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Internet-delivered Cognitive Behavioural Therapy for People with Mild Traumatic Brain Injury: A Feasibility Study

Ujjoyinee France Barua, *The University of Western Ontario*

Supervisor: Loh, Eldon, *The University of Western Ontario*
Co-Supervisor: Mehta, Swati, *The University of Western Ontario*
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Abstract

Individuals with mild traumatic brain injury (mTBI) can experience high levels of emotional distress, leading to decreased quality of life and increased health care costs. Bowen's feasibility framework was used to examine the feasibility, acceptability, and limited efficacy of an innovative clinician-guided internet-delivered cognitive behavioural therapy program (ICBT) specialized for people with mTBI to improve their wellbeing. The data illustrated strong adherence and program satisfaction from participants. Likewise, statistically and clinically significant changes in symptoms of unhappiness and anxiety were found, along with improved self-efficacy and quality of life. The findings of this study contribute new knowledge to the emerging literature on ICBT and its effectiveness on those with neurological conditions (i.e., mTBI). The data will be used to guide more extensive studies that will evaluate the program's effectiveness in a community setting to improve patients' overall wellbeing and access to mental health care services.

Keywords

Mild Traumatic Brain Injury; Mental Health; Internet-delivered Cognitive Behavioural Therapy; Depression; Anxiety; Access-to-care

Summary for Lay Audience

People with mild traumatic brain injury (mTBI) are highly susceptible to experiencing depression and anxiety after their injury. Although these mental health problems are prevalent and disabling, they often go untreated for various reasons (i.e., cost, time, stigma). Unfortunately, untreated and persistent psychological symptoms increase pain, health care costs and risk of suicide and decrease quality of life. Thus, this thesis explores the feasibility of a 10-week clinician-guided internet-delivered Cognitive Behavioural Therapy (ICBT) program for people with mTBI by examining the program's acceptability and effectiveness. The ICBT program was developed to improve the wellbeing of people with mTBI by teaching them skills to manage their symptoms of depression and anxiety. The program includes clinician support once per week intended to strengthen participants' understanding of the program content and provide personalization within the online program. Twenty participants enrolled in the ICBT program. Information on their experiences of depression, anxiety, self-efficacy, and quality of life was collected before and after the program. After completing the program, participants provided information on their satisfaction with the treatment, ICBT content, platform, and clinician support. The results revealed a decrease in participants' experience of depression and anxiety, suggesting that they learned to better manage their mental health by applying the skills learned from the program. Furthermore, all participants were satisfied with the ICBT platform, the treatment, and the support received from the clinician. The impact seen in this study is noteworthy, as access to mental health services for people with mTBI is still limited due to several factors, including cost, stigma, and accessibility. The ICBT program potentially addresses these barriers and provides services on a safe and secure platform from the comfort of the participant's home. Although not evaluated in this study, past research has suggested that online CBT-based programs are equally effective as traditional face-to-face Cognitive Behavioural Therapy. This may be the potential for the current ICBT program. Given the limited research on ICBT for people with mTBI, this study will contribute to the literature and lead as an example for further clinical trials with improved versions of the ICBT program.

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Chapter 1

1 Introduction and Background

According to the World Health Organization ([WHO] 1996), acquired brain injury (ABI) refers to any damage to the brain that occurs after birth and is not related to a congenital or degenerative disease. These impairments may be temporary or permanent, causing partial or functional disability or psychosocial maladjustment (WHO, 1996). ABI is an umbrella term encompassing numerous disorders of varying etiologies affecting heterogeneous groups of individuals (Rees et al., 2007). There are two types of acquired brain injury: non-traumatic and traumatic. In non-traumatic brain injury, damage to the brain is caused by internal factors or a substance introduced into the body. Internal factors may include lack of oxygen to the brain, exposure to toxins, stroke, or aneurysm. Traumatic brain injury (TBI) is a form of ABI that occurs when damage to the brain is caused by external forces and trauma, including sports injuries, falls, violence, and motor vehicle collisions (Buck, 2011; Menon et al., 2010; Valente & Fisher, 2011). Unfortunately, both types of brain injuries lead to alterations in the brain, physical function, neurological and neuropsychological impairments, and brain pathology (Buck, 2011; Menon et al., 2010; Valente & Fisher, 2011).

1.1 Traumatic Brain Injury

TBI is an expanding public health epidemic. WHO predicted TBI to surpass many diseases as the major cause of death and disability by 2020 (Hyder et al., 2007). Globally, there are an estimated 69 million cases (Dewan et al., 2018) and 10 million deaths (Langlois et al., 2006) annually due to TBI, accounting for more death and disability than any other type of trauma. It is the most common neurosurgical presentation to emergency departments at an estimate of over 7 million presentations per year in the United States (Faul et al., 2010; Valente & Fisher, 2011). TBI is a major cause of mortality in Canada, contributing to approximately 23% of all injury-related deaths (Kureshi et al., 2021). In 2017, the head injury-related emergency department (ED) visit and hospitalization rates were 376.9/100,000 and 84/100,000, respectively, in Canada (Public Health Agency of

Canada, 2020). Furthermore, between 2002 and 2016, there were 235,471 injury-related deaths; of those, 53,200 (22.6%), a substantial proportion of individuals were associated with a TBI diagnosis (Public Health Agency of Canada, 2020). In the United States, the approximate death rate due to TBI has been estimated to be 22-25/100,000 individuals, while 275,000 individuals are hospitalized, and 1.365 million individuals are treated and released from an emergency department (Faul et al., 2010; Langlois et al., 2006). In 2020, there were over 64,000 TBI-related deaths in the United States; this equates to about 176 TBI-related deaths every day (Centers for Disease Control and Prevention, n.d.). However, the number of people with TBI not seen or treated by physicians remains unknown.

TBI is also the major cause of disability, morbidity, and mortality among individuals of all ages in the United States (Centers for Disease Control and Prevention, 2022). Anybody can experience a TBI, but some groups of people are at higher risk. A trimodal age distribution of injury risk has been identified; children under the age of 5, individuals between the ages of 15 and 24, and individuals 65 years and older tend to be at the greatest risk for sustaining injuries (Faul et al., 2010). One study found that adults 75 years and older have the highest TBI-related hospitalization and death (Faul et al., 2010), while Salottolo et al. (2014) found that individuals older than 85 are at the greatest risk for TBI. Public Health Agency of Canada (2020) also reports that TBI-related mortality in Canada from 2002 to 2016 sharply rose among those 65 years and older, with those 85 years and older having the highest rate (155.7/100,000 for males and 84.8/100,000 for females). This leads many researchers to suggest that the risk of sustaining a TBI increases with advancing age. Falls, motor vehicle crashes, sports and recreation, and assaults are the most common causes of TBI in Canada and the United Stated (Centers for Disease Control and Prevention, n.d.; Public Health Agency of Canada, 2020), while firearm-related suicide is the most common cause of TBI related deaths in the United States (Daugherty et al., 2019; Miller et al., 2020).

Obtaining accurate statistics regarding the incidence and prevalence of TBI is difficult as the few established registries for TBI often include only those requiring hospital care or those admitted to hospital, thereby omitting many incidences of mild TBI (mTBI).

Classification of TBI severity is an essential step in medical management and determines the prognosis of the condition. The Glasgow Coma Scale (GCS), developed by neurosurgery professors Graham Teasdale and Bryan Jennett in 1974 at the University of Glasgow, is the most widely used clinical diagnosis measure for TBI (Jain & Iverson, 2021). The GCS describes the degree of impaired consciousness in acute medical and trauma patients, including persons with brain injury. The scale assesses three aspects of responsiveness: eye-opening, motor, and verbal responses (Jain & Iverson, 2021; Mena et al., 2011). Reporting these scores separately provides a clear, communicable picture of a patient's state and allows physicians and primary health care workers to proceed appropriately with treatment (Mena et al., 2011). The GCS total score ranges from 3 (worst score) to 15 (best score), and each component is 'scored' from 1 (no response) up to 4 (spontaneous eye-opening), 5 (oriented verbal response) and 6 (obeys motor commands) (Jain & Iverson, 2021). Individuals with GCS scores from 13 to 15 are categorized as having mild injuries, 9 to 12 represent moderate injuries, and scores of 8 and less represent severe injuries (Albicini & McKinlay, 2014).

Another standard measure of TBI severity is the duration of post-traumatic amnesia (PTA), which has been coined to be the best single predictor of functional outcome following TBI (Greenwood, 1997). PTA is defined as the length of time in minutes, hours, or days from the moment of injury until the person returns to normal orientations and continuous memory for events (Ponsford et al., 2016a). For individuals who have a loss of consciousness/coma post-injury, their period of PTA is measured from the moment they regain consciousness. The PTA has been widely used as a classification method for the severity of injury. Mild TBI has a PTA of 0–1 day; moderate TBI has a PTA of > 1 and ≤ 7 days; and severe TBI has a PTA of > 7 days (Cho & Jang, 2021). A meta-analysis reported that longer PTA duration strongly predicts intelligence impairment and depression (Königs et al., 2012).

1.2 Mild Traumatic Brain Injury Prevalence and Diagnosis

MTBI is often termed a concussion, and it accounts for 70-90% of all TBI (Albicini & McKinlay, 2014; Buck, 2011; Cassidy et al., 2014; Sussman et al., 2018; Valente & Fisher, 2011). Sports-related injuries, falls and motor vehicle collisions are among the

most common causes of mTBI (Faux et al., 2011; Marshall et al., 2012). Epidemiological studies noted that as many as 3.8 million sports-related TBIs occur annually in the United States alone (Sussman et al., 2018). Several challenges hinder accurate statistics on the incidence and prevalence of mTBI, even in well-developed countries. This may be related to a lack of awareness of their injury as the symptoms may be subtle enough not to cause alarm or because they are distracted by other concurrent severe injuries (Buck, 2011). The presence of mTBI is often based on self-report rather than physician diagnosis (Buck, 2011). Few studies suggested that the true incidence is above 600 per 100,000 population (Carroll et al., 2004a; Marshall et al., 2015). A 2009 Canadian study suggested the annual incidence in Ontario, Canada, lies between 493–653/100 000, depending on whether the diagnosis was made by primary care providers or based upon a secondary review by an expert (Marshall et al., 2015). Another concern that adds to the lack of clarity in the reported incidence of mTBI statistics is the lack of a standardized definition for this condition (Sussman et al., 2018). Additionally, the stigma associated with having a disability/neurological condition and the willingness to report it concerns diagnosing an mTBI (Buck, 2011; Sussman et al., 2018). Thus, mild injuries are far more challenging to diagnose than their moderate and severe counterpart. The prevalence of undiagnosed mTBI presents a significant public health challenge, especially considering its strong association between mental illness, substance abuse, and criminality (Buck, 2011; Helgeson, 2010).

The most widely accepted definition of mTBI was proposed by the American Congress of Rehabilitation Medicine (ACRM) in 1993. The ACRM describes mTBI as *"a physiologic disruption of brain function due to a traumatic injury as manifested by at least one of the following: (1) any period of loss of consciousness (LOC); (2) any loss of memory regarding the events immediately before or after the injury (i.e., PTA); (3) alteration of mental state at the time of the injury; or (4) focal neurologic deficit that may or may not be transient, but without: (a) LOC greater than 30 minutes; (b) GCS of <13 beyond 30 minutes from the time of the injury; and/or (c) PTA greater than 24 hours"* (Head, 1993). Similarly, the WHO describes mTBI as the following: *"Brain injury due to mechanical energy to head from external physical forces and includes: a) 1 or more of confusion/disorientation, LOC ≤ 30 mins, PTA ≤ 24 hours, and/or other transient*

neurological abnormalities such as focal signs, seizure and intracranial lesions not requiring surgery; b) initial GCS score of 13-15 30 mins after injury c) manifestations not due to drugs, alcohol, medications, or other injuries, treatments for injuries or problems" (Albicini & McKinlay, 2014).

The evaluation process of diagnosing mTBI requires people to report any post-injury symptoms and to answer questions subjectively during a consultation with their primary care physician or emergency physician after the incident. However, challenges exist with self-reported symptoms compared to clinician-reported, including the problem with recall, stigma, or secondary gain (i.e., insurance claims) (Albicini & McKinlay, 2014; Iverson et al., 2010). The most substantial problem is a patient's tendency to check off significantly more symptoms when completing a symptom checklist than in a clinical interview (Albicini & McKinlay, 2014; Iverson et al., 2010; Nolin et al., 2006). This may lead to a misrepresentation of the true severity of the condition.

Another challenge with diagnoses of mTBI compared to more severe forms of TBI is the poor sensitivity of neuroimaging (McCrea et al., 2009). Computerized tomography (CT) scans for people with mTBI appear normal, however if an abnormality is seen, it would be categorized as mTBI with complications, and in some situations, it may also be considered moderate TBI (Haydel et al., 2000; Head, 1993). A recent systematic review compiled a list of recommendations for guidelines for concussions and mTBI. Their top recommendation was the need for *"early neuroimaging that should be determined according to the Canadian CT Head Rule"* because CT scans are the most appropriate investigation for the exclusion of significant neurosurgical lesions, such as hemorrhage, while *"plain skull x-rays are not recommended"* (Marshall et al., 2015).

The initial and early symptoms of mTBI include experiences from the following four categories: 1) physical, e.g., headaches and fatigue, 2) cognitive, e.g., poor concentration, 3) emotional, e.g., poor emotional control, and 4) sleep problems (Albicini & McKinlay, 2014; Nolin et al., 2006). Additional symptoms may be transient and include focal neurological signs, seizures, visual problems, balance and/or gait problems, acute aphasia, anosmia/hyposmia, cranial nerve defects and intracranial lesions (Albicini &

McKinlay, 2014). Most people with mTBI fully recover within days to several weeks. However, 10–15% of individuals with mTBI will continue to experience persistent symptoms even one-year post-injury, this includes post-traumatic headache, sleep disturbance, disorders of balance, cognitive impairments, fatigue, dizziness and mood or affective disorders (Marshall et al., 2015).

