT for anxiety and depression continues to represent a cost-effective and patient-acceptable method of delivering psychotherapy and the current trial is part of a rapidly expanding field of research that seeks to maximize its impact. The current trial was designed to evaluate the effectiveness of a newly developed brief intervention targeting insomnia designed to be offered alongside an existing transdiagnostic ICBT program for anxiety and depression. The results showed that patients who were randomly assigned to receive the new Sleep-Enhanced protocol reported significantly larger reductions in insomnia symptoms than those who received the standard program. Results from treatment satisfaction questionnaires administered to patients at post-treatment indicated high ratings for satisfaction with the resource, understandability, and helpfulness, suggesting high patient acceptability for the new sleep resource. The new sleep resource introduced patients to two CBT-based behavioural strategies (sleep restriction, stimulus control) and there was high variability in how much patients reported using these techniques. Engaging in sleep restriction on a greater number of days over the course of treatment was associated with greater reductions in symptoms of insomnia, while a significant association between stimulus control and insomnia symptom change was not found in this sample. Patients reported a wide variety of factors affected their sleep over the course of treatment and reports of anxiety
interfering with sleep predicted more modest improvements in insomnia symptoms. The current results suggest that targeting insomnia as part of a transdiagnostic protocol can offer many patients who are primarily seeking therapy for anxiety and depression additional relief of insomnia symptoms while still producing large reductions in depression and anxiety. Future dismantling research is needed to understand exactly which components of the intervention for insomnia produce symptom change among those seeking online therapy for anxiety and depression. Notably, this project was conceptualized using a patient-oriented approach and began with careful consideration of past patient outcomes and feedback, as well as input from clinicians, health managers, and research collaborators. The rich data produced by the mixed quantitative and qualitative approach of the current trial provides many potential avenues for future research and continuing to apply a patient-oriented approach will support the Online Therapy Unit in making incremental improvements to the service it offers and to the research literature on ICBT.
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https://doi.org/10.1056/NEJMRA012893


Appendix A: Ethics Approval

The University of Regina Research Ethics Board has reviewed the above-named research project. The proposal was found to be acceptable on ethical grounds. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to this research project, and for ensuring that the authorized research is carried out according to the conditions outlined in the original protocol submitted for ethics review. This Certificate of Approval is valid for the above time period provided there is no change in experimental protocol, or related documents.

Any significant changes to your proposed method, procedures or related documents should be reported to the Chair for Research Ethics Board consideration in advance of its implementation.

ONGOING REVIEW REQUIREMENTS
In order to receive annual renewal, a status report must be submitted to the REB Chair for Board consideration within one month of the current expiry date each year the study remains open, and upon study completion. Please refer to the following website for the renewal and closure forms:

https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html
Chris Street PhD
REB Chair
University of Regina

Please send all correspondence to:
Ethics Office
University of Saskatchewan
Room 305 Kirk Hall, 117 Science Place
Saskatoon SK S7N 5C8
Telephone: (306) 966-4053   Fax: (306) 966-2069
Appendix B: Online Screening Consent

Information & Consent Form for the Wellbeing Course Screening

Please take the time to carefully read the following information. If any information is unclear or for technical assistance, please email us at Online.Therapy.USER@uregina.ca or phone 306-337-3331.

This screening is used for the following research studies:

**Project Title:** Optimizing duration of therapist-guided Internet-delivered Cognitive Behaviour Therapy for Depression and Anxiety

**Project Title:** Addressing Sleep Concerns within a Transdiagnostic Internet-Delivered Cognitive Behaviour Therapy (ICBT) Program for Anxiety and Depression

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<td>Kerry Spice, MEd, Clinical Research Associate</td>
<td>Contact: (306): 337-3331</td>
</tr>
<tr>
<td>Amber Klatt, MEd, Clinical Research Associate</td>
<td>Email: <a href="mailto:Online.Therapy.USER@uregina.ca">Online.Therapy.USER@uregina.ca</a></td>
</tr>
<tr>
<td>Heather Davidson, BSW, Clinical Research Associate</td>
<td></td>
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<tr>
<td>Emma Valli, BSW, Clinical Research Associate</td>
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<tr>
<td>Alexis Urszulan, BA (Hon) Research Associate</td>
<td></td>
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<tr>
<td>Andrew Wilhelms, BA (Hon) Research Associate</td>
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<tr>
<td>Mike Edmonds, MA, Graduate Student</td>
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<tr>
<td>Katherine Owens, PhD, Community Supervisor</td>
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<tr>
<td>Kim Bell, BSW, Community Online Therapist</td>
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<tr>
<td>Annette Kapell, BSW, Community Online Therapist</td>
<td></td>
</tr>
<tr>
<td>Dakota Fell, BSW, Community Online Therapist</td>
<td></td>
</tr>
</tbody>
</table>

Purpose of the Screening:
The purpose of the screening is to assess your present concerns and determine whether you are eligible for the Wellbeing Course and the associated research projects. This consent form is in regards to the Wellbeing Course Screening only. For your information, however, we also describe the Wellbeing Course and the Wellbeing Course Research below. If you are accepted into treatment, a second consent form will be presented at that time.

Purpose & Nature of the Wellbeing Course:
- The Wellbeing Course is a transdiagnostic Internet-delivered cognitive behaviour therapy (ICBT) course designed to assist people managing diverse symptoms of depression and anxiety.
- The course involves clients reviewing course materials online and then practicing cognitive, behavioural, and physical strategies for managing symptoms.
- The course materials are delivered gradually over 8 weeks and take about 1 hour to review and then additional time (1-3 hours) to practice strategies taught in the course.
- Clients are able to email or phone a therapist, who provides support and answers questions, once per week for 8 weeks; a longer time frame is sometimes offered with the research project (e.g., up to 12 weeks, follow-up sessions).
• All therapists have received training and supervision in ICBT and have a background in psychology or social work; therapists are registered or certified to practice in Saskatchewan or are graduate students under supervision of a registered/certified professional. All therapists use the Online Therapy Unit website to deliver services, although they may work from offices located in different parts of Saskatchewan.

• All clients who take part in the Wellbeing Course are asked to complete questionnaires before treatment (~30 minutes), weekly during treatment (~5 minutes) and then at 8, 16, 24 weeks after treatment (20-30 minutes).

**Purpose of the Wellbeing Course Research:**

• While we have learned a lot about the effectiveness of transdiagnostic ICBT since 2012, there is still more for us to learn about how to best deliver ICBT. At this time, the Online Therapy Unit is examining how to improve the course through duration of treatment or new materials.

**Procedure/Format of the Screening:**

• **Brief Online Screening (5 minutes):** After you consent, you will be asked some brief questions to determine if you are eligible for the Wellbeing Course. If you are not eligible, the Online Screening will stop and you will be given information about why you are not eligible. You can contact the office to discuss your eligibility further if you wish.

• **Full Online Screening (20 to 30 minutes):** If you meet basic eligibility for the Wellbeing Course, you will be asked to provide personal information such as name, address, telephone number, and email address before continuing. This information is necessary for our staff to contact you to discuss the results of the Full Online Screening. In the Full Online Screening you will be presented with questions asking about your background, mental health symptoms, health, relationships, occupation, and treatment history. We will request the name and contact information for an emergency medical contact, such as your physician. At this stage, this provider will only be contacted if we are concerned about your safety, or, with your additional consent, to discuss your care. If you are accepted for the Wellbeing Course we will also send a letter to your provider to let them know you are enrolled in the Wellbeing Course. This letter could become part of your provider’s medical file.

• **Telephone Screening (20 to 30 minutes):** Following the completion of the Online Screening, you will schedule a time for a staff member to contact you by phone to discuss the results of the Online Screening and let you know if you are eligible for the Wellbeing Course and our research project. Online Therapy Staff may ask you some brief clarifying questions if more information is needed regarding your responses to the Online Screening. You may also use this time to ask any questions you may have about the program or research. Please note: The Wellbeing Course is not for everyone. Participation in the Online Screening does not guarantee participation in the course.

**Funded by:** The research has received funding from the Government of Saskatchewan, Ministry of Health, Canadian Institutes of Health Research (CIHR), Saskatchewan Health Research Foundation (SHRF), and Saskatchewan Centre for Patient-Oriented Research (SCPOR).
**Potential Risks:**
You may find that sharing information can result in an increase in your emotions. It is also possible that after undergoing the screening it will be determined that the Wellbeing Course is not a good fit for you. If this happens, Online Therapy staff will discuss alternate treatment options with you. In general, your physician is a good source of information about services that may be available to you. Note that there are some risks with respect to confidentiality of information which are described below.

**Potential Benefits:**
It is our hope that by undergoing the screening you will be able to access and benefit from the Wellbeing Course; alternatively, if the course is not a good fit for you, we will do our best to discuss more appropriate alternative services for you.