1.2.1 Economic Burden of mTBI

Persistent symptoms following mTBI present a tremendous economic burden. Neurological conditions account for about 6% of the global burden of disease (Danila et al., 2014). In Canada, the total cost for neurological conditions has been estimated to be $8.8 billion, accounting for 6.7% of the total cost of illness (Danila et al., 2014), while in the United States, the annual cost of mTBI is estimated to be $16.7 billion out of the total cost burden of $56 billion for TBI (National Center for Injury Prevention and Control, 2003). In Ontario, the annual medical cost of patients hospitalized with a TBI in the first follow-up year were approximately $120.7 million, where acute care cost accounted for 46-65% (Chen et al., 2012). A study in the United States found on average total one-year costs for mTBI to be $13,564 USD per individual (Pavlov et al., 2019). This cost is likely to be similar in Canada. Furthermore, the somatic and psychiatric comorbidity burden (i.e., depression, chronic pain) is higher among those individuals with a neurological condition than those without, thus further increasing cost of recovery (Wolfson et al., 2019).

With the rising cost of living in general, the added economic burden of treatment presents a great challenge for those with mTBI. Thus, these statistics reinforce the importance of offering evidence-based and cost-effective rehabilitation programs. Education, informative booklets, or a single information session have effectively reduced persisting symptoms (Faux et al., 2011). It is also recommended that individuals experiencing persistent psychological symptoms (e.g., depression, anxiety) should seek early intervention to increase the rate of recovery and reduce the expense of resources (i.e., medication, rehabilitation) by over 66% (Faux et al., 2011). The prevalence of mTBI is expected to continue to rise with the ageing population. Thus, there is a need for

increased research and funding to evaluate treatment protocols and make interventions, especially psychological therapies, more readily available and accessible.

1.3 Traumatic Brain Injury and Mental Health

Persistent psychological and mental health problems have also been associated with delayed and poor recovery (Buck, 2011). Living with mTBI brings various challenges that can affect long-term mental and physical wellbeing. The risk of psychosocial and psychiatric health issues is substantial. Depression and anxiety disorders are the most common mental health problems experienced by individuals with mTBI and often continue for at least a year after the trauma (Teasdale & Engberg, 2001). For some, it is a lifelong struggle. Symptoms of clinical depression are estimated to be experienced by up to 40% of TBI survivors (Teasdale & Engberg, 2001). Psychiatric diagnoses, including mood, anxiety, and substance abuse disorders, were reported in 75.2% of individuals across the first five years post-TBI, with most (77.7%) emerging in the first year (Alway et al., 2016). Similarly, another study indicated clinically significant psychiatric symptoms in 42% of adults with TBI at six months post-injury (Juengst et al., 2017). In addition, mTBI increases the risk of other psychosocial problems, acute stress disorder, and antisocial and aggressive behaviour (Rao et al., 2010; Valente & Fisher, 2011). These behaviours include anger, swearing, yelling, physical violence and sexually offensive behaviour, which can become challenging to manage, increasing the risk for suicidal behaviours if proper psychological intervention is not attained (Valente & Fisher, 2011).

Other neuropsychiatric complications include impaired consciousness, post-traumatic amnesia, dementia, post-traumatic epilepsy, aphasia, mania, psychosis, and other cognitive disorders (Menon et al., 2010). Cognitive difficulties include problems with learning, memory, information processing, and communication. Reasoning, problem-solving, judgment, attention, thinking, and multitasking may be altered and cause difficulties and challenges in daily life (Menon et al., 2010). Persistent psychological symptoms among individuals with mTBI increase the risk of suicide; individuals with a head injury are four times more likely to have attempted suicide post-injury than the general population, emphasizing the importance of detecting and providing effective treatment for depressive symptoms (Fleminger, 2008). Further studies suggest that this

risk may be higher among individuals who are least likely to get a diagnosis or treatment—those with mTBI (Buck, 2011; Teasdale & Engberg, 2001). Cognitive rehabilitation and psychological support programs are growing in popularity and effectiveness as they can be tailored to target specific behaviour and cognitive problems, such as memory or stress management. Incorporating these interventions is pertinent when managing persistent psychological symptoms following mTBI to improve quality of life and recovery.

1.3.1 Traumatic Brain Injury and Depression

Depression is the most common psychiatric complication of TBI. Although the prevalence varies greatly, a systematic review found that the frequency of depression following TBI ranges from 6% to 77% (Bryant et al., 2010; Jorge & Starkstein, 2005; Rapoport, 2012). In a recent Canada-wide study, the prevalence of depression in persons with TBI was 33%; this was the highest rate observed across nine other neurological condition groups (i.e., Alzheimer's Disease, migraine, multiple sorosis, dystonia, spina bifida, Epilepsy, Parkinson's Disease and related dementia, Stroke, brain/spinal cord tumor; Bulloch et al., 2015). Interestingly, regardless of TBI severity (i.e., mild-to-severe TBI), the frequency of depression is consistent, but severity-related differences may exist in the course of the disorder. For example, Rao et al. (2010) reported that individuals with mTBI have higher rates of depression and poor global outcomes than those with more severe disease. Another study also found that the presence of major depression in people with TBI is evaluated to be at least six times greater than in the general Canadian population (Pearson et al., 2013).

Studies have also found that self-awareness is potentially a significant factor that may increase the development of psychological distress (Malec et al., 2007; Ouellet et al., 2018). Individuals sustaining milder TBIs may be at risk of experiencing depressive symptoms earlier due to their increased awareness of their newly sustained deficits and an urge to return to their pre-injury activities (Malec et al., 2007; Ouellet et al., 2018). However, early detection of depression may also allow for early intervention. Semi-structured psychiatric interviews have been crowned as the gold standard for diagnosing depression 1-year post-injury, along with a series of quantitative assessments (i.e., Patient

Health Questionnaire; Juengst et al., 2017). The World Health Organization Collaborating Centre Task Force on Mild Traumatic Brain Injury recommended early treatment interventions for depression to improve functional recovery (Carroll et al., 2004b). Persistence and worsening depression delay recovery; several studies, including the National Institute for Health and Care Excellence (2009) guidelines, have strongly recommended early, continuous monitoring (e.g., with scheduled screenings) and treatment as necessary, continuing over several months and even years after injury. Self-management, such as patient education on how to better manage symptoms, can be an important aspect of treatment.

The most common symptoms of depression across the first ten years post-TBI are fatigue, distractibility, and rumination. Rumination, self-criticism, and guilt are the symptoms that best differentiate individuals with depression from those without depression after TBI (Seel et al., 2010). Furthermore, depression post-TBI has been characterized more by irritability, anger, and aggression than by sadness or tearfulness (Seel et al., 2010). The research found that long-term monitoring may be necessary even in persons who have seemingly recovered from major depression (MD), given that an MD episode is a significant risk factor for a subsequent one (Juengst et al., 2017). Persistent depressive symptoms up to and beyond ten years post-injury have been associated with lower and declining life satisfaction and poorer quality of life after TBI (Bombardier et al., 2010; Diaz et al., 2012; Juengst et al., 2015; Williamson et al., 2013). Diaz et al. (2012) reported that those with depression after TBI had greater impairments in all domains of the Short Form Health Survey, health-related quality of life measure, than those without depression (Juengst et al., 2017). Thus, health service organizations that promote easy access to mental health services specialized for TBI months and years after the injury are instrumental.

Thus, depression can impact aspects of both physical and psychological health. Depression negatively influences neuropsychological function, social relationships, caregiver burden, and more global long-term outcomes such as social participation (i.e., aggression), life satisfaction, and quality of life after injury (Lin et al., 2010; Stålnacke et al., 2007). Several studies found that depression after mTBI was associated with poor

cognitive function, including poor working memory, processing speed, verbal memory, and executive function (Rapoport, 2012). Untreated depressive symptoms increase costly clinic visits, hospitalizations, substance abuse, risky behaviours, reduced adherence to treatment and quality of life, and can lead to prolonged recovery (Menon et al., 2010).

1.3.2 Traumatic Brain Injury and Anxiety

Like depression, individuals with TBI have an elevated risk of developing anxiety following injury. The prevalence rates for anxiety vary greatly, ranging between 10% to 70%; the co-occurrence with depression can be as high as 75% (Ponsford et al., 2016b; Scholten et al., 2016). One study reported that for individuals with mTBI, at least 23% suffer from an anxiety disorder as a repercussion of the injury; most often, these individuals are diagnosed with a generalized anxiety disorder (Meyer et al., 2012; Moore et al., 2006). Furthermore, several reviews found that the severity of the injury does not significantly impact prevalence. Conversely, pre-morbid anxiety increases the risk of anxiety disorders following injury. Furthermore, from 1.5-5.0 years post-injury, the prevalence of anxiety ranges from 9 to 50% (Ashman et al., 2004; Diaz et al., 62012; Whelan-Goodinson et al., 2009). Comorbidity between anxiety and depression is relatively high; the prevalence rate for depressive disorders in those with anxiety was reported to be up to 21–57% 1.5–3.0 years post-injury (Ashman et al., 2004; Diaz et al., 2012; Whelan-Goodinson et al., 2009). Thus, this further worsens the individual's health, wellbeing, and quality of life.

Considering the high incidence of anxiety disorders after TBI, it is crucial to understand the pathophysiological mechanisms underlying their development. MTBI has been frequently localized to medial temporal lobe regions of the brain, including the amygdala, a key area associated with long-term psychiatric symptoms, specifically anxiety-related disorders (Almeida-Suhett et al., 2014; Meyer et al., 2012). The amygdala is a limbic structure deep within the temporal lobe and is a core part of the neural system responsible for processing fearful and threatening stimuli (Almeida-Suhett et al., 2014; Baxter et al., 2012). A study on an animal model involving rats found that mTBI alone can increase anxiety-like behaviours, while stress after the injury can further lead to the development of long-term symptoms of anxiety (Almeida-Suhett et al., 2014). Specifically, they found

significant functional alternations in the Basolateral amygdala —an area responsible for cognition, motivation, and stress response that induces anxiety disorders (Almeida-Suhett et al., 2014; Truitt et al., 2009). Although this is seen in an animal model, it does reflect the complex relationship between anxiety-related behaviours/disorders and brain function and how deeply rooted it is.

As mentioned earlier, a history of psychiatric disorders pre-injury significantly increases the risk for psychiatric disorders post-injury (Gould et al., 2011; Scholten et al., 2016; Whelan-Goodinso et al., 2010). Likewise, the prevalence of comorbid psychiatric disorders is high. Anxiety disorders tend to precede or emerge simultaneously with depressive disorders. Both anxiety and depressive disorders significantly impact the functional outcome of patients with mTBI, drastically reduce their quality of life, and can contribute to prolonged recovery (Scholten et al., 2016; Yehene et al., 2020). Furthermore, research indicates a strong association between quality-of-life post-injury and emotional factors, as there is a significant decline in social participation and interactions with others (Yehene et al., 2020). Therefore, it is pertinent to understand patients' emotional adjustment and ability to cope with new challenges in life; providing early intervention is beneficial. Unfortunately, most studies examining CBT as a treatment for anxiety in individuals with TBI are limited as their study design fails to address anxiety (Ponsford et al., 2016b; Tiersky et al., 2005; Waldron et al., 2013). However, few studies showed promising results whereby CBT has been associated with improvements in anxiety (Ponsford et al., 2016b). As anxiety is significantly comorbid with depression, trials must be developed that address both anxiety and depression following TBI, thus leading to interventions that can effectively improve psychological health and quality of life.

1.4 Mental Health Intervention

This section of this chapter describes Cognitive Behavioural Therapy (CBT) and Internet-delivered Cognitive Behavioural Therapy (ICBT) in treating depression and anxiety.

CBT has been regarded as the most widely researched and established evidence-based treatment for psychological disorders (Hofmann et al., 2012). Dr. Aaron T. Beck, an

American psychiatrist, developed this treatment method in the 1960s. Beck found that patients experiencing depression have a stream of continuous negative thoughts coming from the conscious mind rather than the unconscious, as suggested by psychoanalytical theory; thus, he began to conceptualize depression differently. Beck categorized these negative thoughts into three categories —1) cognitive bias; 2) negative self-schemas; 3) the negative triad (Beck & Alford, 2009). He explained that patients could have these negative thoughts about themselves, the world and/or the future; having such negative thoughts automatically and spontaneously suggested that these people start to become depressed. With this newfound information, Beck began to help patients with depression by guiding them to identify and evaluate their automatic negative thoughts. These instructions helped the patients think realistically by changing their underlying beliefs about themselves, the world, and other people, resulting in them feeling better emotionally and physically and becoming more resilient. (Beck & Alford, 2009). Conceptualizing depression in this manner was revolutionary - not only did it give rise to a new form of treatment (CBT), but it also provided evidence that Freud's psychoanalysis may not be the most effective therapy.

In simple terms, CBT is described as a theoretical approach where a therapist works with their patient to recognize the distortion in their thoughts, feelings and behaviours that is creating problems in their life and contributing to difficult emotions (i.e., fear, anger; Benjamin et al., 2011). For example, suppose someone is experiencing a negative thought (i.e., I am not lucky like other people) instead of self-loathing and allowing one to feel sorry about their situation, CBT techniques help them to recognize this thought and behaviour pattern and understand what is causing them to arise and what can be done to improve their current situation. Traditional face-to-face CBT treatment is collaborative work between the therapist and the patient; thus, it can be customized to suit one's goals and specific difficulties. CBT can be used for many psychological disorders, including depression, anxiety, marital crisis, obsessive-compulsive disorder, post-traumatic stress disorder, and many others (Hofmann et al., 2012).