**Compensation:** No compensation will be provided for taking part in the screening.

**Voluntary Participation & Right to Withdraw:**
Participation in the screening process is entirely voluntary and you can answer only those questions that you are comfortable with. Should you choose not to participate in the screening, or if you wish to stop the screening at any time after starting, you may do so without explanation or generally without consequences. The one exception, however, is that if certain questions are not answered it may not be possible for us to offer you the Wellbeing Course (e.g., your therapist requires certain information, such as your name and contact information, in order to offer you services).

Your right to withdraw your online screening data from the research results will apply until one week after you complete the online screening. After this date, it is possible that some results have been analyzed, written up and/or presented, and it may not be possible to withdraw your data. If you want your online screening data to be excluded from research results please contact the Online Therapy Unit Coordinator at the contact information above and your data will be removed from the research database. It is not possible to exclude online screening data from clinical files until 7 years after services have been provided as this represents a record of care.

**Confidentiality:**
The responses you provide are confidential and will not be released to any outside source including your employer except in situations in which there is:
1. potential, imminent harm to yourself or others;
2. suspected neglect or harm to a child, including the witnessing of violence; or
3. a court order to release client information; or
4. where required by legislation.

**Risks to Privacy:**
There are unique risks that may compromise your privacy that exist with any internet-based service, including that the responses to the questionnaires are temporarily stored on your computer connected to the internet in the browser’s history and cache.
Methods Used to Protect Your Information:
The Online Therapy staff has taken precautions to protect the security of your information. Both the University of Regina server and REDCap servers are protected with generally available security technologies, including firewalls and data encryption. In addition, information transmitted from your machine to the server is encrypted using secure socket layer technology (SSL).

Things You Should Do to Protect Your Information:
It is important for all users of internet-delivered services to take additional security precautions when submitting sensitive information electronically to ensure the safety of your information.
1. Use your home computer instead of a computer in a shared space, such as a library or office.
2. When you leave your computer or are done working with the web application, ensure you have exited the Online Screening.
3. Since your internet browser stores information in its memory, or disk cache, you can clean the cache or browse history after you use the computer to ensure the information has been discarded. Certain browsers have "Privacy" modes that can be enabled. Once in this mode, the user's interactions are not saved to browser history, and no data is stored in browser cache. Once the browser is closed or this mode is exited, there are no browser records of any of the interactions that occurred while in the "Privacy" mode. Firefox has this feature, and is, therefore, highly recommended when completing the Online Screening. Browsers that do not have this mode, or users that do not use this feature, must manually purge their browser history and cache to prevent others from seeing their web interactions.
4. Use a secure internet connection (private home or work network) instead of a public Wi-Fi network. If you are connected to an unsecured public wireless network, using a Virtual Private Network (VPN) service (e.g. Norton Secure VPN, TunnelBear) to encrypt all of the data you send online will ensure your privacy and anonymity are protected.
5. Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable third party software, such as ZoneAlarm. Firewalls protect your computer and information from network attacks and threats.
6. Use anti-virus software to both prevent and recover from virus programs. While most anti-virus software is for purchase, there are free software options available to download. However, one must still be cautious in order to avoid downloading and installing malicious software that appears to be legitimate.
7. Malware-detection software (such as Spybot: Search and Destroy, Microsoft Security Essentials) can be used to scan your computer for software and files that may be leaking your personal information to third parties.
8. Ensure your software (operating system updates, anti-virus software) is updated with the latest version as developers are continually patching security holes and vulnerabilities with software upgrades.

Use of Information Collected through the Screening:
1. Information gathered through the online screening will be used to determine your eligibility for participation in the Wellbeing Course. If you are not eligible for the Wellbeing Course it will be used to attempt to provide you with options available to you in your community.

2. If you are accepted for the Wellbeing Course, the online screening will be provided to your therapist and be part of your clinical record of care. The clinical record is kept securely by the Online Therapy Unit therapists.

3. Information will also be provided to the research team with your identity removed to evaluate the screening process and Wellbeing Course in order to guide the development of future screening methods and online treatment programs. The research will be published and presented to diverse stakeholders, such as to individuals with anxiety or depression, researchers, providers, healthcare managers, and government in order to advance understanding of how to use ICBT. Any publications and presentations stemming from the evaluation of this information will examine respondents as a whole and you will not be personally identified.

**Storage of Online Screening Information:**

1. Your responses to the Online Screening will be collected by REDCap and then stored on the secure server housed at the Saskatchewan Health Authority. This server is located in Canada and information on the server is covered by the Canadian *Privacy Act*.

2. All information collected from you will be retrieved from REDCap and kept securely on University of Regina secure servers as well as password protected for a period of seven years, which is consistent with professional practice.

**Study Results:**

To obtain results from research on the Wellbeing Course please visit [www.onlinetherapyuser.ca](http://www.onlinetherapyuser.ca) where the results of our research will be posted once they are available. We expect results related to optimizing the therapist-guided Internet-delivered cognitive behaviour therapy for depression and anxiety to be available by January 2022.

**Questions or Concerns:**

Please contact any member of our team using the information at the top of page 1.

This project has been approved on ethical grounds by the U of R Research Ethics Board on February 10, 2020. Any questions regarding your rights as a participant may be addressed to the committee at 306-585-4775 or research.ethics@uregina.ca. Out of town participants may call collect.

**Continued or Ongoing Consent:**

Once you complete the Online Screening and book your Telephone Screening appointment, someone from our team will contact you to discuss your results. If the Wellbeing Course is recommended for you, we will provide with additional information and a consent form related to the treatment.
Consent:
By completing and submitting this form, YOUR FREE AND INFORMED CONSENT IS IMPLIED and indicates that you understand the above conditions of participation in the Online Screening.

☐ I understand that by submitting this form, MY FREE AND INFORMED CONSENT IS IMPLIED and indicates that I understand the above conditions of participation in the Wellbeing Course Screening.
Appendix C: Online Screening Questionnaire

Basic Eligibility Questions:

Are you currently experiencing any of the following symptoms? Anxiety, worry, difficulties with depression, loss of pleasure in activities, pain and/or problems related to alcohol use.

- Yes
- No

Are you a Saskatchewan resident and intending to remain in Saskatchewan while participating in the 8-week course?

- Yes
- No

Are you 18 years of age or older?

- Yes
- No

Do you have access to a computer and internet at home or in a place where it is appropriate to use a computer for personal use?

- Yes
- No
Do you feel comfortable using the Internet and writing emails?

- Yes
- No

Do you feel that you will have time available over the next 8 weeks to consistently work through one of our courses? Participants need at least 1 hour per week to work on our courses. Many participants spend 3 hours reviewing materials and practicing skills to improve well being.

- Yes
- No

If accepted into one of the Online Therapy Unit courses, are you willing to provide the Online Therapy Unit with a medical contact (e.g., Family Physician or Nurse Practitioner) for emergency purposes and coordination of care?

- Yes
- No
Appendix D: Fullscreen Questionnaire

Full Screen Questionnaire-2019

First Name:  ____________________________________________

Last Name:  ____________________________________________

Street Address:  ____________________________________________

City/Town:  ____________________________________________

Province:  

- [ ] Alberta  
- [ ] British Columbia  
- [ ] Manitoba  
- [ ] New Brunswick  
- [ ] Newfoundland and Labrador  
- [ ] Northwest Territories  
- [ ] Nova Scotia  
- [ ] Nunavut  
- [ ] Ontario  
- [ ] Prince Edward Island  
- [ ] Quebec  
- [ ] Saskatchewan  
- [ ] Yukon

Postal Code:  ____________________________________________

How would you describe the location that you live?

- [ ] 1. Farm or Acreage  
- [ ] 2. Village or Hamlet (1-200 citizens)  
- [ ] 3. Small Town (200-800 citizens)  
- [ ] 4. Town (800 - 7,000 citizens)  
- [ ] 5. Big Town (7,000 - 20,000 citizens)  
- [ ] 6. Small City (20,000 - 100,000 citizens)  
- [ ] 7. City (100,000 - 500,000 citizens)  
- [ ] 8. Large City (500,000+ citizens)  
- [ ] 9. First Nations community  
- [ ] 10. Other (Please specify)

Please enter your 10 digit phone number (e.g., 5555555555)

Please ensure that you are willing to receive phone calls in relation to your participation in online therapy from the Online Therapy Unit at the number you provided.

(Please provide a valid Canadian Phone Number)

Do you feel comfortable with us leaving a message for you at this phone number?  
- [ ] Yes  
- [ ] No

Please explain....

Email:  ____________________________________________

__________________________________________

Please retype your email address
**Personal Background**

**Age**

________________________

Which gender do you identify with?

- Woman
- Man
- Non-Binary
- Two-Spirit
- Transgender
- Prefer not to disclose
- Not listed (please specify)

Would you like to expand?

________________________

What is your date of birth? (yyyy/mm/dd)

________________________

What is your highest level of education?

- Less than high school
- High school diploma
- Some college or university
- College diploma - 2 to 3 year
- University undergraduate degree
- University professional degree (e.g., MD)
- University graduate degree (e.g., MA, PhD)

How would you describe your ethnicity?

- White/Guasian
- Spanish/Hispanic/Latino
- Black/African American
- Asian
- Southeast Asian
- Pacific Islander
- First Nations, Metis, Inuit
- Middle Eastern
- Prefer not to answer
- Other

What language did you first learn at home in your childhood?

- English
- French
- Other (please specify)

Please specify:

**Social Relationships**

What is your relationship status?

- Single never married
- Dating
- Married or common law
- Living with partner
- Separated
- Divorced
- Widowed

If you are in a relationship, will your partner know that you are receiving services from us?

- No
- Yes

Please explain:

________________________
If you are in a relationship, please indicate the statement that best describes the degree of happiness, all things considered, of your relationship.

- Extremely unhappy
- Fairly unhappy
- A little unhappy
- Happy
- Very happy
- Extremely happy
- Perfect

If you are in a relationship, do you have any concerns regarding your relationship at this time?

- Yes
- No

Please explain difficulties you are experiencing in your relationship.

Were you in a serious romantic relationship that has recently ended?

- Yes
- No

In your opinion, did the romantic relationship end because of mental health problems you have been experiencing?

- Yes
- No
- At least in part

Do you have children?

- Yes
- No

How many?

What ages are your children?

Do you have any concerns regarding your children at this time?

- Yes
- No

Please explain:

Are you living alone?

- Yes
- No

If you are living with someone please check all that apply:
- Living with spouse or partner
- Living with dependent adult
- Living with children
- Living with extended family
- Living with roommates
- Other

Please explain what other living arrangement you have.
Do you feel you are able to ask for help when things are not going well?  
- Yes  
- No

Are there persons in your life who help you if you need them to?  
- Yes  
- No

Are you experiencing any legal difficulties at this time?  
- Yes  
- No

Who do you rely on for support?  
- Spouse  
- Children  
- Parents  
- Extended family  
- Friends  
- Coworkers  
- Medical professional  
- Faith/spiritual community  
- Other

Please briefly explain the legal difficulties you are experiencing:

Medical Contact Information

The Online Therapy Unit involves receiving treatment over the internet, and, therefore, we are unable to provide support in the case of an emergency. For this reason, we ask individuals that are interested in this service to provide a medical contact (Family doctor, Psychiatrist, or Nurse Practitioner) who they have seen in person in the past.

If you are accepted into treatment and provided a username and password for treatment. In the event of an emergency (e.g., concern about suicide), we will contact the medical provider if we become concerned about your safety and need to coordinate care.

Furthermore, some of our courses involved therapist assistance. In this case we will also write to your medical contact notifying them of the nature of our Online Therapy Unit courses and your participation.

Name of Medical Contact

_____________________________

Type of Medical Contact  
- Family Doctor/Physician  
- Psychiatrist  
- Nurse Practitioner

Clinic Name (if available)

_____________________________

Clinic Phone Number

(Please provide in the following format: XXXXXXXXXX)

(Please provide a valid Canadian Phone Number)
Please provide a mailing address below

Clinic Street Address/ or P.O. box number

________________________________________

City/Town

________________________________________

Province

- Alberta
- British Columbia
- Manitoba
- New Brunswick
- Newfoundland and Labrador
- Northwest Territories
- Nova Scotia
- Nunavut
- Ontario
- Prince Edward Island
- Quebec
- Saskatchewan
- Yukon

Postal Code
Appendix E: Telephone Screen

Telephone Screen

Client ID:

Health Card Number:

Wellbeing Plus Sleep

Date

Start

Finish

Introduction: Hi my name is XXXX from the Online Therapy Unit. I am following up from your online application. Is this a convenient time to talk? (If no, schedule a time. If yes-continue). The telephone screen will take approximately 15 to 20 minutes.

Verbal review online screening consent form: Before we begin, can I ask if you have any questions from the online screening consent form. I also would like to remind you that although this phone call and notes taken based on the phone call are confidential there are some limits to confidentiality. These include:

1. potential imminent harm to the you or others;
2. suspected neglect or harm to a child, including the witnessing of violence or
3. a court order to release your information;
4. or where required by legislation

Do you agree to the telephone call?
- No... cannot participate - discuss alternative treatment options for client.
- Yes

Contact information: To start, I'd like to review your contact information provided during the online screening. Is this accurate or would you like change any of this information at this time?
- Name:
- Address:
- Phone:
- Permission to leave a message:
- Email:
- Date of birth:
- Gender:

Can you confirm that you are comfortable with me mailing and emailing you?
- No... cannot participate - discuss alternative treatment options for client.
- Yes

Also can you confirm that you are available for the 8 week treatment period and that you will primarily be in SK?
- No... cannot participate - discuss alternative treatment options for client.
- Yes

Medical Contact: I'd also like to review your medical contact information. This contact is for emergency purposes.
- Name of Medical Contact:
- Medical Clinic Name:
- Address: Clinic: Phone Number:

Do you agree to the use of the medical contact?
- No... cannot participate - discuss alternative treatment options for client.
- Yes
In the next sections we are going to be reviewing your symptoms for depression, anxiety, post-traumatic stress and (possible) history/current use of substances. I have a few additional questions for follow up.

**Alcohol (AUDIT) Review Online Scores & Discuss with Client if Score above 20**

- How often do you have a drink containing alcohol? [audit_q1]
- How many drinks containing alcohol do you have on a typical day when you are drinking? [audit_q2]
- How often do you have six or more drinks on one occasion? [audit_q3]
- How often during the last year have you found that you were not able to stop drinking once you had started? [audit_q4]
- How often during the last year have you failed to do what was normally expected from you because of drinking? [audit_q5]
- How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session? [audit_q6]
- How often during the last year have you had a feeling of guilt or remorse after drinking? [audit_q7]
- How often during the last year have you been unable to remember what happened the night before because you had been drinking? [audit_q8]
- Have you or someone else been injured as a result of your drinking? [audit_q9]
- Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down? [audit_q10]

**AUDIT total score**: [audit_total_score]

---

**Drugs (DUDIT) Review Online Scores & Discuss with Client if Score above 25**

- How often do you use drugs other than alcohol? [dudit_q1]
- Do you use more than one type of drug on the same occasion? [dudit_q2]
- How many times do you take drugs on a typical day when you use drugs? [dudit_q3]
- How often are you influenced heavily by drugs? [dudit_q4]
- Over the past year, have you felt that your longing for drugs was so strong that you could not resist it? [dudit_q5]
- Has it happened, over the past year that you have not been able to stop taking drugs once you started? [dudit_q6]
- How often over the past year have you taken drugs and then neglected to do something you should have done? [dudit_q7]
- How often over the past year have you needed to take a drug the morning after heavy drug use the day before? [dudit_q8]
- How often over the past year have you had guilt feelings or a bad conscience because you used drugs? [dudit_q9]
- Have you or anyone else been hurt (mentally or physically) because you used drugs? [dudit_q10]
- Has a relative or friend, a doctor or a nurse, or anyone else, been worried about your drug use or said to you that you should stop using drugs? [dudit_q11]

**DUDIT total score**: [dudit_total_score]
Begin this section by reviewing their concerns/history of anxiety with the questions outlined below. Then completed the depression concerns/history with the questions outlined below.

Review Depression/Anxiety Scores — Scores should be above 5 on GAD-7 or PHQ-9. Make notes for therapist.

- When did this episode start?
- How many episodes have occurred?
- What is the duration of symptoms?
- Current symptom manifestation:
- Past symptoms (if applicable):
- Most troubling symptom/goal/motivation for course:
- Which symptoms do you find are most troubling for you?

After exploring their history and concerns regarding anxiety and depression, please follow up with:

- What past/current treatment have you received for your mental health?
- What are your current coping strategies (e.g., meditation, mindfulness, walking, talking with a friend, reading, counsellor, CBT techniques, etc.)?
- What are your current supports networks (partner, family, colleagues, supervisor, roommates, EFAP, etc.)?
- Has anything happened to cause the problems to get worse or better?