Recently, my colleagues and I conducted a meta-analysis on the effectiveness of CBT in treating depression and anxiety in people with TBI. This meta-analysis has been

submitted to the Brain Injury journal for publication. To summarize, the review found that the pooled analysis of 13 randomized controlled trials (RCT) demonstrated that CBT significantly improved depression and anxiety symptoms among participants following TBI. In addition, the three-month follow-up examination of CBT on depression suggested that the benefits of CBT are sustainable long term. Finally, the effect sizes reported in this meta-analysis are consistent with a previous review examining the effects of CBT among participants with brain injuries and further extend the evidence base by examining additional sub-analyses (Stalder-Lüthy et al., 2013).

1.4.1 Internet-delivered Cognitive Behavioural Therapy

As technology expands, the world evolves, impacting people's lives in every aspect. Compared to just two decades ago, technology has changed our livelihoods, from complete automation of communication to how we shop, bank, learn, travel, and access health care. In addition, due to the internet, access to information about psychiatric conditions and diagnoses, assessments, and procedures has become more available and accessible to the public (Andersson et al., 2019).

ICBT programs provide web-based access to materials and courses to teach people suffering from mental health problems the core cognitive and behavioural skills presented in traditional in-person CBT (Webb et al., 2017). For example, in an ICBT course, people will learn skills to identify negative thoughts and process them to modify their behaviours rather than letting those thoughts dictate them. ICBT is a modernized version of CBT. Some of the first experiments on internet-delivered psychological treatments started around the mid-1990s (Ruwaard et al., 2011). In 1996, when the internet was merely five years old, researchers from the University of Amsterdam studied Internet-based psychotherapy. These researchers created a website and developed an online therapy platform called "Interapy" to treat participants with post-traumatic stress disorder. They found compelling results; 19 out of 20 participants reduced stress symptoms after the treatment. This study was crucial and encouraged others to develop such treatment platforms further to make them an integral part of the mental health field (Ruwaard et al., 2011).

Some early research in ICBT and related topics (i.e., internet interventions, computerized interventions) focused more broadly on understanding its effects as a treatment option. Over 300 controlled trials of ICBT have been conducted targeting psychological disorders (e.g., social phobia, acute stress disorder, obsessive-compulsive disorder) and other health problems (e.g., chronic pain, insomnia, tinnitus) across various target populations (e.g., spinal cord injury, epilepsy; Andersson et al., 2019). Several studies have found no significant difference between clinician-guided ICBT and traditional face-to-face CBT for managing anxiety disorder symptoms (Andersson et al., 2019). For example, a systematic review of RCTs comparing clinician-guided ICBT to a waiting list control, online discussion group, unguided CBT, and traditional face-to-face CBT found that participants preferred clinician-guided ICBT compared to the waiting list and online discussion group (Andersson et al., 2019). Similar results have been seen in systematic reviews examining ICBT, psychological placebo, pill placebo, and face-to-face CBT (Andrews et al., 2018). Along with anxiety disorders, clinician-guided ICBT programs have been found to improve depressive symptoms compared to waiting lists or placebo controls (Andersson & Cuijpers, 2009).

A recent study found that clinician-guided ICBT compared to a waiting list control was associated with a reduction in depressive symptoms, and these results were maintained at 6- and 12-month follow up (Johansson et al., 2019). ICBT has also been shown to improve psychosocial wellbeing in various somatic health conditions (Mehta et al., 2018; Mehta et al., 2019; Mehta et al., 2020). A recent meta-analysis investigated the effect of ICBT among those with chronic health conditions (i.e., tinnitus, fibromyalgia, rheumatoid arthritis, cardiovascular disease, diabetes, cancer, and spinal cord injury; Mehta et al., 2018). The review reported that ICBT significantly improved overall anxiety (Standard mean difference (SDM)=0.34±0.04, Confidence Interval (C.I.) =0.18-0.49, p<.001) and overall depression (SDM=0.33±0.04, C.I.=0.17-0.49, p <.001; Mehta et al., 2018). Additionally, a pilot pre-post study found significant effects of guided ICBT on the primary outcome of depression (Cohen's d=1.20, p=.02) post-intervention and gains were maintained at 3-month follow-up among persons with spinal cord injury (Mehta et al., 2019; Mehta et al., 2020). Significant improvements in secondary outcomes, including pain interference, resilience, positive affect, and self-efficacy, were

also found (Mehta et al., 2019; Mehta et al., 2020). These studies demonstrate that guided ICBT is a safe and effective alternative to face-to-face CBT and may be particularly beneficial for underserviced neurological populations.

For the current study, researchers from Western University and Lawson Health Research Institute developed an online 10-week course comprising six ICBT lessons for people with neurological conditions (i.e., brain injury, stroke) who are experiencing mental health problems. This program is called The Wellbeing Mild Traumatic Brain Injury Course, and it was inspired by an existing course developed in Australia by Dr. Black Dear from the eCentreClinic, called The Wellbeing Neuro Course (Lawson Health Research Institute, 2019). Due to Australia's sparse geographic population, some early web-based CBT programs were started there, such as MoodGym. MoodGym was launched in 2001 by two researchers, Professor Helen Christensen and Professor Kathy Griffiths, from Australian National University, and the platform's goal is to offer online self-help programs to help users prevent and manage symptoms of depression and anxiety through CBT-based exercises (MoodGym, n.d.; Webb et al., 2017). Since the early 2000s, ICBT programs and literature have expanded rapidly. However, the popularity of ICBT also leads to an increase in questions about its effectiveness in treating people with mental health problems and whether it can deliver similar results to its precursor, the traditional face-to-face CBT. Thus, it is pertinent to continue conducting clinical research in this area to build ICBT as an evidence-based practice for mental health care.

1.5 Statement of Problem and Objective

Traditional CBT is still considered a new concept; however, modernizing CBT and incorporating new changes is essential as technology advances. There are benefits to using ICBT over traditional face-to-face CBT. Many people suffering from depression and other mental health conditions do not receive the treatment they require for various reasons, including public stigma and lack of accessibility (Hansson et al., 2014). ICBT can enhance access to treatments over traditional CBT as individuals can participate from the comfort and convenience of their home (or anywhere with an internet connection; Webb et al., 2017). Over 20 years of research and development have been invested in making ICBT, specifically clinician-guided ICBT, an efficacious treatment with lasting

effects (Johansson et al., 2019). Furthermore, clients can receive the treatment immediately or after a brief wait time. In contrast, with traditional CBT, sessions are scheduled weeks in advance, depending on the therapist's availability. Another reason why people sometimes do not seek treatment is due to the associated financial burden. Global News reports that private therapy can range from $50 to $240 per hour in Canada (Collie, 2019). In the United States, treating depressive disorders was the sixth-most-costly health condition at $71 billion (Dieleman et al., 2016). Many people do not have insurance, while others cannot afford to pay premium prices for traditional face-to-face CBT. Not receiving adequate mental health care can further prolong the course of recovery, and this is strongly evident for people with TBI (American Psychiatric Association, 1980; Buck, 2011; Faux et al., 2011; Menon et al., 2010; Scholten et al., 2016; Yehene et al., 2020). ICBT programs are free or can be accessed after paying a relatively small membership fee; thus, ICBT can be a more cost-effective alternative to traditional CBT (Donker et al., 2015). Additionally, with ICBT, people can receive treatment without ever leaving the comfort of their homes, increasing access to services (Hansson et al., 2014).

The most important factor for successful health and rehabilitation services is the inclusion of, and access to, well-coordinated multidisciplinary health care services, which address the varying needs of patients with TBI (Andelic et al., 2021). Unfortunately, psychological services and counselling for mental health problems are the least provided services post-TBI (Andelic et al., 2021). The ICBT literature presents a solid evidence base for the effectiveness of such programs. However, a gap exists in the literature as it has not been explicitly tested among individuals brain injuries, in particular people with mTBI. As established above, depression and anxiety are two of the most common psychological disorders affecting a person with mTBI and their wellbeing. Several studies have reported that persistent and untreated depressive and anxiety symptoms delay recovery and increase the global economic burden through costly clinic visits and hospitalizations (Menon et al., 2010; Scholten et al., 2016; Yehene et al., 2020). Furthermore, it increases the risks of substance abuse, risky behaviours, and suicides and decreases the quality of life (Menon et al., 2010).

Though traditional face-to-face CBT is an effective mode of providing mental health care to treat depression and anxiety, several barriers exist, lowering its accessibility. Past research on ICBT suggests that it is effective and can be just as effective as traditional CBT. However, no past research has examined a clinician-guided ICBT tailored for people with mTBI. A specialized 10-week clinician-guided ICBT program has been developed for people with mTBI to address symptoms of depression and anxiety and improve their wellbeing. The objective of this study is to evaluate the feasibility of the ICBT program within an mTBI population using Bowen's Feasibility Framework. Feasibility was measured using feasibility-specific outcome measures along with acceptability and limited efficacy (Bowen et al., 2009). The program's limited efficacy was evaluated through changes on symptoms of depression and anxiety, self-efficacy, and quality of life. It is hypothesized that the guided ICBT program for those with mTBI will be feasible to participants and improve patient-reported outcomes from pre-treatment to post-treatment. The current research aims to improve outcomes and mental health care delivery for individuals with mTBI. This is critical as these conditions are highly prevalent, disabling, costly and frequently untreated. Furthermore, it is pertinent to identify and examine whether ICBT, in general, is an effective and efficacious way to treat psychological symptoms (i.e., depression, anxiety) for people with mTBI. The results from this study will be critical for researchers and clinicians to further enhance and develop the ICBT program to ensure the program meets the needs of people with mTBI to enhance their wellbeing. These results also are critical for policymakers and stakeholders to further standardize the mental health care procedure and post-injury protocol for people with mTBI.

It is also important to note that the current ICBT has several limitations that will benefit from further research and development. The ICBT programs are not well-equipped to handle acute crises such as "active suicidality" (Webb et al., 2017). During face-to-face CBT, clinicians can assess the risk of suicide and treat the person as required, such as facilitating hospitalization. However, in ICBT, when a client self-reports any sign of suicide ideation, their assigned clinician is informed, and the client is contacted for further evaluation; the clinician then determines whether the client requires a higher level of treatment (i.e., face-to-face CBT, hospitalization, etc.). Interestingly, many ICBT

programs specifically exclude clients with high risks of suicide to minimize such risks. This is one critical area of ICBT that requires further research and development. The second part of this study, which will not be a part of this thesis, will utilize qualitative research methods to improve the challenges and limitations of the current ICBT program. Through semi-structured interviews, valuable information will be gathered to identify areas for improvement and highlight strengths to aid in the further development of such programs at Parkwood Institute and across Canada. Overall, ICBT is a novel form of psychological treatment, and it is expected to continue to evolve to better meet the needs of a wide variety of patients.

Chapter 2

2 Methods

This chapter discusses the quantitative research methods used to carry out this single-group open-trial pre-post research study. It begins with a description of Bowen's feasibility framework, followed by a description of the ICBT program, ethics, recruitment strategy, inclusion/exclusion criteria for participants and outcome measures. In addition, it includes the detailed procedures used for data collection, management, and analysis.

2.1 Methodological Framework

Our ICBT program is a psychological intervention developed for people with mTBI. Through a patient-oriented approach, the program aims to instill and sustain behaviours and thought processes to improve symptoms of depression and anxiety. Currently, no similar program exists that is tailored for people with mTBI and —due to resource constraints —conducting a large-scale study that tests both efficacy and effectiveness is not possible nor cost-effective. The objective of this study is to evaluate the feasibility of a clinician-guided ICBT program delivery among those with mTBI. Thus, this study employed Bowen's feasibility framework to evaluate and determine whether the program is relevant and sustainable for improving the psychological health of people with brain injury.

Bowen's feasibility framework describes eight key areas to consider when evaluating the feasibility of an intervention or program in a target population to assist clinicians and policymakers in decision-making about long-term implementation and evidence-based large-scale studies (Bowen et al., 2009). The eight key areas include the following, (1) acceptability, (2) demand, (3) implementation, (4) practicality, (5) adaptability, (6) integration, (7) expansion, and (8) limited-efficacy testing (Bowen et al., 2009). In addition, there are three phases of intervention development, which are (1) Can it work? (2) Does it work? and (3) Will it work? (Bowen et al., 2009). Not all areas or phases need to be evaluated in every study of feasibility. Previous feasibility trials for online psychological interventions focused on acceptability and limited-efficacy testing to

evaluate for feasibility (Dear et a., 2018b; Gandy et al., 2016; Gandy et al., 2020; Mehta et al., 2020). For example, Gandy et al. (2020) examined the feasibility of an internet-delivered psychological intervention for people with neurological conditions called the Wellbeing Neuro Course. Using multiple post-intervention questionnaires, they employed a longitudinal single-group open trial to evaluate feasibility through acceptability and efficacy data. Dear et al. (2018a) also examined an internet-delivered pain management intervention and —similar to Gandy et al. (2020) —they also used acceptability and limited-efficacy testing to evaluate feasibility. Overall, examining feasibility data helps research teams decide if an intervention is suitable for further testing and allows for refinements before the future study to better serve the target population (Bowen et al., 2009; Quintiliani et al., 2016).

Consistent with previous trials, this study also examined program feasibility by focusing on two key areas: acceptability and limited-efficacy testing. Acceptability assesses the perspectives of both individuals receiving the intervention and those implementing the intervention and evaluates whether the intervention is suitable and satisfying (Bowen et al., 2009). At the same time, limited efficacy testing evaluates whether the program is successful within the targeted population. It uses quantitative measures such as surveys and follow-up questionnaires to measure limited statistical power (i.e., effect-size estimation, measuring changes from different time points of program administration; Bowen et al., 2009).