Please outline this information in the client notes section on the website. This information will be provided to the therapist assigned to the client.
<table>
<thead>
<tr>
<th>Risk Follow-up on PHQ-9 item 9 score above 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoughts that you would be better off dead or hurting yourself in some way: PHQ-9 item 9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you ever thought about or attempted to kill yourself?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Never</td>
</tr>
<tr>
<td>○ It was just a brief passing thought</td>
</tr>
<tr>
<td>○ I have had a plan at least once to kill myself but did not try to do it or I have had a plan at least once to kill myself and really wanted to die</td>
</tr>
<tr>
<td>○ I have attempted to kill myself, but did not want to die or I have attempted to kill myself, and really hoped to die</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How often have you thought about killing yourself in the past year?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Never</td>
</tr>
<tr>
<td>○ Rarely (1 time)</td>
</tr>
<tr>
<td>○ Sometimes (2-3 times)</td>
</tr>
<tr>
<td>○ Often (4-6 times)</td>
</tr>
<tr>
<td>○ Very Often (5 or more times)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you ever told someone that you were going to commit suicide, or that you might do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ No</td>
</tr>
<tr>
<td>○ Yes, at one time, but did not want to die or... Yes, at one time, and really wanted to die</td>
</tr>
<tr>
<td>○ Yes, more than once, did not want to do it or... Yes, more than once, and really wanted to do it</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How likely is it that you will attempt suicide someday?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Never</td>
</tr>
<tr>
<td>○ No chance at all</td>
</tr>
<tr>
<td>○ Rather unlikely</td>
</tr>
<tr>
<td>○ Unlikely</td>
</tr>
<tr>
<td>○ Likely</td>
</tr>
<tr>
<td>○ Rather likely</td>
</tr>
<tr>
<td>○ Very likely</td>
</tr>
</tbody>
</table>

SBQ Score:

_________________________

Notes on suicidal ideation.

Consult name:

(Consults are required with SBQ >7 or indication of likely or above on final question 4)

Consultation Notes

_________________________

Suicide Risk—Refer out?  ○ Responses indicate client is at a significant suicide risk and would be best treated in person
### Hospitalization/Crisis Service Use Review

**Have you ever been hospitalized for mental health problems in the past?**

---

**Have you been hospitalized or received emergency services (police, mobile crisis, hospital emergency, called 911) for a mental concern in the past year?**

---

**Have you accessed any of the following services in the last three months?**

- **Emergency Room:**
- **Ambulance or paramedics:**
- **Crisis Services:**

---

**Screening notes on recent hospitalization or crisis service usage**

---

**Recent MH hospitalization/crisis service use:**

- Refer

  O Response reveals a recent hospitalization that suggests client’s mental health status is not sufficiently stable for ICBT and would benefit from in-person treatment.

- Accept

---

### Trauma History Review for clients with PCL-5 above 33 — consider whether those above 60 are best for program.

In this next section we are going to discuss exposure to traumatic events, PTSD’s, and symptoms. From the looks of your online screen, you have identified:

**Nature of trauma of concern:**

**Number of times experienced:**

**How long ago?**

**How did you experience the event?**

**Was someone’s life in danger?**

**Was someone seriously injured or killed?**

**Was there sexual violence?**

---

### Psychosis/Bipolar/Other Disorder Diagnosis

**Has a psychiatrist or another health professional ever diagnosed you with Psychosis (e.g., Schizophrenia)?**

**Screening notes on psychosis endorsement**

**Psychosis—Refer out?**

- Refer out

  O Client is experiencing significant symptoms of psychosis and would be best treated with in-person treatment.

- Accept
Has a psychiatrist or another health professional ever diagnosed you with Bipolar?
Screen out on bipolar endorsement.

Bipolar/Mania-Refer out?
- Client is experiencing significant symptoms of mania and would be best treated with in-person treatment.
- Accept

Has a psychiatrist or another health professional ever diagnosed you with any other mental health disorder?

How are you managing?
How is being treated? (depending on response explore referring out)
How often do you find your daily life is being impacted by symptoms?
Screen out on other mental health disorder endorsement.

Other mental health concern- Refer out?
- Response reveals a mental health concern requiring primary treatment other than anxiety or depression.
- Accept

The Wellness Course may not meet the needs of clients with severe symptoms. In this case, the screener will provide the client with a referral to more appropriate services in the community. This may be a referral to the client’s family physician, a mental health clinician, and/or to an emergency service. An example of the kind of feedback that could be provided to a client whose symptoms are too severe is:

Based on your responses, it seems as though you are having a difficult time right now. What do you think about this? From the difficulties that you’ve described, it sounds as though at this time, you might be better helped by meeting with a therapist or other health care provider in person. This way the treatment you receive can be more specific to your needs. What I’d like to do is provide you with some options that might be better able to meet your needs.

**Medical Conditions**

Do you have any current or past medical problems?

Do you think these medical problems will interfere with your ability to take part in one of our courses?

Medical problem- Refer out?
- Response reveals medical problems that would inhibit active participation in the online course as delivered.
- Accept

**Sleep Concerns**

? [Textbox]
<table>
<thead>
<tr>
<th>Other Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have any other problems that you would like to share that you have not been asked about in this screening?</td>
</tr>
<tr>
<td>☐ Yes</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other problems Refer out?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ client reports another problem that is significant and would interfere in their success with LGBT</td>
</tr>
<tr>
<td>☐ Accept</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Legal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you experiencing any legal difficulties at this time?</td>
</tr>
<tr>
<td>(Screeners to note if client is mandated to receive treatment)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Legal difficulties that would interfere with treatment Refer out?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Reports significant legal difficulty that would interfere</td>
</tr>
<tr>
<td>☐ Accept</td>
</tr>
</tbody>
</table>

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### Inclusion/Exclusion Summary

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmanaged psychosis</td>
<td></td>
</tr>
<tr>
<td>Minimal Symptoms</td>
<td></td>
</tr>
<tr>
<td>Drug Use</td>
<td></td>
</tr>
<tr>
<td>Alcohol Use</td>
<td></td>
</tr>
<tr>
<td>Suicide Risk</td>
<td></td>
</tr>
<tr>
<td>Recent Mental Health Hospitalization/ Crisis</td>
<td></td>
</tr>
<tr>
<td>Unmanaged Bipolar Disorder/ Mania</td>
<td></td>
</tr>
<tr>
<td>Low motivation for treatment</td>
<td></td>
</tr>
<tr>
<td>Significant concerns with the format of treatment (messages, phone, online treatment in general)</td>
<td></td>
</tr>
<tr>
<td>Significant concerns about having the time to commit to treatment</td>
<td></td>
</tr>
<tr>
<td>Client did not agree to the terms of confidentiality.</td>
<td></td>
</tr>
<tr>
<td>Will not give permission for email contact during treatment</td>
<td></td>
</tr>
<tr>
<td>Will not give permission for contact with Doctor or Medical Professional</td>
<td></td>
</tr>
<tr>
<td>Basic eligibility not met</td>
<td></td>
</tr>
<tr>
<td>Legal issues</td>
<td></td>
</tr>
<tr>
<td>Other Mental Health Concerns</td>
<td></td>
</tr>
</tbody>
</table>
Decision

Final decision
Accepted to WellbeingPlus Sleep
Accepted to Wellbeing
Refer out

There is something important I would like to tell you about. We are able to offer this course free of charge because it's a research project. We are trying to do something very unique by using CBT for anxiety and depression. We ask that you commit to supporting our research by completing questionnaires at many different points of treatment - at the very beginning, brief questionnaires on a weekly basis, and else at 3 month, 6 month, and 10 month follow-up treatment.

Our hope is to hear from you even if for some reason you do not finish all five lessons. These questionnaires are extremely important and can help us to improve what we are doing and improve mental health services for Canadians. It's a great opportunity to help others who are living with mental health concerns. Is this something that you are willing to do?

How are you feeling? Do you want to join our course?

☐ Yes

Wellbeing Description

Based on this screening, I think the Wellbeing Course would be a good fit for you. The way the course is set up, you will log onto a secure website and practice five core lessons over 8 weeks. It generally takes about 1 to 2 hours per week to work on each lesson, which includes a slideshow, Do-it-Yourself guide, and stories of other people who've worked through the course. In addition to those core materials, there are also readings related to sleep, problem solving or assertiveness, which your therapist may recommend to you depending on your concerns.

Do you have any questions about the course and how it works?

Summary

<table>
<thead>
<tr>
<th>Exclusion Reason</th>
<th>GAD7 and PHQ9 both below 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Suicide Risk PHQ9 ≥ 9 above 2</td>
</tr>
<tr>
<td></td>
<td>AUDIT 20 or above</td>
</tr>
<tr>
<td></td>
<td>DUDIT 2.5 or above</td>
</tr>
<tr>
<td></td>
<td>Medical condition interference</td>
</tr>
<tr>
<td></td>
<td>Se or Psychosis</td>
</tr>
<tr>
<td></td>
<td>Bipolar/mania unmanaged</td>
</tr>
<tr>
<td></td>
<td>Hospitalization ER in last year</td>
</tr>
<tr>
<td></td>
<td>Wants primary help with another condition</td>
</tr>
<tr>
<td></td>
<td>Mental health treatment more than 2 times month</td>
</tr>
<tr>
<td></td>
<td>Wait for mental health treatment and will drop</td>
</tr>
<tr>
<td></td>
<td>Concerns about CBT and format of treatment (low motivation, not available, no computer)</td>
</tr>
<tr>
<td></td>
<td>Concerns about medical contact</td>
</tr>
<tr>
<td></td>
<td>Will not be in province during treatment</td>
</tr>
<tr>
<td></td>
<td>Client will not be 18 yrs of age at start of course</td>
</tr>
<tr>
<td></td>
<td>Referral not wanted</td>
</tr>
<tr>
<td></td>
<td>Referral made to:</td>
</tr>
<tr>
<td>Primary service referred:</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td></td>
</tr>
<tr>
<td>○ Doctor</td>
<td></td>
</tr>
<tr>
<td>○ Mental Health Clinic</td>
<td></td>
</tr>
<tr>
<td>○ Community Counseling Agency (Family service)</td>
<td></td>
</tr>
<tr>
<td>○ Self-guided online materials with another provider</td>
<td></td>
</tr>
<tr>
<td>○ Other (Explain in field below)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Do you think we could have better served this client by varying our service delivery in some way?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Yes</td>
</tr>
<tr>
<td>○ No</td>
</tr>
<tr>
<td>(This question is to inform future development. Available options should be utilized for this client where appropriate.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What modification would you have suggested if it was possible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Brief solution focused telephone contact</td>
</tr>
<tr>
<td>○ Current course with phone contact only</td>
</tr>
<tr>
<td>○ EBT for another condition Other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What other modification would you have suggested if it was possible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>(This question is to inform future development. Available options should be utilized for this client where appropriate.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Telephone screening complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thank you very much for taking the time to participate in this telephone screening. At this time do you have any questions or concerns that I might be able to answer for you?</td>
</tr>
</tbody>
</table>

| Have a good day. |
Appendix F: Treatment Consent Form

Information & Consent Form for the Wellbeing Course

Please take the time to carefully read the following information. If any information is unclear or for technical assistance, please email us at Online.Therapy.USER@uregina.ca or phone 306-337-3331.

**Project Title:** Addressing Sleep Concerns within a Transdiagnostic Internet-Delivered Cognitive Behaviour Therapy (ICBT) Program for Anxiety and Depression

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heather Hadjistavropoulos, PhD, R. D. Psych</td>
</tr>
<tr>
<td>Professor, Department of Psychology</td>
</tr>
<tr>
<td>University of Regina</td>
</tr>
<tr>
<td>Contact # (306) 585-5133</td>
</tr>
<tr>
<td>E-mail: <a href="mailto:heather.hadjistavropoulos@uregina.ca">heather.hadjistavropoulos@uregina.ca</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Online Therapy Unit Team:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Marcie Nugent, MSW, Coordinator</td>
<td>Online Therapy Unit</td>
</tr>
<tr>
<td>Kelly Adlam, MSW, Clinical Research Associate</td>
<td>Department of Psychology</td>
</tr>
<tr>
<td>Lee Bourgeault, MA, Clinical Research Associate</td>
<td>University of Regina</td>
</tr>
<tr>
<td>Kerry Spice, MEd, Clinical Research Associate</td>
<td>Contact: (306) 337-3331</td>
</tr>
<tr>
<td>Amber Klatt, MEd, Clinical Research Associate</td>
<td>Email: <a href="mailto:Online.Therapy.USER@uregina.ca">Online.Therapy.USER@uregina.ca</a></td>
</tr>
<tr>
<td>Heather Davidson, BSW, Clinical Research Associate</td>
<td></td>
</tr>
</tbody>
</table>

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**Purpose of Wellbeing Course:** Since 2012, the Online Therapy Unit has been offering transdiagnostic Internet-delivered cognitive behaviour therapy (ICBT).

Transdiagnostic ICBT represents a convenient method for individuals to access care for depression and anxiety. In transdiagnostic ICBT, clients receive access to standardized lessons that provide the same information and skills as traditional face-to-face CBT. Depression and anxiety are targeted within the same program which helps to ensure multiple concerns are addressed in an efficient manner. This is important given that it is very common for clients to have more than one mental health concern. In addition to weekly lessons, clients are encouraged to complete homework assignments to facilitate learning. Most commonly, ICBT is delivered with brief weekly therapist assistance (~20 minutes) via the telephone or secure email. Research shows that transdiagnostic ICBT with therapist assistance is effective at reducing symptoms of anxiety, depression and trauma. The weekly time commitment for clients to work on ICBT is ~ 1 to 3 hours.
**Purpose of the Wellbeing Course Research:**

While we have learned a lot about the effectiveness of transdiagnostic ICBT since 2012, there is still more for us to learn about how to best deliver ICBT. In this study, the Online Therapy Unit is examining how different treatment content impacts outcomes of ICBT. More specifically, we are exploring how different information about sleep impacts client engagement, outcomes as well as therapist support. The research will be used to ultimately improve how we deliver ICBT.

**Procedure:**

1. **The Wellbeing Course:** The Wellbeing Course is made up of 5 core lessons as well as extra resources that can be accessed by clients as needed. Lessons consist of materials that are accessed and read online and printable materials that you can retain for longer term use. With each lesson, clients also complete various exercises to assist them in learning skills. It is generally recommended that you spend one week on lessons 1 and 3, and 2 weeks on lessons 2, 4, and 5. On average, clients spend about an hour reading materials and another 1-2 hours practicing strategies. Your program will cover the following information:

<table>
<thead>
<tr>
<th>Lesson 1 (1 week):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to the purpose and content of the course; education about depression, anxiety, and post-traumatic stress; and an opportunity to learn about the 3 primary symptoms and the cycle of symptoms.</td>
</tr>
<tr>
<td>Lesson 2</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>Lesson 3</td>
</tr>
<tr>
<td>Lesson 4</td>
</tr>
<tr>
<td>Lesson 5</td>
</tr>
</tbody>
</table>

| Extra resources | Additional resources will be available and recommended depending on your individual concerns (e.g., sleep, communication, problem solving, coping with panic). |

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2. **Therapist Support:**
a) **Therapist Training:** All clients are assigned a designated therapist who is trained in delivering ICBT and signs a confidentiality agreement before working for the Online Therapy Unit. Your therapist will have training in Psychology or Social Work and be registered or certified to practice in Saskatchewan or be a graduate student or professional under supervision of a registered or certified provider in Saskatchewan. All therapists use the Online Therapy Unit web application to deliver services although therapists work in diverse locations across the province of Saskatchewan.

b) **Amount Contact:** When you are enrolled in the Wellbeing Course you will be matched to a therapist who will contact you once a week during the course. Your therapist will let you know the specific day each week that they will contact you.

c) **Type of Contact:** Therapist contact is primarily by secure messaging using the [www.onlinetherapyuser.ca](http://www.onlinetherapyuser.ca) website. Most commonly, as you work on lessons, you will message your therapist when it is convenient for you. Your therapist will then respond on their designated check-in date, which you will be informed about when you enroll in the course. When your therapist logs in they will be able to review pages you have viewed, your responses to questionnaires, and any messages you have sent. By reviewing this information, your therapist is able to provide you with feedback and support and answer any questions you may have. While most contact is by secure messaging, if your therapist notices that there has been a large increase in your symptoms and/or you are having frequent thoughts about death or hurting
yourself, then your therapist will contact you by telephone to gain more information and to provide support. Your therapist may also call you if he or she feels this would be helpful to assist you with your treatment.

d) **Length of Therapist Support:** ICBT is not meant for long-term therapy; therefore, therapists offer 8 weeks of support.

e) **Avoidance of Multiple Therapist Roles:** It is the responsibility of Online Therapy staff to avoid holding multiple roles with clients (e.g., friend, business partner) and to establish and maintain professional relationships with clients. Likewise, clients are expected to respect this obligation. The therapist will also be unable to meet requests through social networking websites (e.g., Facebook).

f) **Potential Therapist Unavailability:** In the event that your therapist is unable to access their messages due to unforeseeable circumstances (e.g., sickness, injury), then your therapist or another member of the Online Therapy team will advise you of the situation and you will be given options for how you would like to continue with ICBT. For example, if your therapist will be gone for an extended period, a replacement therapist may be assigned to you. Alternatively, similar to face-to-face therapy, there may be an occasional week period when no check-ins take place if your therapist has a planned temporary absence (e.g., holiday).
g) **Privacy of Therapist Communications:** As a client, you agree not to share your therapist’s communications with anyone else unless your therapist’s written and informed consent is first obtained. You also agree not to give advice based on the therapist’s communications, or show therapist communications to others, out of context.

3. **Automated emails:** Throughout treatment you will also receive periodic notification emails to your email address. These emails provide brief but important reminders from the team (e.g., notification that new lesson materials are available or that a secure message is waiting for you on the web application). These emails do not contain personal information. In order to facilitate the delivery of these notification emails to your off-system email, it is necessary to store your email address on our secure server.