Another essential feature of Bowen's feasibility model is its application to "real world" situations. The "Will it work?" phase achieves this goal by determining whether an intervention or program will be effective in real-life contexts, settings, and cultures/populations. Bowen et al. (2009) reported a need for more studies to be tested in a 'real-world' scenario without the most optimal conditions present, and feasibility studies can help bridge this gap in the literature. However, before we can answer the "Will it work?" question, we need to ensure that there is evidence suggesting the intervention is efficacious under ideal or actual conditions, and this can be achieved through the "Does it work?" phase of development (Bowen et al., 2009). One of the significant feasibility issues that precede the execution of a complete evaluation trial is

the need to derive an effect size estimate for the treatment and more importantly having some level of evidence that a treatment might work. Hence, in this study we applied the "Can it work?" phase through a small-scale feasibility trial is a more cost-effective method to examine the ICBT program and gain some evidence on whether it can be delivered in any setting and yield trends in the predicted direction for better outcomes compared to usual practice (Bowen et al., 2009). The ICBT program provided a 'real-world' snapshot of the feasibility of online mental health service delivery. The program is intended to integrate into the daily lives of people with mTBI and teach them essential skills to improve their wellbeing.

The feasibility framework was implemented into a single-group pre-post open-trial research design to test whether the program can be deployed in the target clinical community. A pre-post interventional study measures the occurrence of an outcome (i.e., depression, anxiety) before and after a particular intervention (i.e., ICBT program) is implemented (Thiese, 2014). Participants received survey questionnaires at baseline and post-treatment; patient-reported outcome measures were used to evaluate the ICBT program. Since this was also a clinician-guided ICBT program, it allowed for personalization and allocation of additional treatment resources (i.e., CBT-based homework activities), which may have been necessary for people with mTBI. Several past studies evaluating ICBT programs have successfully utilized similar approaches (Dear et a., 2018b; Gandy et al., 2016; Gandy et al., 2020; Hadjistavropoulos et al., 2018; Mehta et al., 2020). Thus, this study design was modelled to remain consistent with these past feasibility trials (Dear et a., 2018b; Gandy et al., 2016; Gandy et al., 2020; Hadjistavropoulos et al., 2018; Mehta et al., 2020).

2.2 The Wellbeing Mild Traumatic Brain Injury Program

The Wellbeing Mild Traumatic Brain Injury (WMTBI) program is a 10-week specialized clinician-guided ICBT program tailored for persons with mTBI. The ICBT program was initially developed by Dr. Black Dear and Dr. Nick Titov at Macquarie University, Australia. It was adapted and tailored at Lawson Health Research Institute by Dr. Swati Mehta for those with neurological conditions collaboratively with persons with lived experience, caregivers, researchers, and specialized clinicians (e.g., Physiatrist,

Psychologist). The WMTBI program is a transdiagnostic intervention targeting multiple diagnosis such as symptoms of depression, anxiety, memory, and attention. It is comprised of six online lessons that provide psychoeducation about: 1) Psychoeducation –Symptom identification and the cognitive behavioural model; 2) structured problem solving; 3) thought monitoring and challenging; 4) de-arousal strategies and pleasant activity scheduling; 5) graduated exposure/pacing, memory and attention, and 6) relapse prevention. These six lessons are described in detail in the next section. Please refer to Figure 1 for an overview of each of the lesson along with their allotted time.

Materials for the WMTBI program are presented in a didactic (i.e., text-based with visual images) and case-enhanced learning format (i.e., educational stories demonstrate the application of skills). The six modules are released gradually in a standardized order. All participants were presented with six lesson summaries, homework assignments that facilitate skill acquisition, and access to Do-It-Yourself guides that complement each lesson. Additional resources and case stories are provided to participants to further facilitate understanding.

Each participant was also in contact with a Guide, Mr. Randy Upper, a registered Social Worker with specialized training in delivering ICBT, once per week for the 10-week duration of the program. The Guide spent approximately 20 minutes per week/per participant through either telephone calls or emails, whichever method of contact the participant preferred. Weekly contact motivated participants to complete the weekly lessons and clarify any questions regarding the course materials. Most importantly, the Guide helped them apply the knowledge and skills learned from the course each week in their everyday life.

To ensure the safety of participants during the program and to assess any increase in distress, participants completed two outcome measures each week before the Guide check-in: 1) depression (Patient Health Questionnaire (PHQ-9)); 2) anxiety (Generalized Anxiety Disorder (GAD-7)). These questionnaires allowed the Guide to systematically monitor client symptoms each week of the program and determine if anyone requires further attention. Specifically, if the total score increased by 5 or more on either the PHQ-

9 or GAD-7 or the PHQ-9 item 9 (“Thoughts that you would be better off dead or of hurting yourself in some way”) had a score of 2 or greater, additional contact was arranged with the Guide. This allowed the researchers to understand the participant’s wellbeing, whether the ICBT would still be a good fit, or whether they needed direct intervention. Of note, PHQ-9 and GAD-7 were used as screening tools, not diagnostic ones. Furthermore, the web platform alerted the Guide when participants have not been online for over seven days and when symptoms significantly change, thus allowing the Guide to personalize care easily. However, no therapeutic intervention was provided by the Guide.

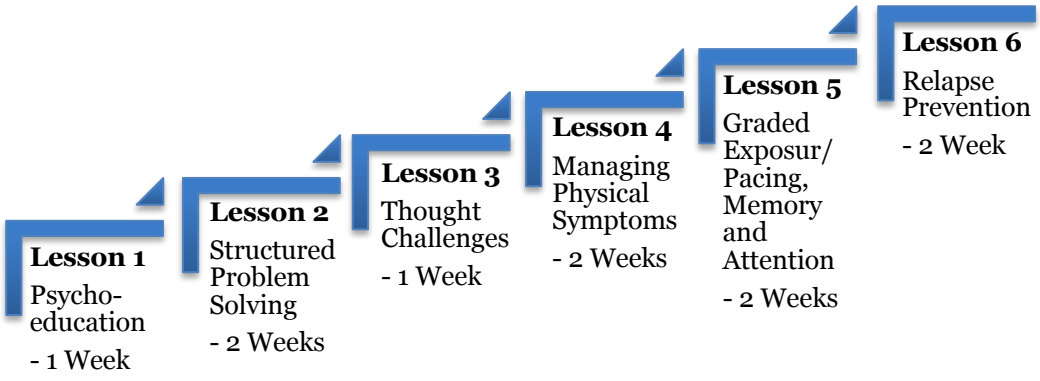

Figure 1. The Wellbeing Mild Traumatic Brain Injury Program

2.2.1 Lesson Content of the WMTBI Program

There are six lessons in the WMTBI program. Each of the lessons is described in detail below. Each lesson also incorporated three case vignettes to reflect the experiences of those with mTBI and described how they applied the knowledge and skills learned to manage their wellbeing. Homework activities were also provided at the end of each lesson to help participants apply the skills learned. Supplementary lessons were also provided and could be accessed at any time (e.g., sleep, communication, problem-solving, assertiveness training). Please refer to Figure 1 again for an overview of each of the lesson along with their allotted time.

1. **Lesson One: Psychoeducation –Symptom Identification and Cognitive Behavioural Model**

The first lesson introduces participants to the program and its goal of improving wellbeing. It provides education regarding the definition and prevalence of mTBI and

how mTBI impacts wellbeing. It also introduces participants to the CBT model and explains the functional relationship between physical feelings, thoughts, and behaviours, referred to as the Cycle of Symptoms. The Cycle of Symptoms involves three categories: Unhelpful Thoughts, Physical Symptoms and Unhelpful Behaviour. These categories and the neurological symptoms of mTBI are interconnected and impact one another (i.e., unhelpful thoughts can lead to physical symptoms and subsequent unhelpful behaviours). The lesson also provides instructions to participants to aid in understanding their Cycle of Symptoms.

2. **Lesson Two: Structured Problem Solving**

This lesson of the WMTBI program introduced participants to Structured Problem Solving. It had step-by-step instructions on applying these strategies to manage the impact of neurological symptoms with a specific focus on improving cognitive wellbeing. By the end of this lesson, participants identified possible solutions to self-identified problems to improve their wellbeing.

3. **Lesson Three: Thought Monitoring and Challenging**

In this lesson, the program focused on differentiating helpful from unhelpful thoughts. It also taught participants practical and proven skills to learn to manage their unhelpful thoughts. In addition, step-by-step instructions for monitoring and challenging thoughts were detailed.

4. **Lesson Four: De-arousal Strategies and Pleasant Activity Scheduling**

This lesson of the WMTBI program introduced participants to the physical symptoms of Under-Arousal (i.e., symptoms of fatigue and exhaustion, depression) and Over-Arousal (i.e., symptoms of stress and tension, anxiety). In addition, it provided detailed instructions to aid in controlling physical symptoms, including de-arousal strategies such as controlled breathing (i.e., combat over-arousal symptoms) and scheduling pleasant activities (i.e., combat under-arousal symptoms).

5. **Lesson Five: Graduated Exposure, Activity Pacing, Memory, and Attention**

In this lesson, the WMTBI program introduced participants to the behavioural symptoms of anxiety, depression, and neurological symptoms. First, it explained the overdoing-underdoing activity cycle and issues around the fear and avoidance of social and physical

activities. Then it taught some practical techniques for managing these symptoms through activity pacing and gradually tackling avoidance while remaining safe and as active as possible.

6. **Lesson Six: Relapse Prevention**

The last lesson of the WMTBI program focused on the occurrence of relapses in depression, anxiety, and neurological symptoms. Information to support identifying the signs of relapse was provided. In addition, it provided instructions to identify signs of relapse, create a relapse prevention plan, use goal setting to overcome hurdles, and continue to improve even after completing the program.

2.3 Ethics

As an intervention study examining a form of CBT, this study was registered on ClinicalTrials.gov PRS (**ID NCT04561011**). Before data collection began, ethics applications were submitted and approved by the Health Sciences Research Ethics Board (HSREB) at Western University (**HSREB file number 116271**) and the Lawson Ethics Board at Lawson Health Research Institute (***ReDA* file number** 10209**; LORA file number 5416**). Refer to Appendix A for notices of approval.

2.4 Participant Recruitment and Screening

An a priori sample size of 20 was calculated based on the depression outcome measure to be sufficient to detect a power of 90% with alpha at .05 and an effect size of 0.8, while accounting for a potential dropout of 30%. This strategy was employed in previous studies by our and other research teams conducting similar transdiagnostic ICBT with individuals with cancer and kidney disease (Dear et al., 2018a; Alberts et al., 2017; Chan et al., 2016; Mehta et al., 2020).

Participants were recruited through several avenues. First, a significant number of participants were recruited from the Parkwood Institute outpatient brain injury clinic by their health care providers (i.e., Physiatrists). The study poster was also shared on the lab's social media accounts (e.g., Twitter) with a short description. Additionally, prior to

launching this study, the research was featured on CTV London, gaining attention across Canada. This led to a list of potential participants and their contact information.

Potential participants were deemed eligible if they met the following inclusion criteria:

1. Adults≥ 18 years
2. Diagnosed with mTBI (duration ≥ 3 months)
3. Reporting symptoms of anxiety (GAD-7) and/or depression (PHQ-9)
4. Able to access a computer and the internet
5. Have the cognitive capacity to read and understand the content (The Telephone Interview for Cognitive Status (TICS) > 21)

Similarly, participants were excluded if one or more of the following was true:

1. High risk of suicide (PHQ-9 item 9 > 2 or SBQ-R > 8)
2. Primary problems with psychosis, alcohol or drug problems, mania
3. Currently receiving active (more than twice a month) psychological treatment for anxiety or depression
4. Concerns about online therapy (i.e., security-related reasons, being uncomfortable with ICBT, having doubt on the program's credibility, etc.)
5. Physically unable to perform the tasks

Participants that met the eligibility criteria listed above completed screening questionnaires for demographic characteristics, baseline/pre-treatment scores for PHQ-9, GAD-7, etc. They also booked an appointment for a telephone screen with Dr. Swati Mehta to further discuss their eligibility for the program. The telephone screen was done to ensure appropriateness for ICBT. During the telephone interview, participants were assessed for suicide risk (Suicide Behaviours Questionnaire-Revised (SBQ-R); Osman et al. 2001) and cognitive status (The Telephone Interview for Cognitive Status (TICS); https://www.parinc.com/Products/Pkey/445; Desmond et al. 1994). Refer to Appendix B and C for notices of Letters of Information and Consent forms for online screening and the ICBT program.

The SBQ-R is a 4-item self-report measure of the presence, severity, and frequency of lifetime suicidal ideation and attempts and the likelihood of a future suicide attempt (i.e.,

"How often have you thought about killing yourself in the past year?"). The overall score can range from 0 to 16, where higher scores reflect greater suicide risk. The recommended total SBQ-R cut-off score for a clinical adult population is 8 or less (Osman et al., 2001). The SBQ-R has acceptable-to-good internal consistency for clinical and non-clinical adult populations (α=0.76 – 0.87; Osman et al., 2001). Thus, utilizing the SBQ-R helped us identify whether this program was a good fit for potential participants or if they required more direct and immediate treatment (i.e., referring to a psychiatrist, psychologist, or psychotherapy).

TICS is an 11-item clinician-reported interview measure that gathers information in the domains of orientation, concentration, short-term memory, mathematical skills, praxis and language. It takes between five and ten minutes to perform, is sensitive and specific, and has high test-retest reliability for detecting cognitive difficulties in a population with neurological conditions (i.e., Alzheimer's Disease (Brandt et al., 1988), stroke (Desmond et al., 1994; Barber & Stott, 2004)). Considering the ICBT program is content-heavy, participants must have adequate cognitive functioning and an ability to learn and apply the materials and skills being taught. Thus, utilizing TICS, a practical and valid tool, for telephone assessment of cognitive function was an effective way to determine whether a participant was a good fit for this program.