4. **Technical assistance:** If you require technical assistance during the course you can message technical assistance at Online.Therapy.USER@uregina.ca on the website or call the office at 306-337-3331.

5. **Questionnaires:** When you log into www.onlinetherapyuser.ca, you will periodically complete brief questions to check in your symptoms and use of online materials; typically these questionnaires come once a week and require 5 minutes of your time. Your therapist will receive a summary of your responses and will use these questionnaires to assess your treatment progress.
To fully understand whether this program is effective, you will be asked to complete additional questions about your symptoms, functioning, and satisfaction with treatment. These questionnaires will be completed at 8, 16, and 24 weeks. These questionnaires should take ~30 minutes to complete. Questionnaires at 16 and 24 weeks are used for research purposes only while the other questionnaires are used by your therapist to guide your care.

You are not obligated to answer any questions which you find objectionable or which make you uncomfortable.

**Funded by:** The research has received funding from the Government of Saskatchewan, Ministry of Health, and Canadian Institutes of Health Research (CIHR).

**Potential Benefits & Risks:** There are potential benefits and risk associated with ICBT.

<table>
<thead>
<tr>
<th>Potential Benefits</th>
<th>Potential Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• You do not need to schedule an appointment for ICBT.</td>
<td>• ICBT may require more self-motivation than other forms of therapy.</td>
</tr>
<tr>
<td>• You avoid having to visit an office if things like transportation, stigma, or your own availability are of concern.</td>
<td>• Without nonverbal cues, there is some potential for misinterpretation of e-mail messages between you and your therapist.</td>
</tr>
</tbody>
</table>
• You can have more control when you work on therapeutic activities.
• You can access the online material from the location of your choice at your convenience. If you would like, you can print off pages to keep longer term.
• You can e-mail your therapist through our secure website.
• You may feel more comfortable disclosing personal information online than in person.
• This service is provided free of charge.

• There is a risk for breaches of confidentiality (see below for “Limits to Confidentiality”).
• There is potential for technology failures that may result in messages not being received by either you or your therapist.
• ICBT is a newer form of treatment, so there has been less research conducted when compared to face-to-face CBT.

Limitations of ICBT: This form of therapy is not intended to replace face-to-face therapy and is not designed for long-term use. This form of therapy is also not intended for emergency purposes and we may not be able to respond immediately to your concerns. If, during the course of therapy, you feel that ICBT does not meet or address your needs you are advised to consult with your designated therapist or closest health or mental health professional. In the event that you become unsure of your ability to keep yourself safe, we ask you to immediately contact your family physician, or Emergency Services (911) to ensure that you receive the help you need.
without delay. Please inform us of any changes in your physical or mental health status that may impact your ability to participate in the Wellbeing Course.

**Alternatives to ICBT:** Before consenting to ICBT, you should consider the alternatives to ICBT including in-person therapy, confiding in friends, family or clergy, taking part in community programs that may be available to you, written or online self-help resources, visiting a family physician or psychiatrist, or not seeking treatment at all. It is also possible that during the course of ICBT, the therapist may determine that in-person therapy would be more suitable for you. Situations where ICBT is not appropriate include if you were to become involved in a crisis situation, if there are risks to personal safety, if you require specialized medical treatment, or if you need support that is more long-term, interactive, or intensive. ICBT may also not be suitable for you if you difficulties reading or participating in the treatment.

**Compensation:** No compensation will be provided for taking part in ICBT or the associated research project.

**Confidentiality & Limits of Confidentiality:** The information you provide is confidential and will not be released to any outside source except in the specific circumstances detailed below. Although these circumstances are rare, there are certain limits to confidentiality that every client must be aware of, and include:

- potential, imminent harm to yourself or others;
- suspected neglect or harm to a child, including the witnessing of violence; or
• a court order to release client information; or

• where required by legislation.

If confidentiality needs to be broken, only those who need to be informed will be contacted.

**Emergency Situations:** In the event that your therapist or Online Therapy staff suspect you are at risk for harming yourself or others, they will first attempt to contact you by telephone to gain additional information about your situation. If the therapist determines that you are at high risk of harming yourself or others, then confidentiality may need to be broken. The therapist will have to contact either: your family physician or 911 depending on the situation.

If the staff is unable to make contact with you directly and significant concerns exist about your psychological status and safety, the therapist may utilize the emergency contact you provided during the screening interview (Family Physician) to ensure your safety. In communication with your physician, Online Therapy staff will include your name, health card number, and your birth date to identify you to the physician.

**Communication with other Providers:** Once you consent we will write to the physician or provider you designated as your emergency medical contact to let your provider know that you are enrolled in the Wellbeing Course. Other than this, the provider will only be contacted if we are concerned about your safety, or, with your additional consent, to discuss your care.
**Collection of information**

The Online Therapy Unit team will collect online information from you using the Online Therapy Unit website application and a survey tool called REDCap.

1. **Online Therapy Website:** The website application is used to display your course material, facilitate communication with your assigned provider and administer questionnaires. Information that is collected from you when use [www.onlinetherapyuser.ca](http://www.onlinetherapyuser.ca) is stored securely on University of Regina servers.

2. **REDCap:** REDCap was used to collect information from you during the online screening process and will be used to administer follow-up questionnaires. Information gathered by REDCap will be stored on a secure server housed at the Saskatchewan Health Authority. At the end of the study, we will retrieve all information from REDCap and store this information on a University of Regina server.

**Risks to Privacy:** There are unique risks that may compromise your privacy that exist with any Internet-based service, including that the responses to the questionnaires are temporarily stored on your computer connected to the internet in the browser’s history, cookies, and cache.

**Methods Used to Protect Your Information:**
In order to meet the standards of *The Local Authority Freedom of Information and Protection of Privacy Act* at section 23.1 and *The Health Information Protection Act* at section 16 to protect the privacy of your information while you are a user of the course, we have several precautions in place. However, you should be aware that it is not possible to safeguard against every possible risk. When submitting information to your therapist through the internet, including questionnaires and messages, although rare, there is a possibility your information will be intercepted by unauthorized third parties using sophisticated tools. The precautions we use are as follows:

1. The email address you provide will only be used by us for matters related to the course. Your email address will never be released to any third parties.

2. Your login username and password are specific to you.

3. Information transmitted from your machine to the server is encrypted using secure socket layer technology (SSL).

4. Messages exchanged within the Online Therapy program are encrypted to transmit the data both to and from yourself and your therapist. This reduces the likelihood of unauthorized access to your communications.

5. The University of Regina, which hosts the Online Therapy website, has firewall protection to protect from external threats.
   
   - The access to the Online Therapy server is strictly controlled, and the server is housed in a secure environment within the University of Regina. This means that limits are in place for who has access to the server. The only people with access are the primary project developers, the server administrators, and the service administrator.
All questionnaires responses will be periodically retrieved for research purposes. This data will be kept on a secure server by the researchers. No identifying information will be stored with the questionnaires.

**Things You Should Do to Protect Your Information:**

There are also various things that you can do to protect your information:

1. Use your home computer instead of a computer in a shared space, such as a library or office.
2. Make sure the computer you are sending emails from is secure.
3. Do not share your login information with anyone. Online Therapy staff will never ask you for your password. In the event you were contacted and asked for your password please contact the team directly to report the issue.
4. Do not use a password that is easily guessed by others, or a password that you have used before.
5. When you leave your computer or are done working with the web application, ensure you have logged out.
6. Since your internet browser stores information in its memory or disk cache, you can clean the cache after you use the computer. Certain browsers have "Privacy" modes that can be enabled. Once in this mode, the user's interactions are not saved to browser history, and no data is stored in browser cache. Once the browser is closed or this mode is exited, there are no browser records of any of the interactions that occurred while in the "Privacy" mode. Firefox has this feature, and is, therefore, highly recommended for use with the Online Therapy system. Browsers that do not
have this mode, or users that do not use this feature, must manually purge their browser history and cache to prevent others from seeing their web interactions.

7. Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable third party firewall program. Firewalls protect your computer and information from network attacks and threats.

8. Use anti-virus software to both prevent and recover from virus programs. While most anti-virus software is for purchase, there are free software options available to download. However, one must be cautious in order to avoid downloading and installing malicious software that appears to be legitimate.

9. Malware-detection software (such as Windows Defender) can be used to scan your computer for software and files that may be leaking your personal information to third parties.

   **Storage of Clinical Files:** When you seek services from the Online Therapy Unit, we create an online file for each client. The online file consists of the information you provided during the online and telephone screening interview, an id number, the e-mails you exchange with your therapist, notes your therapist takes related to your case, and questionnaires you complete online. All information is kept securely as described above for a period of seven years consistent with standards of professional practice. Also note your physician will receive a letter indicating that you enrolled in the course and this may be part of your medical record. Finally, if you are assigned to work with an online therapist who works in the Saskatchewan Health Authority that therapist will enter a note in your file indicating you have enrolled in the Wellbeing Course.
Access to Clinical Files: You have the right to access your online clinical file. To do so, you must make a written request to the Online Therapy Unit Coordinator. After a copy of your file is released to you, a therapist on our team will be in touch with you to assist you with understanding any terminology. If you disagree with information in the file, you can make a request in writing to add a note to your file.

Use and Storage of Research Information: For the purpose of evaluating ICBT, information you share on the Online Therapy server, such as response to questionnaires and communication with therapists, will be extracted from the server and kept in a computer file that will be available to the research team on a secure server at the University of Regina. This file will not contain any of your identifying information but instead will include only your id number. Of note, clinical members of the team, who sign confidentiality agreements, are the only ones who would be able to link your id number to your identity. All information collected for research purposes will be kept for at least seven years after publication or presentation.

Research information, where your identifying information has been removed, will be used to evaluate and improve ICBT including to develop future courses and services. Our intent is to prepare publications and presentations that will be shared with others who have an interest in treatment for depression and/or anxiety, such as individuals themselves, providers, researchers, health care managers, or government. You will not be personally identified in any publication or presentation. Scores from any questionnaires you respond to will be summarized across all participants so that individual responses will not be linked to a specific person in any publication or presentation. If individual
quotations or an exchange between therapist and client is used, care will be taken so that any details that could reveal your identity will be excluded from publications or presentation.

Voluntary Participation & Right to Withdraw:

1. Withdrawal from Wellbeing Course. Participation in the Wellbeing Course is voluntary and you can answer only those questions that you are comfortable with. Of note, however, should you choose not to disclose some information, your therapist may be limited in their ability to assist you. Should you choose to not participate, or if you wish to withdraw from treatment at any time after starting, you may do so without any consequences to your present or future health care. Please note that if you withdraw from the Wellbeing Course, consistent with professional standards for providing mental health care, the Online Therapy Unit will retain your information as part of your clinical record of care. If you decide to discontinue the Wellbeing Course, please inform the therapist that has been assigned to you. If you do not communicate your withdrawal to your therapist, your therapist will continue to contact you as outlined in the procedures.

2. Withdrawal from Research Study. Participation in the associated research study, namely completion of questionnaires, is also voluntary. You can answer only those questions that you are comfortable with. As described above, unless you withdraw from the study, you will continue to be contacted to complete questionnaires. After you have completed questionnaires, you may also withdraw
your questionnaires from use in the research study up until 8 weeks after you have
been enrolled in the study. After this date, it is possible that some results have
been analyzed, written up and/or presented and it may not be possible to withdraw
your data. If you want your data to be excluded from the research database please
contact the Online Therapy staff at the contact information above and your data
will be removed from the research database.

**Study Results:** A summary of this study’s results and any publications derived
from the data gathered in this study will be posted on this website
(www.onlinetherapyuser.ca). Full study results are expected in March 2022, but
preliminary findings will be posted as they become available.

**Questions or Concerns:**

Please contact us 306-337-3331 or email Online.Therapy.USER@uregina.ca. You
can also contact any member of our team using the information at the top of page 1.

This project has been approved on ethical grounds by the U of R Research Ethics
Board on February 10, 2020. Any questions regarding your rights as a participant may be
addressed to the committee at 306-585-4775 or research.ethics@uregina.ca. Out of town
participants may call collect. This study also has operational approval from the
Saskatchewan Health Authority.

**Ongoing Consent:** During the course of the treatment or the study, your therapist
or a member of the research team will remind you of information in the consent form if
they feel this is needed. Furthermore, your therapist or a member of the Online Therapy Team will advise you of new information that could impact your decision to participate in the Wellbeing Course or research study.

**Consent:**

By completing and submitting this form, **YOUR FREE AND INFORMED CONSENT IS IMPLIED** and indicates that you understand the above conditions of participation in this study.

☐ I understand that by submitting this form, **MY FREE AND INFORMED CONSENT IS IMPLIED** and indicates that I understand the above conditions of participation in the Wellbeing Course and this study.
Appendix G: PHQ-9 Measure

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Please tick the most appropriate number). The rating scale is as follows:

0 = Not at all  
1 = Several days  
2 = More than half the days  
3 = Nearly every day

<table>
<thead>
<tr>
<th></th>
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<th>0</th>
<th>1</th>
<th>2</th>
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</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things?</td>
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<tr>
<td>2. Feeling down, depressed, or hopeless?</td>
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<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much?</td>
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<tr>
<td>4. Feeling tired or having little energy?</td>
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<td></td>
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<tr>
<td>5. Poor appetite or overeating?</td>
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<tr>
<td>6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down?</td>
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<td>7. Trouble concentrating on things, such as reading the newspaper or watching television?</td>
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<tr>
<td>8. Moving or speaking so slowly that other people have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual?</td>
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<tr>
<td>9. Thoughts that you would be better off dead, or of hurting yourself in some way?</td>
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</tr>
</tbody>
</table>
Appendix H: GAD-7 Measure

<table>
<thead>
<tr>
<th>Instructions: Over the LAST 2 WEEKS, how often have you been bothered by any of the following problems? (Please tick the most appropriate box). The rating scale is as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = Not at all</td>
</tr>
<tr>
<td>1 = Several days</td>
</tr>
<tr>
<td>2 = More than half the days</td>
</tr>
<tr>
<td>3 = Nearly every day</td>
</tr>
<tr>
<td>1. Feeling nervous, anxious, or on edge</td>
</tr>
<tr>
<td>2. Not being able to stop or control worrying</td>
</tr>
<tr>
<td>3. Worrying too much about different things</td>
</tr>
<tr>
<td>4. Having trouble relaxing</td>
</tr>
<tr>
<td>5. Being so restless that it is hard to sit still</td>
</tr>
<tr>
<td>6. Becoming easily annoyed or irritable</td>
</tr>
<tr>
<td>7. Feeling afraid as if something awful might happen</td>
</tr>
</tbody>
</table>
Appendix I: Panic Disorder Severity Scale

The rating scale for this question is as follows:

0 = None
1 = Mild: occasional fear and/or avoidance.
2 = Moderate: noticeable fear and/or avoidance.
3 = Severe: extensive avoidance.
4 = Extreme: pervasive disabling fear and/or avoidance.

<table>
<thead>
<tr>
<th>0</th>
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</table>

4. During the past week, were there any places or situations you avoided, or felt afraid of, because of fear of having a panic attack? Are there any other situations that you would have avoided or been afraid of if they had come up during the week, for the same reason? If yes to either question, please rate your level of fear and avoidance this past week.

- Dizziness or faintness
- Breathlessness
- Feelings of unreality
- Fear of dying
- Feeling of choking
- Numbness or tingling

To recap, panic attacks are comprised of 4 or more symptoms, and a limited symptom attack is made up of fewer than 4 symptoms.

The rating scale for this question is as follows:

0 = No panic or limited symptom episodes
1 = Mild: no full panic attacks and no more than 1 limited symptom attack per day
2 = Moderate: 1 or 2 full panic attacks and/or multiple limited symptom attacks per day
3 = Severe: more than 2 full attacks but not more than 1 per day on average
4 = Extreme: full panic attacks occurred more than once a day, more days than not

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

1. How many panic and limited symptoms attacks did you have during the past week?

The rating scale for this question is as follows:

0 = Not at all distressing
1 = Mildly distressing
2 = Moderately distressing
3 = Severely distressing
4 = Extremely distressing

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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</thead>
</table>

2. If you had any panic attacks or limited symptom attacks during the past week, how distressing were they while they were happening?

The rating scale for this question is as follows:

0 = Not at all
1 = Occasionally or only mildly
2 = Frequently or moderately
3 = Very often or to a very disturbing degree
4 = Nearly constantly and to a disabling extent

<table>
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<tr>
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<th>4</th>
</tr>
</thead>
</table>

3. During the past week, how much have you worried or felt anxious about when your next panic attack would occur, or about fears related to the attacks?
The rating scale for this question is as follows:

0 = None  
1 = Mild: occasional fear and/or avoidance.  
2 = Moderate: noticeable fear and/or avoidance.  
3 = Severe: extensive avoidance.  
4 = Extreme: pervasive disabling fear and/or avoidance.

<table>
<thead>
<tr>
<th>0</th>
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<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

5. During the past week, were there any activities that you avoided, or felt afraid of, because they caused physical sensations like those you feel during panic attacks or that you were afraid might trigger a panic attack? Are there any other activities that you would have avoided or been afraid of if they had come up during the week, for that reason? If yes to either question, please rate your level of fear and avoidance of those activities this past week.