Those not found to be appropriate for the online program were provided sources of community support during the telephone screen.

2.5 Data Collection

Figure 2 provides an overview of the timeline of participant recruitment and when questionnaires were administered. Demographic variables were obtained through a self-report questionnaire, including age, sex, ethnicity, relationship status, current living situation and education. Feasibility-specific and acceptability outcome measures were collected only post-intervention. Limited efficacy outcome measures were collected pre-intervention (i.e., immediately before starting the course) and post-intervention (i.e., after the 10-week course was finished). To monitor participant progress and safety, the anxiety (GAD-7; Kroenke et al., 2007) and depression (PHQ-9; Kroenke et al., 2003) measures,

as well as item 9 from the PHQ-9 (Kroenke et a., 2001) was administered weekly. All data on the consent form, pre-treatment, and post-treatment questionnaires were collected by REDCap software which is available through Lawson Health Research Institute.

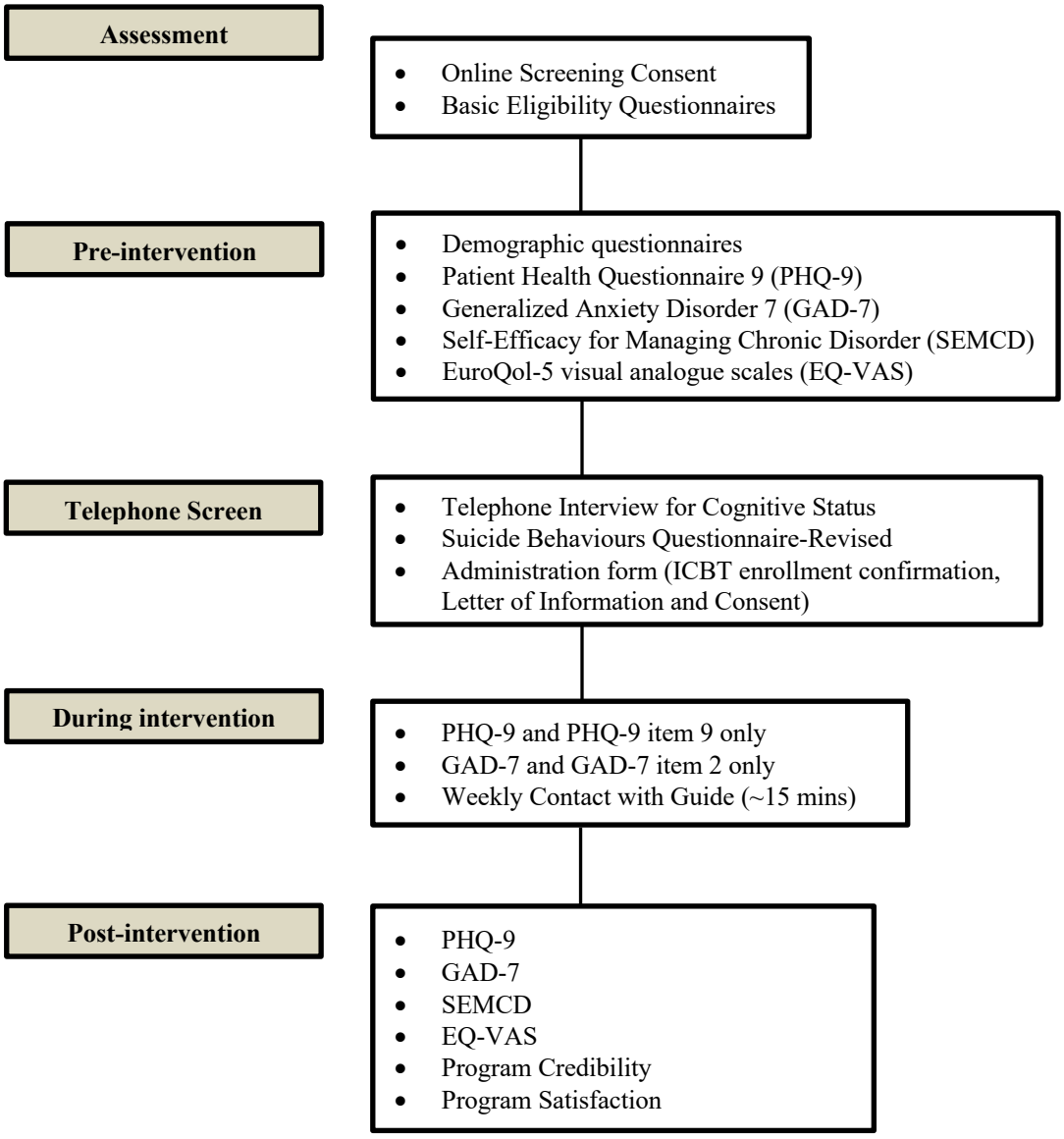

Figure 2. Flow Chart of the Timeline of Questionnaires Administered

2.6 Outcome Measures

Feasibility was assessed through acceptability, limited efficacy and a series of post-treatment questionnaires were used to evaluate the success of patient recruitment, participant engagement, program completion (i.e., attrition) and treatment satisfaction. *Success of participant* recruitment was measured by reporting the dates on when the first and last participants were recruited and how long it took to recruit the target goal of 20 participants. *Participant engagement* was measured by the average time spent with the Guide. *Program completion* was defined as completing at least five of the six lessons in the course. *Completeness of data* was evaluated by examining the number of participants who submitted the post-treatment measures. Similar strategies were used by past ICBT programs to evaluate their feasibility (Dear et a., 2018b; Gandy et al., 2016; Gandy et al., 2020; Mehta et al., 2020).

2.6.1 Acceptability Outcome Measures

Acceptability was based on patient satisfaction using the Treatment Satisfaction Questionnaire (TSQ) and Program Credibility instrument. The TSQ contains 18 items to evaluate treatment satisfaction for people enrolled in the ICBT program. This instrument has been used in previous research examining the acceptability of other internet-delivered treatments and were found to be effective (Gandy et al., 2020; Dear et al., 2018a; Verwer et al., 2016; Hadjistavropoulos et al., 2018). The *Program Credibility* instrument was used to measure the participant's experience with the online program and whether it helped them achieve their wellbeing goals.

2.6.2 Limited Efficacy Outcome Measures

To evaluate the ICBT program's limited efficacy, outcome measures on depression and anxiety, self-efficacy and quality of life were used.

The PHQ-9 was used to measure participants' experiences of depression (Kroenke et a., 2001). The PHQ-9 uses nine items to measure the presence and severity of depression symptoms according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria. Items on the PHQ-9 scale range from 0 (not at all) to 3 (nearly every day) with a total score ranging from 0 to 27 (Kroenke et a.,

2001). Higher scores indicate greater depression symptom severity, where scores of ≤4 indicate no symptoms of depression, scores of 5–9 indicate mild symptoms of depression, scores of 10–14 indicate moderate symptoms of depression, scores of 15–19 indicate moderate-severe symptoms of depression, and scores ≥ 20 indicate severe symptoms of depression (Kroenke et a., 2001). The PHQ-9 has good psychometric properties, is sensitive to treatment-related change, and is reliable and valid for use in people with mTBI (Kroenke et a., 2001). The PHQ-9 has been shown to have high internal consistency (α = 0.86–0.89) and good construct validity (Kroenke et a., 2001). Participants were asked to complete the PHQ-9 pre-treatment and post-treatment.

During the program, suicidal ideation was assessed and monitored each week through PHQ-9 item 9 ("Thoughts that you would be better off dead or of hurting yourself in some way"). Previous studies have reported that PHQ-9 item 9 is useful and valuable for identifying suicidality (i.e., risk, severity) and treatment resistance and it has been widely used as a single measure to assess the prevalence of suicidal ideation in research studies (Bauer et al., 2013; Simon et al., 2013; Uebelacker et al., 2011).

Participants' experiences of anxiety were measured using the Generalized Anxiety Disorder Scale-7 (GAD-7; Spitzer et al., 2006). Items on GAD-7 scale range from 0 (not at all) to 3 (nearly every day), with a total score ranging from 0 to 21. Higher scores indicate greater severity of anxiety symptoms, where scores of ≤4 indicate minimal symptoms of anxiety, scores of 5–9 indicate mild symptoms of anxiety, scores of 10–14 indicate moderate symptoms of anxiety, and scores ≥ 15 indicate severe symptoms of anxiety (Löwe et al., 2008). The GAD-7 possesses excellent psychometric properties, is sensitive to treatment-related change and is a reliable and valid screening tool for detecting GAD in people with mTBI and other neurological conditions (Gandy et al., 2020). In addition, psychometric studies show that GAD-7 has excellent internal consistency (α = 0.92) and strong construct validity (Spitzer et al., 2006; Bandelow & Brasser, 2009).

Self-efficacy is described as the perceived capability of a person to perform a specific action required to achieve a concrete goal (Freund et al., 2011; Bandura, 1997). This

study measured self-efficacy using the Self-Efficacy for Managing Chronic Diseases (SEMCD), a 6-item instrument with a 10-step Likert scale ranging from 1 'not at all confident' to 10 'totally confident' (Lorig et al., 2001). Ritter and Lorig (2014) reviewed multiple studies to investigate the psychometric properties of the SEMCD scale. They reported Cronbach's alpha to be a minimum of .88 across all studies, and the measure was sensitive to changes.

Finally, quality of life was measured using only the visual analogues scale from the EuroQol-5 Dimension (EQ-VAS, EuroQoL Group, 1990). EQ-VAS records an individual's self-rated health on a vertical visual analogue scale where the values range between 100 (best imaginable health) and 0 (worst imaginable health; Van Reenen et al., 2018; EuroQoL Group, 1990). The EQ-VAS score asks patients to score their health on the day that they complete the questionnaire and is used as a measure of overall self-rated health status (EuroQoL Group, 1990). The psychometric properties of validity and reliability have been more or less confirmed to be high in published literature, while evidence of responsiveness is somewhat varied (Alderman et al., 2001; Feeny, 2005; Feng et al., 2014).

2.7 Data Analysis

All analyses were conducted using SPSS version 28 (SPSS, Inc., Chicago, IL; IBM Corp., 2016). Descriptive statistics (e.g., measures of central tendency, frequency tables and distributions) were conducted to describe the most important demographic characteristics of the participants. Demographic characteristics included the following: age, sex, ethnicity, highest level of education, relationship status, living arrangements, province, location (i.e., big city, small city), whether they are currently receiving psychological treatment (i.e., psychologist, psychiatrist, psychotherapist) for their mental health concerns, and whether they are currently taking medications for mental health concerns.

To evaluate the feasibility-specific and acceptability outcome measures of the ICBT program, descriptive statistics and frequency tables were used to examine participant engagement, program completion (i.e., attrition) and participant satisfaction.

To assess limited efficacy outcome measures of the ICBT program, repeated measures t-test (also known as paired sample t-test) was used to evaluate changes over time from baseline to post-treatment for depression (PHQ-9) and anxiety (GAD-7). Prior to repeated measures t-tests analyses, the distribution of each dependent variable was examined to address skewness, along with testing for assumptions. Several statistics were calculated based on the repeated measures t-test analyses to assist with interpreting the results and finding clinical significance. First, for each outcome variable, we calculated (1) the average change across time with 95% confidence intervals and (2) Cohen's d effect sizes and associated 95% confidence intervals for the group effects based on the estimated marginal mean values derived from the repeated measures t-tests models. Finally, consistent with recommendations for reporting negative outcomes in ICBT trials, the number of clients reporting symptom deterioration or reduction at 30% or greater and at 50% or greater on the GAD- 7 and PHQ-9 are reported (Rozental et al., 2014; Dear et al., 2015). These analyses were designed to provide information on participants who demonstrated meaningful change in symptoms. Finally, for SEMCD and quality of life (EQ-VAS), the average change across time and effect sizes scores were calculated to evaluate for limited efficacy through descriptive statistics analyses.

2.8 Conclusion

This chapter discusses the study's methodological framework, provides a detailed description of the WBMTBI program and lessons, ethical considerations, processes of participant recruitment, the primary and secondary outcome measures used and explains the data collection and analysis processes. The following chapter provides an in-depth overview of the findings produced from the data analysis.

Chapter 3

3 Results

3.1 Participant Demographics and Baseline Data

Participants' demographic and clinical characteristics are presented in Table 1. A total of 24 participants met the initial inclusion criteria and completed the online screening (Figure 3). However, four participants that met the inclusion criteria could not be reached for the telephone interview and screening procedures; thus, 20 participants were enrolled. Among the entire sample, 25% were male, and 75% were female. All participants were Caucasian (100%). The mean age was 47.85 years (Standard Deviation (SD) = 9.326), ranging from 34 to 67 years. Most of the participants were married/common-law or in a relationship (60%), currently living with family members (85%), and had achieved a post-secondary education (trade, college, university) (70%). Most participants were from Ontario (90%), while 5% were from British Columbia and 5% from Saskatchewan. Approximately 40% of the sample population were currently residing in a large city, where the population is over 200,000, 30% in a small city, where the population is between 10,000 to 200,000, and 5% in a town or farm, where the population is less than 10,000. At the time of study enrollment, 35% were receiving psychological treatment from either a psychiatrist, psychologist, or psychotherapist for their mental health concerns. At the same time, 50% of the sample population were taking medications to address their mental health needs.

Table 1. Participants' Demographic Characteristics

	n	***Weighted %***
Age (years)	Mean (SD) = 47.85 (9.326)	Range = 34 to 67
Sex		
Female	15	75%
Male	5	25%
Ethnicity		
White	20	100%
Highest Education		
High School Diploma	5	25%
Post-secondary Education	14	70%

Relationship Status		
Single/Never Married	5	25%
Married/Common law/In a Relationship	12	60%
Separated/Divorced	3	15%
Living Arrangements		
Living Alone	1	5%
Living with Family/living with extended family	17	85%
Living with Roommates	1	5%
Other	1	5%
Province		
British Columbia	1	5%
Ontario	18	90%
Saskatchewan	1	5%
Location		
Large City (Population over 200K)	8	40%
Small City (Population of 10-200K)	6	30%
Town or Farm (<10K)	5	25%
Currently Receiving Psychological Treatment (i.e., psychologist, psychiatrist, psychotherapist) for Mental Health Concerns		
No	13	65%
Yes	7	35%
Currently taking Medication for Mental Health Concerns		
No	10	50%
Yes	10	50%

The scoring of pre-treatment measures is presented in Table 2. Participants, on average, had moderate levels of depression symptoms, PHQ-9 = 12.100 (SD = 5.572), where scores ranged from 1 to 23. Similarly, on average, participants had moderate anxiety symptoms, GAD-7 = 10.3.50 (SD = 4.725), where scores ranged from 2 to 18. In addition, participants reported their quality of life on the day they completed this questionnaire to be average/normal, with a mean EQ-VAS score of 59.105 (SD = 22.151), ranging from 19 to 87. Finally, on average, participants' SEMCD score was 5.067 (SD = 2.083), ranging from 1.67 to 9.17, with higher scores indicating higher self-efficacy.

Table 2: Pre-Treatment Measures

	n	Min	Max	Mean (SD)	Skewness (Std. Error)	Kurtosis (Std. Error)
PHQ-9 Total Baseline Score	20	1	23	12.100 (5.572)	-.309 (.512)	0.14 (.992)
GAD-7 Total Baseline Score	20	2	18	10.300 (4.725)	-.185 (.512)	-1.096 (.992)
SEMCD Total Baseline Score	20	1.67	9.17	5.067 (2.083)	.011 (.512)	-.574 (.992)
EQ5D5L-VAS Total Baseline Score	20	10	87	59.105 (22.151)	-.887 (.524)	-.141 (1.014)

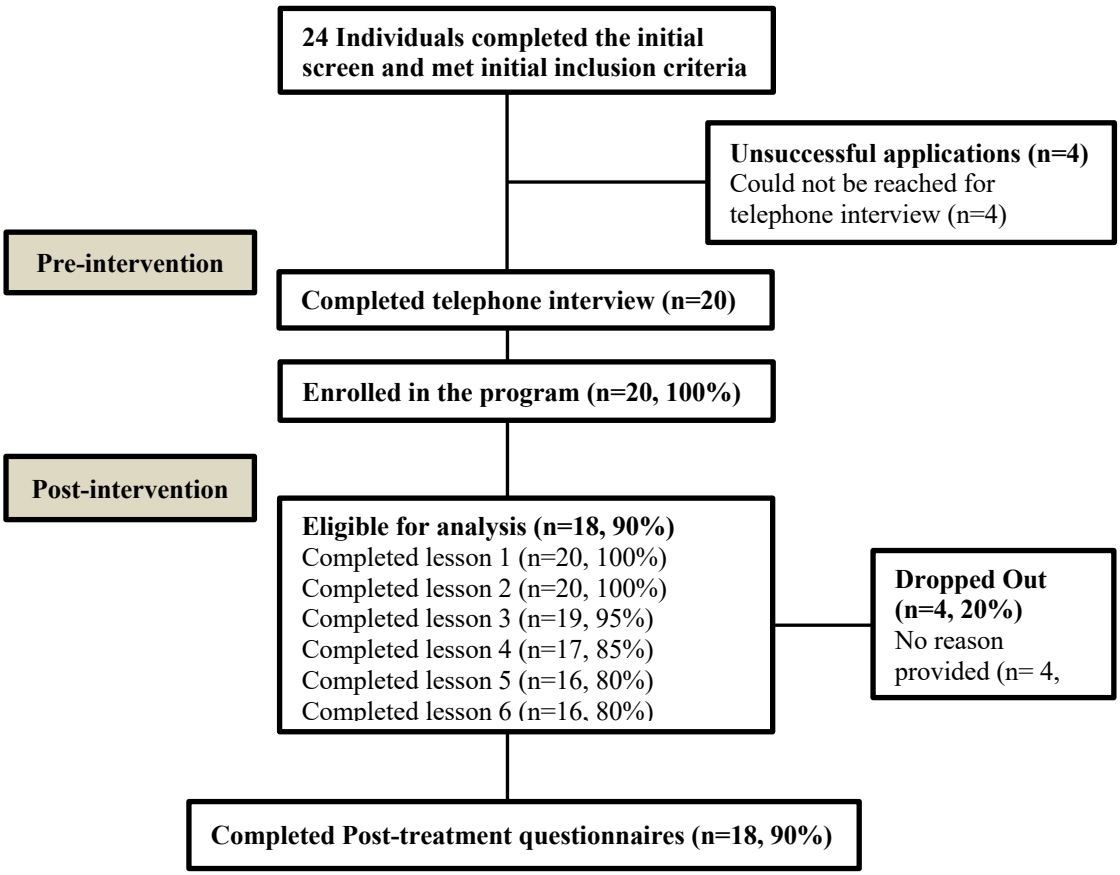

Figure 3. Participant Flow.

3.2 Outcome Measures

3.2.1 Feasibility and Acceptability Outcome Measures

To evaluate program feasibility and acceptability, the following data were used: success of patient recruitment, participant engagement, program completion (i.e., attrition), treatment satisfaction and program credibility. The first participant was recruited on April 13th, 2021, and the last was recruited on March 21st, 2022. We were actively recruiting for approximately ten months; on average, two participants were recruited per month. Eighty percent (n=16) of the participants completed at least 5 out of the 6 lessons of the ICBT program. One participant dropped out after completing Lesson 3, another dropped out after Lesson 5 and neither of them completed post-treatment outcome measures. The other two participants dropped out after Lesson 4, but both participants completed post-treatment outcome measures. The Guide reached out to check in with the participants multiple times and left voicemails. Ultimately, the Guide could not make contact or determine why they decided not to continue with the program. Overall, 90% (n=18) of the participants completed the post-treatment measures, which also suggest that two participants who dropped out also completed the post-treatment survey. It is possible that the data captured from those two specific participants may provide sight into the feasibility and efficacy of this study and in particular for the qualitative study their experiences may highlight some of the key challenges and or strength of the ICBT program. However, for the purpose of this thesis this will not be analyzed at the moment.

In terms of participant engagement, the Guide spent 20 minutes with each participant during their weekly check-in. Acceptability was reported through the Treatment Satisfaction Questionnaire. Of the 18 participants who completed the ICBT program, 100% reported being satisfied with the ICBT program. All 18 participants reported that they would recommend this ICBT program to a friend and 94% (n=17) reported that it was worth their time. All 18 participants revealed that this course increased their confidence and motivation in self-managing their symptoms. Seventy-eight percent and 89% of the participants were satisfied with the e-mails and telephone calls from the Guide, respectively. Finally, none of the participants experienced any unwanted negative effects or events associated with participating in this ICBT program.

Program Credibility was evaluated using a 4-item 9-point Likert scale instrument that has been used by similar ICBT programs (Jones et al., 2016). All 18 participants found the ICBT program logical, and, on average, they found that ICBT improved their functioning by approximately 48.9% (SD = 18.10%).

3.2.2 Limited Efficacy Outcome Measures

Table 3 provides details on mean, SD, confidence intervals (CI), and effect sizes for the secondary outcome measures of depression (PHQ-9) and anxiety (GAD-7). Repeated measures (or paired) sample t-test analyses were utilized to evaluate the changes in these outcome measures from baseline to post-treatment. A repeated measures sample t-test has three assumptions: a) Independence; b) Normality; c) No extreme outliers. For quality of life (EQ5D-VAS) and self-efficacy (SEMCD), only the descriptive statistic and effect size was calculated to evaluate the limited efficacy of the ICBT program.

3.2.2.1 Pre-analysis Evaluations: Test for Assumptions

The assumption for independence examined whether each of the observations are independent of every other observation, this means that the behaviour observed in one participant does not influence the behaviour of another (Field, 2009). In the study, we used a repeated-measures designs, where participants are measured in more than one experimental condition (baseline and post-treatment). Thus, we expected scores in the experimental (baseline and post-treatment) conditions to be non-independent for a given participant, but behaviour between different participants should be independent (Field, 2009).

The assumption for normality examined whether the difference between pairs is approximately normal (Field, 2009). In this study, we examined normality using two methods: statistically through the Shapiro – Wilk test and graphically through a histogram and a probability–probability (P – P) plot. The Shapiro – Wilk test is deemed to be an appropriate method to test for normality for small sample sizes ($n<50$; Mishra et al., 2019).

The last assumption is that there should be no extreme outliers in the mean differences. In this study, we tested for outliers graphically through boxplots, also known as box-whisker diagrams. Prior to the paired sample t-test analysis for depression (PHQ-9) and anxiety (GAD-7) scores, all three assumptions were tested and satisfied. Please refer to Figures 4 to 9 in Appendix D to review the results of each test of assumptions for depression (PHQ-9) and anxiety (GAD-7) scores.

Table 3: Paired Sample t-Test Statistics.

	n	**Mean (Std. Deviation)**	**95% C. I. Lower Bound**	**95% C.I. Upper Bound**	**t**	**df**	**Significance (*p*-value)**	**Effect Size**
PHQ-9	18	- 8.056 (5.589)	5.276	10.835	6.115	17	<.001	1.441
GAD-7	18	- 6.944 (4.659)	4.628	9.261	6.324	17	<.001	1.491
SEMCD	18	2.676 (2.083)	-3.712	-1.64				1.285
EQ-VAS	17	15.882 (16.885)	-24.564	-7.201				.941

3.2.2.2 Depression

As all assumptions were met and the paired sample t-test analysis was conducted. The post to pre-treatment mean difference in PHQ-9 scores was - 8.056 (SD = 5.589, CI 95% +/- 2.779, t = 6.115, df = 17, p<.001, Table 3) and revealed significant effects. The effect size (Cohen's d) was high with a score of d = 1.441. To evaluate clinical significance, 30% and 50% decreases in depressive symptoms were measured (Table 4). Fifteen (83.3%) participants experienced at least 30% reduction in symptoms of depression, and out of those 13 (72.2%) experienced at least 50% reduction.

3.2.2.3 Anxiety

All the assumptions for paired sample t-test were met. The post to pre-treatment mean difference in GAD-7 score was - 6.944 (SD = 4.659, CI 95% +/- 2.316, t = 6.324, df=17, p<.001, Table 3). The effect size (Cohen's d) was high, with a score of 1.491. Among the 18 participants, 16 (88.9%) experienced at least 30% reduction in symptoms of anxiety and out of those, 14 (77.8%) experienced a reduction of at least 50% (Table 4).

Table 4: Frequency of Symptoms Deterioration and Reduction by At Least 30% and 50%.

	Symptom Deterioration at 30% (n=18)	Symptom Deterioration at 50% (n=18)	Symptom Reduction at 30% (n=18)	Symptoms Reduction at 50% (n=18)
Depression (PHQ-9)	1 (5.6%)	1 (5.6%)	15 (83.3%)	13 (72.2%)
Anxiety (GAD-7)	0	0	16 (88.9%)	14 (77.8%)

3.2.2.4 Self-efficacy and Quality of Life

The mean post to pre-treatment difference in SEMCD score evaluating self-efficacy was 2.676 (SD = 2.083, CI 95% +/- 1.036, Table 3); the effect size was Cohen's d = 1.285. The mean difference in EQ5D-VAS score evaluating quality of life was 15.882 (SD = 16.885, CI 95% +/- 8.682, Table 3) with an effect size score of Cohen's d = .941.

Chapter 4

4 Introduction

The primary purpose of the current study was to evaluate the feasibility of a transdiagnostic clinician-guided internet-delivered cognitive behavioural therapy (ICBT) program called the Wellbeing Mild Traumatic Brain Injury Course. The program aimed to improve the overall wellbeing of those with Mild Traumatic Brain Injury (mTBI). The efficacy of the program was evaluated by measuring changes seen across time in depression, anxiety, self-efficacy, and quality of life. Based on a thorough literature review, the use of online CBT in neurological conditions, such as mTBI, is limited. Overall, the findings of this study demonstrate that online therapy programs such as ICBT can be successfully implemented by individuals with mTBI to significantly improve their symptoms of depression and anxiety, along with their self-efficacy and quality of life.

4.1 Feasibility of the ICBT Program – Feasibility and Acceptability Outcome Measures

This study demonstrated that the delivery of clinician-guided ICBT is feasible in a clinical setting for people with mTBI, supporting the hypothesis of this study. Feasibility outcome measures highlighted high levels of treatment adherence and study completion among participants, along with low levels of dropout and attrition. In addition, acceptability specific outcome measured found treatment satisfaction and program credibility to be highly rated. Suggesting that participants strongly agreed with most statements regarding the quality of treatment, program content, structure, and delivery. High levels of satisfaction with ICBT due to convenience, ability to proceed at one's own pace, low cost, and privacy have previously been reported (Andrews & Willams, 2015).

Four participants (20%) dropped out of the program; unfortunately, no reason for this could be obtained despite the Guide trying to reach out several times. Another study that evaluated an online CBT program among those with mild to moderate TBI reported dropout levels of 38% (Topolovec-Vranic et al., 2010). However, it is important to note that the study was comprised predominantly of male (62%) participants, all with high

levels of depression at baseline and other co-morbid conditions, thus direct comparison is difficult (Topolovec-Vranic et al., 2010). Furthermore, they reported that participants needed more time to understand and complete each module due to difficulties with concentration and memory; some participants also believed that the structure of the website might be better suited for young people rather than adults with TBI (Topolovec-Vranic et al., 2010). Conducting research with people from the traumatically injured patient population (i.e., TBI) is challenging as follow-up rates tend to be low (Topolovec-Vranic et al., 2010; Michaels et al., 2000).