The rating scale for this question is as follows:

0 = No interference  
1 = Slight interference  
2 = Significant interference  
3 = Substantial impairment  
4 = Extreme, incapacitating impairment

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

6. During the past week, how much did the above symptoms altogether, interfere with your ability to work or carry out your responsibilities at home? (If your work or home responsibilities were less than usual this past week, answer how you think you would have done if the responsibilities had been usual.)

The rating scale for this question is as follows:

0 = No interference  
1 = Slight interference  
2 = Significant interference  
3 = Substantial impairment  
4 = Extreme, incapacitating impairment

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
</table>

7. During the past week, how much did panic and limited symptom attacks, worry about attacks, and fear of situations and activities because of attacks, interfere with your social life? (If you didn’t have many opportunities to socialize this past week, answer how you think you would have done if you did have opportunities.)

The rating scale for this question is as follows:

0 = No interference  
1 = Slight interference  
2 = Significant interference  
3 = Substantial impairment  
4 = Extreme, incapacitating impairment

| 0 | 1 | 2 | 3 | 4 |
Appendix J: Social Interaction Anxiety Scale 6

Instructions: For each question, please circle a number to indicate the degree to which you feel the statement is characteristic or true of you. The rating scale is as follows:

0 Not at all characteristic or true of me
1 Slightly characteristic or true of me
2 Moderately characteristic or true of me
3 Very characteristic or true of me
4 Extremely characteristic or true of me

1. I have difficulty making eye contact with others. 0 1 2 3 4
2. I find it difficult mixing comfortably with the people I work with. 0 1 2 3 4
3. I tense up if I meet an acquaintance on the street. 0 1 2 3 4
4. I feel tense if I am alone with just one person. 0 1 2 3 4
5. I have difficulty talking with other people. 0 1 2 3 4
6. I find it difficult to disagree with another's point of view. 0 1 2 3 4
7. I get nervous that people are staring at me as I walk down the street. 0 1 2 3 4
8. I worry about shaking or trembling when I'm watched by other people. 0 1 2 3 4
9. I would get tense if I had to sit facing other people on a bus or train. 0 1 2 3 4
10. I worry I might do something to attract the attention of other people. 0 1 2 3 4
11. When in an elevator, I am tense if people look at me. 0 1 2 3 4
12. I can feel conspicuous standing in a line. 0 1 2 3 4
Appendix K: Treatment Satisfaction Questionnaire

1. Overall, how satisfied were you with treatment?
   - Very dissatisfied
   - Dissatisfied
   - Neutral
   - Satisfied
   - Very Satisfied

2. Overall, how satisfied were you with using the Online Therapy Unit website?
   - Very dissatisfied
   - Dissatisfied
   - Neutral
   - Satisfied
   - Very Satisfied

3. How satisfied were you with the quality of the Lessons and Do It Yourself Guides?
   - Very dissatisfied
   - Dissatisfied
   - Neutral
   - Satisfied
   - Very Satisfied

4. Would you feel confident recommending this treatment to a friend?
   - Yes
   - No

5. Was it worth your time doing this course?
   - Yes
   - No
6. How has participating in this course affected your confidence that you can learn to manage your symptoms?

- Greatly increased
- Increased
- No change
- Reduced
- Greatly Reduced

7. How has participating in this course affected your motivation to seek more treatment if you need it in the future?

- Greatly increased
- Increased
- No change
- Reduced
- Greatly Reduced

8. For you, what was the most helpful skill taught in this course? (for example, thought challenging, becoming more active, graded exposure, controlled breathing, other)

Can you give us an example of how a skill or strategy from the Wellbeing Course made a difference in your life?

9. What did you like about the course? (for example, comments about the lessons, DIY Guides, Stories, or Resources)
10. What did you not like about the course? What should we do to improve it? (for example, comments about the lessons, DIY Guides, Stories, or Resources)

11. If you we able to offer any advice to someone about to start this course about how to get the most out of it, what would you suggest? Or, what would you like to have known before starting this course?

In research, it is considered standard practice to investigate the occurrence of potential unwanted negative events or unwanted negative effects. Below we will ask you about these effects.

12. During the online course, have you experienced any unwanted negative events that you believe are related to the online treatment or have you encountered any unwanted negative effects that could be related to the online treatment?

☐ Yes
☐ No

13. If yes, please describe the unwanted negative events or unwanted negative effects, and define when during treatment these events/effects occurred, how often they happened, and how long they lasted. If you have experienced more than one event/effect, please describe each one separately. If no unwanted negative effects or events were experienced enter NA.

14. Thinking back to when you experienced the unwanted negative effect/event, how much impact do you feel it had on your life?
• I did not experience any unwanted negative effects/events
• No negative impact (the effects/events had no impact on my life)
• Minimal negative impact (the effects/events had minimal impact on my life)
• Moderate negative impact (the effects/events had moderate impact on my life)
• Severe negative impact (the effects/events had severe impact on my life)

15. At this time how much impact do you feel the unwanted negative effects/events continue to have on your life?

• I did not experience any unwanted negative effects/events
• No negative impact (the effects/events have no impact on my life)
• Minimal negative impact (the effects/events have minimal impact on my life)
• Moderate negative impact (the effects/events have moderate impact on my life)
• Severe negative impact (the effects/events have severe impact on my life)

The following questions are specifically about the sleep materials you received.

16. How satisfied were you with the materials you received on sleep concerns?

[Very unsatisfied 1-7 Very Satisfied]

17. How easy was it to understand the materials on sleep concerns?

[Very difficult 1-7 Very Easy]

18. How helpful have the materials on sleep concerns been for addressing your sleep concerns?

[Not helpful at all 1-7 Very Helpful]
19. How much did your knowledge of sleep concerns change during the course?

[No change 1-7 A great deal]

20. How much do you feel you’ve changed your sleep-related behaviours as a result of the course?

[No change 1-7 A great deal]

21. How likely would you be to recommend the sleep materials to a friend experiencing sleep problems?

[Very Unlikely 1-7 Very Likely]

22. Did your therapist provide you with additional support for your sleep concerns?

☐ Yes, my therapist offered additional support for my sleep concerns
☐ Some support
☐ Minimal/no support

23. Do you have any feedback about the sleep materials you received?
Appendix L: Sleep Questionnaire

Insomnia Severity Index

For each question, please CIRCLE the number that best describes your answer.

*Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).*

<table>
<thead>
<tr>
<th>Insomnia Problem</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Difficulty falling asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Difficulty staying asleep</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Problems waking up too early</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

4. How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

<table>
<thead>
<tr>
<th></th>
<th>Very Satisfied</th>
<th>Satisfied</th>
<th>Moderately Satisfied</th>
<th>Dissatisfied</th>
<th>Very Dissatisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
<td>2</td>
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</table>

5. How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

<table>
<thead>
<tr>
<th>Noticeable</th>
<th>A Little</th>
<th>Somewhat</th>
<th>Much</th>
<th>Very Much Noticeable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
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<td>2</td>
<td>3</td>
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</table>

6. How WORRIED/DISTRESSED are you about your current sleep problem?

<table>
<thead>
<tr>
<th>Worried</th>
<th>A Little</th>
<th>Somewhat</th>
<th>Much</th>
<th>Very Much Worried</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
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</table>

7. To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, mood, etc.) CURRENTLY?

<table>
<thead>
<tr>
<th>Interfering</th>
<th>A Little</th>
<th>Somewhat</th>
<th>Much</th>
<th>Very Much Interfering</th>
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</table>
Appendix M: Weekly Sleep Measure

1. Sleep Quality: Rate how well you slept over the past week overall.
   1- Extremely Poor Sleep
   2-
   3-
   4-
   5-
   6-
   7- Excellent Sleep Quality

2. Fatigue: Rate how fatigued you felt over the past week.
   1- No Fatigue
   2-
   3-
   4-
   5-
   6-
   7- Incapacitating Fatigue

3. On average, how many hours did you spend in bed each night this week?
   [0-16 in ¼ hour increments]

4. Of the time you spent in bed, approximately how many hours were you awake each night?
   [0-16 in ¼ hour increments]

5. Over the past week, how many days did you engage in Sleep Restriction (i.e., sleeping on a strict schedule)?
   [0-7 days]
6. Over the past week, how many days did you practice good Stimulus Control (i.e., reserving bed for only sleep and sex, getting up if not able to fall asleep)?

[0-7 days]

7. Over the past week, how many days did you nap over the past week?

[0-7 days]

8. What other things affected your sleep this week?

[ ] Interruptions due to noise or other external factors

[ ] Family / children

[ ] Medications for sleep

[ ] Alcohol (e.g., drinking to fall asleep)

[ ] Drug use

[ ] Anxiety (e.g., unable to sleep due to worry or alertness)

[ ] Low mood (e.g., no energy/motivation to get out of bed)

[ ] Other, Explain: __________________________