The lower levels of dropout in our current study may be due to several factors. Tailoring treatment to participants through guided support is an effective strategy for improving adherence and is associated with high levels of satisfaction in web-based interventions (Kelders et al., 2012). In the current study, the program content was developed in collaboration with persons with lived experience through an iterative process. The program was tailored to the needs of the population in the following ways: 1) visually adapting materials to aid readability and comprehension; 2) presenting materials in interactive and multiple formats (e.g., written, audio, video); 3) incorporating memory and planning aids; 4) avoiding the use of triggering language (e.g., "disability"); 5) encouraging participant to complete the course with a support person, such as a care partner, friend, if available. Additionally, the content was adapted through: 1) addition of a module related to enhancing memory and attention; 2) development of case vignettes aligned with experiences of those post mTBI integrated with components of CBT, e.g., thought challenging, managing cognitive problems; 3) material on communicating with health care providers; 4) normalizing lapses and lapse prevention plans. These practices of tailoring and personalizing the program may have resulted in greater adherence rates.

The lower dropout rate may also be due to the greater level of guided clinician support; the Guide spent approximately 20 minutes per week with each participant. A review by Andrews and Williams (2015) reported that adherence rates to clinician-guided ICBT for various patient populations were up to 96%, which is superior to adherence rates in some psychotherapy research studies and regular clinical practice. Tsaousides et al. (2014) evaluated an 8-week group-based therapist-guided online emotion regulation program

with 16 one-hour virtual sessions for people with TBI. They reported that group engagement and therapist guidance led to strong program satisfaction and completion rate. Mehta et al. (2019; Mehta et al., 2020) also conducted a similar clinician-guided ICBT program for people with Spinal Cord Injury (SCI). They reported that guided support allowed people to complete the program. It also provided a greater level of accountability in completing program and homework assignments, similar to that seen in a traditional face-to-face session. Research suggests that clinician-patient alliance and communication in mental health care are associated with more favourable patient adherence rates, which are comparable to the rates seen in traditional face-to-face therapy (Thompson & McCabe, 2012; Cook & Doyle, 2002).

In this study, the majority of the sample population was female (75%), had post-secondary education (70%) and had moderate levels of depression at baseline (mean = 12.100, SD = 5.572). Batterham et al. (2008) previously found that female gender, younger age, higher education levels and higher baseline depression scores were predictors of completing two or more program modules within an online CBT program compared to one or none. Thus, the demographics of our sample population may also explain the low level of attrition observed, specifically when compared to the study by Topolovec-Vranic et al. (2010).

Overall, the pilot study's findings demonstrated the feasibility of this tailored clinician-guided ICBT program for people with mTBI.

4.2 Feasibility of the ICBT Program – Limited Efficacy Outcome Measures

4.2.1 The ICBT Program on Symptoms of Depression and Anxiety

People with mTBI often report significant difficulties in areas such as depression and anxiety, which can be further complicated by the course of the condition and treatment regimens (Hesdorffer, 2016; Gandy et al., 2018). Fortunately, in this study, participants experienced a significant reduction in symptoms of depression (PHQ-9) and anxiety (GAD-7). In addition, a clinically significant improvement (at least a 30% reduction in symptoms of depression and anxiety) was obtained by over 80% of participants. The

encouraging findings are consistent with previous studies examining the use of ICBT programs on people with traumatic brain injury (Topolovec-Vranic et al., 2010; Caplan et al., 2016), spinal cord injury (Mehta et al., 2020; Migliorini et al., 2011), and other neurological conditions (Hadjistavropoulos et al., 2018; Gandy et al., 2016; Gandy et al., 2020).

Effect sizes for pre- to post-treatment mean differences were high for depression (PHQ-9; Cohen's d = 1.441) and anxiety (GAD-7; Cohen's d = 1.491), suggesting that the ICBT was effective. A review by Andrews and Williams (2015) suggests that therapist-guided ICBT produces equivalent effect sizes to time-limited traditional face-to-face CBT interventions. Hadjistavropoulos et al. (2014a) also found a strong association between increased therapist/guide contact and modules completed, leading to better ICBT patient outcomes in depression and generalized anxiety. Additionally, this study's magnitude of clinically significant improvements and effect sizes compares favourably to a meta-analysis of CBT-based interventions for patients with acquired brain juries (Waldron et al., 2013). However, direct comparative trials with large sample sizes are needed to solidify equivalency and detect small differences.

Traditionally, psychological interventions are designed for a specific neurological disorder and target specific psychological outcomes. Topolovec-Vranic et al. (2010) is the only research study that can be closely compared to the current study, as they examined an online CBT-based program, MoodGym, on people with TBI to improve depression. However, unlike the current ICBT program, MoodGym was not a specialized program that was targeted for people with TBI. As such, differences were seen in the results, MoodGym did not demonstrate a clinically significant decline —indicated by a reduction in symptoms of 50% and absence of symptoms of depression for 6 months (Topolovec-Vranic et al., 2010). A significant strength of the current study was tailoring the ICBT content and delivery to meet the needs of patients with mTBI. Specifically, broad psychological skills in navigating the challenges of mTBI were taught, including case examples and stories of people with mTBI integrated throughout the intervention.

Unlike the study by Topolovec-Vranic et al. (2010), our ICBT program targeted depression and anxiety. Anxiety and depressive disorders share many characteristics. In the general primary health care population, anxiety disorders are the most frequent comorbid condition in patients with depression (Kobak et al., 2017), and there is a strong association between depression and anxiety (Kumar et al., 2017). Studies have reported that ICBT programs could be directed at the related diagnoses of generalized anxiety disorder and major depressive disorder, whether comorbid or not, without loss of efficacy (Newby et al., 2014; Titov et al., 2010).

It is possible that the current ICBT program was effective due to its transdiagnostic approach to delivering online mental health care, precisely addressing concerns related to depression and anxiety and teaching participants how to manage their symptoms. Gorman (1996) reported that among participants with both anxiety and depression, those that resolved their anxiety first were more likely to remain compliant with therapy. However, it is difficult to determine if this is why participants found the current ICBT program effective. More research is needed to understand the essential components of effective internet-delivered programs.

4.2.2 The ICBT Program on Self-efficacy and Quality of Life

In this study, participants experienced increased self-efficacy and quality of life post-treatment. The effect sizes for pre- and post-treatment mean differences were high for self-efficacy (Cohen's d = 1.285) and quality of life (Cohen's d = .941), demonstrating the ICBT programs' effectiveness.

Existing research suggests several reasons why ICBT may lead to better outcomes. ICBT provides the opportunity to review material at one's own pace, removed from the constraints of a group-based or even traditional individualized setting, which may facilitate learning and acquisition of core CBT principles (Andersson et al., 2013). Andrews and Williams (2015) suggested that people who internalize the skills of CBT principles and develop a sense of self-efficacy throughout treatment are better equipped to develop more adaptive responses when difficulties arise in the future. Participants had access to the program material beyond the active 10-week intervention period; this

provided an opportunity to review and consolidate the program content long term after the study have been completed. From the first lesson, the current ICBT program emphasized psychoeducation on mTBI, identifying and replacing dysfunctional beliefs about mTBI with realistic beliefs, and enhancing effective coping and a sense of self-control. Here, self-efficacy can be characterized as the skills and behaviours that prompt and reinforce the participant to spontaneously engage in the health-promoting behaviours they have learned through the ICBT program.

In the current study, people experienced at least a 50% increase in their quality-of-life post-treatment. Cicerone and Azulay (2007) found that perceived self-efficacy for managing cognitive symptoms is strongly and consistently associated with life satisfaction and quality of life post-TBI. Other studies have also found a strong association between high self-efficacy and quality of life (Schønning & Nordgreen, 2021). Evidence suggests that the influence of ICBT on self-efficacy could be indirectly mediated by improvements in depressive symptoms (Johansson et al., 2022). This is also supported by Schønning and Nordgreen (2021), who reported that high ICBT treatment self-efficacy predicted more significant symptom reduction for anxiety and lower dropout rates. Additionally, they suggested that evaluating for self-efficacy can help to identify patients at risk of dropping out and implement tools to prevent dropouts from ICBT (Schønning & Nordgreen, 2021). Thus, measuring self-efficacy and quality of life in clinician-guided ICBT can help researchers and clinicians understand who is most likely to benefit from it, and adaptions can also be made for those less likely to benefit. The current study did not evaluate the relationship between self-efficacy, quality of life, symptom reduction in depression and anxiety, and the dropout rate. However, it does indicate that these are areas that need to be addressed in future studies to further strengthen the application of the ICBT program, especially for people with mTBI.

4.3 Clinical Implications

This study expanded knowledge on the feasibility of ICBT programs to improve overall wellbeing after mTBI. There is a strong emphasis on the need for more targeted psychosocial rehabilitation programs and services to meet the needs of individuals recovering from mTBI (Pickelsimer et al., 2007; Andelic et al., 2021; Roy et al., 2002),

which the ICBT program could help to address. Several research studies suggest that one of the significant barriers to people receiving mental health care is stigma and access to services; this is especially challenging for people in rural communities (Sinclair et al., 2013; Thornicroft, 2008). Despite numerous past research studies indicating that a substantial proportion of people with TBI reported poor psychosocial health at 1-year post-injury, psychological counselling is the least frequently provided service to people with TBI (McCarthy et al., 2006; Andelic et al., 2021).

Some concerns exist regarding the use of ICBT among participants with TBI as they may experience difficulty accessing resources over the internet due to cognitive impairment (Bergquist et al., 2009). Studies found a trend where participants with more severe cognitive impairment post-TBI require longer time and assistance from others to access and use resources online through the internet (Diamond et al., 2003). However, Bergquist et al. (2008) found that people with a history of moderate-to-severe TBI and associated memory impairment can learn to use an internet-delivered cognitive rehabilitation program independently. In the current study, it was evident through the program credibility measures that people with mTBI was able to navigate the ICBT platform and content independently and found the program to be logical. Thus, this opens an opportunity to explore whether such programs can meet the needs of people with more severe cognitive impairment.

ICBT plays an important role in reaching a wider range of people, including those who have never received mental health care before (33% never sought care before), patients who want ICBT to complement medical care (45%) or as a resource while they wait for face-to-face care (13%; Hadjistavropoulos et al., 2014b). In this study, most participants were not receiving any psychological treatment (from a psychologist, psychiatrist, or psychotherapist), while half were taking medications to improve their mental health. Thus, with further evidence of efficacy it would be reasonable for primary health care providers to encourage their patients to seek a clinician-guided ICBT program as it can meet their mental care needs and eliminate the scarcity of mental health services.

This study had a broad distribution of participants from various areas, from large metropolitan cities to small towns and farms. People in rural areas are less likely to have access to medical care. Compared to their urban counterparts, patients from these areas need to travel two to three times further to see medical specialists than those living in urban areas (Chan et al., 2006). Therefore, providing mental health care services through the internet can improve accessibility. However, rural internet availability, although improving, can be a barrier to accessing care (Hale et al., 2010). For example, in 2015, 69% of rural residents reported using the internet, versus 75% of urban residents in America (Kumar et al., 2017). Topolovec-Vranic et al. (2010) also reported that half of the people (n=4) who dropped out from their online CBT program did so due to computer-related issues and lack of internet. Thus, although internet delivered mental health care services slowly breaks the urban-rural divide in accessibility by bringing the "office to the patient," issues related to internet access equity may still exist.

4.4 Limitations and Future Directions

This study has several limitations. The current study's goal was to assess feasibility rather than efficacy; thus it is limited on its ability to draw firm conclusions about the treatment effects of the ICBT program. The study's small sample size further adds to these limitations as there may be significant differences between the study sample and the population. Strong inferences about large populations from the study of small samples are difficult (Tipton et al., 2017). Further, the sample population in this study may not be representative of the larger brain injury population. In this study, all participants were Caucasian, with the majority of the sample female (75%), educated (70%), and with a mild-to-moderate level of depression and anxiety at baseline. A national survey conducted in the United States found that most people with TBI are Caucasian (72%), followed by African Americans (18%) and Hispanics (10%; Sander et al., 2018). Additionally, the sample consisted of an unequal proportion of males and females, which does not align with the proportions seen in the general TBI population, where males are overrepresented. Only one-third of individuals with TBI are women, and the odds of sustaining a TBI are 2.22 times higher in men than in women (Krishna et al., 2020). Furthermore, as most of the sample population have post-secondary education and less

severe depression and anxiety, the findings may be limited in generalizability. Larger studies with a more heterogeneous and diverse sample of participants may be necessary to establish the generalizability of the findings.

This study is further limited by its short follow-up, ten weeks. Although a longer-term follow-up of 3 months is planned and will be reported in the future, it is currently unclear if a longer study will demonstrate a similar level of feasibility given the clinician-engagement required for the ICBT program. Due to the lack of a control group, it is not possible to ascertain the effect of the intervention compared with other factors, including the natural trajectory of recovery. However, it is important to note that the magnitude of improvement observed is comparable to that observed in similar past trials (Gandy et al., 2016; Mehta et al., 2020; Gandy et al., 2020). Therefore, future trials with extended follow-up periods are necessary to assess whether improvements and benefits of ICBT are maintained long-term and whether the program can facilitate resilience to psychological difficulties.

In this study, participants were not restricted from receiving concurrent treatments elsewhere. Therefore, there is a possibility that participants could have started, changed, and stopped various treatments during the trial, which may have caused positive and/or negative effects on their wellbeing. Factors such as positive changes in personal health, interpersonal relationship, or other psycho-social factors may have also contributed to the improvement in symptoms, as has been reported in past studies (Gomez-Hernandez et al., 1997). Furthermore, participant self-report data on prescription medication use (50%) and mental health service (35%) use were collected, but their impacts were not evaluated. Thus, participants' medication use during the ICBT program could have influenced how they managed their depression and anxiety and contributed to the positive results in the patient-reported outcomes measure. More extensive randomized controlled trials may be necessary to evaluate the intervention's direct effect as well as to understand the use of pharmacotherapy while undergoing ICBT.

Lastly, ICBT requires comfort with computers and internet access; although no significant concerns were identified in this study, it may limit the ability of some

individuals to access the program. Cognitive linguistic (i.e., aphasia) and fine motor and/or age-related motor impairments after TBI may require specialized training materials and support so that increased independence in basic internet tasks can be achieved (Egan et al., 2005). In this study, the researchers attempted to overcome these barriers by strategically tailoring the web platform to increase access, comfort, and usability (e.g., access to materials through the mail; Guide telephone support; text-to-speech, user-centred design; Brunner et al., 2017; Martin et al., 2018).

4.5 Conclusion

In conclusion, this pilot study's findings support the use of ICBT among persons with mTBI. The study demonstrated the feasibility of the ICBT through ease of recruitment, high levels of adherence and program satisfaction. Weekly guidance from a clinician may have significantly increased satisfaction by tailoring the program to meet the needs of participants. Depression and anxiety are the most common psychological concerns experienced by people with mTBI. However, access to mental health services is often limited due to multiple factors, including socioeconomic disadvantage and stigma, issues of accessibility, geographical constraints and cost of services. Clinician-guided ICBT can help to overcome these barriers. While not its primary aim, this study was statistically and clinically significant in reducing symptoms of depression and anxiety, self-efficacy and quality of life.

From our experience in this pilot study, future clinical trials should evaluate: (1) the effects of ICBT on clinical outcome measures and possible mediating relationships between them; and (2) the duration of ICBT intervention effects over the long term. In addition, future studies should recruit a larger heterogeneous sample that best represents the overall mTBI population to allow for better generalizability of results.

Overall, ICBT is a feasible form of psychosocial service delivery among those with mTBI and mental health concerns. However, uncertainties regarding its effectiveness still stands thus further research is needed to solidify evidence and address the gaps seen in this study.

References

Alberts, N. M., Hadjistavropoulos, H. D., Dear, B. F., & Titov, N. (2017). Internet-delivered cognitive-behaviour therapy for recent cancer survivors: a feasibility trial. *Psycho-Oncology*, *26*(1), 137-139.

Albicini, M., & McKinlay, A. (2014). Mild traumatic brain injury: A review of terminology, symptomatology, clinical considerations and future directions. *Traumatic brain injury*, *1*.

Alderman, N., Dawson, K., Rutterford, N. A., & Reynolds, P. J. (2001). A comparison of the validity of self-report measures amongst people with acquired brain injury: A preliminary study of the usefulness of EuroQol-5D. *Neuropsychological Rehabilitation*, *11*(5), 529-537.

Almeida-Suhett, C. P., Prager, E. M., Pidoplichko, V., Figueiredo, T. H., Marini, A. M., Li, Z., ... & Braga, M. F. (2014). Reduced GABAergic inhibition in the basolateral amygdala and the development of anxiety-like behaviors after mild traumatic brain injury. *PloS one*, *9*(7), e102627.

Alway, Y., Gould, K. R., Johnston, L., McKenzie, D., & Ponsford, J. (2016). A prospective examination of Axis I psychiatric disorders in the first 5 years following moderate to severe traumatic brain injury. *Psychological medicine*, *46*(6), 1331-1341.

American Psychiatric Association, A. (1980). *Diagnostic and statistical manual of mental disorders* (Vol. 3). Washington, DC: American Psychiatric Association.

Andelic, N., Røe, C., Tenovuo, O., Azouvi, P., Dawes, H., Majdan, M., ... & CENTER-TBI Participants and Investigators. (2021). Unmet rehabilitation needs after traumatic brain injury across europe: results from the CENTER-TBI study. *Journal of clinical medicine*, *10*(5), 1035.

Andersson, G., & Cuijpers, P. (2009). Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. *Cognitive behaviour therapy*, *38*(4), 196-205.

Andersson, G., Hesser, H., Veilord, A., Svedling, L., Andersson, F., Sleman, O., ... & Carlbring, P. (2013). Randomised controlled non-inferiority trial with 3-year follow-up of internet-delivered versus face-to-face group cognitive behavioural therapy for depression. *Journal of affective disorders*, *151*(3), 986-994.

Andersson, G., Titov, N., Dear, B. F., Rozental, A., & Carlbring, P. (2019). Internet-delivered psychological treatments: from innovation to implementation. *World Psychiatry*, *18*(1), 20-28.

Andrews, G., Basu, A., Cuijpers, P., Craske, M. G., McEvoy, P., English, C. L., & Newby, J. M. (2018). Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: an updated meta-analysis. *Journal of anxiety disorders*, *55*, 70-78.

Andrews, G., & Williams, A. D. (2015). Up-scaling clinician assisted internet cognitive behavioural therapy (iCBT) for depression: a model for dissemination into primary care. *Clinical psychology review*, *41*, 40-48.

Ashman, T. A., Spielman, L. A., Hibbard, M. R., Silver, J. M., Chandna, T., & Gordon, W. A. (2004). Psychiatric challenges in the first 6 years after traumatic brain injury: cross-sequential analyses of Axis I disorders. *Archives of physical medicine and rehabilitation*, *85*, 36-42.

Bandelow, B., & Brasser, M. (2009). P. 4. c. 002 Clinical suitability of GAD-7 scale compared to hospital anxiety and depression scale-A for monitoring treatment effects in generalized anxiety disorder. *European Neuropsychopharmacology*, (19), S604-S605.

Bandura, A. (1997) Self-Efficacy: The Exercise of Control. NewYork:Freeman.

Barber, M., & Stott, D. J. (2004). Validity of the Telephone Interview for Cognitive Status (TICS) in post-stroke subjects. *International journal of geriatric psychiatry*, *19*(1), 75-79.

Batterham, P. J., Neil, A. L., Bennett, K., Griffiths, K. M., & Christensen, H. (2008). Predictors of adherence among community users of a cognitive behavior therapy website. *Patient preference and adherence*, *2*, 97.

Bauer, A. M., Chan, Y. F., Huang, H., Vannoy, S., & Unützer, J. (2013). Characteristics, management, and depression outcomes of primary care patients who endorse thoughts of death or suicide on the PHQ-9. *Journal of general internal medicine*, *28*(3), 363-369.

Baxter, M. G., & Croxson, P. L. (2012). Facing the role of the amygdala in emotional information processing. *Proceedings of the National Academy of Sciences*, *109*(52), 21180-21181.

Beck, A. T., & Alford, B. A. (2009). *Depression: Causes and treatment*. University of Pennsylvania Press.

Benjamin, C. L., Puleo, C. M., Settipani, C. A., Brodman, D. M., Edmunds, J. M., Cummings, C. M., & Kendall, P. C. (2011). History of cognitive-behavioral therapy in youth. *Child and Adolescent Psychiatric Clinics*, *20*(2), 179-189.

Bergquist, T., Gehl, C., Lepore, S., Holzworth, N., & Beaulieu, W. (2008). Internet-based cognitive rehabilitation in individuals with acquired brain injury: A pilot feasibility study. *Brain Injury*, *22*(11), 891-897.

Bergquist, T., Gehl, C., Mandrekar, J., Lepore, S., Hanna, S., Osten, A., & Beaulieu, W. (2009). The effect of internet-based cognitive rehabilitation in persons with memory impairments after severe traumatic brain injury. *Brain Injury*, *23*(10), 790-799.

Bombardier, C. H., Fann, J. R., Temkin, N. R., Esselman, P. C., Barber, J., & Dikmen, S. S. (2010). Rates of major depressive disorder and clinical outcomes following traumatic brain injury. *Jama*, *303*(19), 1938-1945.

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., ... & Fernandez, M. (2009). How we design feasibility studies. *American journal of preventive medicine*, *36*(5), 452-457.

Brandt, J., Spencer, M., & Folstein, M. (1988). The telephone interview for cognitive status. *Neuropsychiatry Neuropsychol Behav Neurol*, *1*(2), 111-117.

Brunner, M., Hemsley, B., Togher, L., & Palmer, S. (2017). Technology and its role in rehabilitation for people with cognitive-communication disability following a traumatic brain injury (TBI). *Brain injury*, *31*(8), 1028-1043.

Bryant, R. A., O'donnell, M. L., Creamer, M., McFarlane, A. C., Clark, C. R., & Silove, D. (2010). The psychiatric sequelae of traumatic injury. *American Journal of Psychiatry*, *167*(3), 312-320.

Buck, P. W. (2011). Mild traumatic brain injury: a silent epidemic in our practices. *Health & social work*, *36*(4), 299-302.

Bulloch, A. G., Fiest, K. M., Williams, J. V., Lavorato, D. H., Berzins, S. A., Jetté, N., ... & Patten, S. B. (2015). Depression—a common disorder across a broad spectrum of neurological conditions: a cross-sectional nationally representative survey. *General hospital psychiatry*, *37*(6), 507-512.

Caplan, B., Bogner, J., Brenner, L., Arciniegas, D., Raina, K. D., Morse, J. Q., ... & Whyte, E. (2016). Feasibility of a cognitive behavioral intervention to manage fatigue in individuals with traumatic brain injury: a pilot study. *Journal of head trauma rehabilitation*, *31*(5), E41-E49.

Carroll, L., Cassidy, J. D., Holm, L., Kraus, J., & Coronado, V. (2004a). Methodological issues and research recommendations for mild traumatic brain injury: the who collaborating centre task force on mild traumatic brain injury. *Journal of Rehabilitation Medicine*, *36*(1), 113-125.

Carroll, L., Cassidy, J. D., Peloso, P., Borg, J., Von Holst, H., Holm, L., ... & Pépin, M. (2004b). Prognosis for mild traumatic brain injury: results of the WHO Collaborating Centre Task Force on Mild Traumatic Brain Injury. *Journal of rehabilitation medicine*, *36*(0), 84-105.

Cassidy, J. D., Boyle, E., & Carroll, L. J. (2014). Population-based, inception cohort study of the incidence, course, and prognosis of mild traumatic brain injury after motor vehicle collisions. *Archives of physical medicine and rehabilitation*, *95*(3), S278-S285.

Centers for Disease Control and Prevention. National Center for Health Statistics. Mortality data on CDC WONDER. (n.d.) Available at: https://wonder.cdc.gov/mcd.html.

Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Traumatic Brain Injury & Concussion: Get the Facts About TBI. Atlanta (GA): Centers for Disease Control and Prevention. 2022. Available at: https://www.cdc.gov/traumaticbraininjury/get_the_facts.html

Chan, R., Dear, B. F., Titov, N., Chow, J., & Suranyi, M. (2016). Examining internet-delivered cognitive behaviour therapy for patients with chronic kidney disease on haemodialysis: a feasibility open trial. *Journal of psychosomatic research*, *89*, 78-84.

Chan, L., Hart, L. G., & Goodman, D. C. (2006). Geographic access to health care for rural Medicare beneficiaries. *The Journal of Rural Health*, *22*(2), 140-146.

Cho, M. J., & Jang, S. H. (2021). Relationship between post-traumatic amnesia and white matter integrity in traumatic brain injury using tract-based spatial statistics. *Scientific Reports*, *11*(1), 1-8.

Cicerone, K. D., & Azulay, J. (2007). Perceived self-efficacy and life satisfaction after traumatic brain injury. *The Journal of head trauma rehabilitation*, *22*(5), 257-266.

Collie, M. (2019). Therapy is expensive – here's how to make the most of your sessions. Global News. Available at: https://globalnews.ca/news/5495155/therapy-tips/

Cook, J. E., & Doyle, C. (2002). Working alliance in online therapy as compared to face-to-face therapy: Preliminary results. *CyberPsychology & Behavior*, *5*(2), 95-105.

Danila, O., Hirdes, J. P., Maxwell, C. J., Marrie, R. A., Patten, S., Pringsheim, T., & Jetté, N. (2014). Prevalence of neurological conditions across the continuum of care based on interRAIassessments. BMC health services research, 14(1), 29.

Daugherty, J., Waltzman, D., Sarmiento, K., & Xu, L. (2019). Traumatic brain injury–related deaths by race/ethnicity, sex, intent, and mechanism of injury—United States, 2000–2017. *Morbidity and Mortality Weekly Report*, *68*(46), 1050.

Dear, B. F., Fogliati, V. J., Fogliati, R., Gandy, M., McDonald, S., Talley, N., ... & Jones, M. (2018a). Transdiagnostic internet-delivered cognitive-behaviour therapy (CBT) for adults with functional gastrointestinal disorders (FGID): A feasibility open trial. *Journal of psychosomatic research*, *108*, 61-69.

Dear, B. F., Gandy, M., Karin, E., Staples, L. G., Johnston, L., Fogliati, V. J., ... & Titov, N. (2015). The Pain Course: a randomised controlled trial examining an internet-delivered pain management program when provided with different levels of clinician support. *Pain*, *156*(10), 1920.

Dear, B. F., Nicholson Perry, K., Siddall, P., Middleton, J. W., Johnson, J., Katte, L., ... & Titov, N. (2018b). The Pain Course: Exploring the feasibility of an internet-delivered pain management programme for adults with spinal cord injury. *Spinal Cord*, *56*(10), 931-939.

Desmond, D. W., Tatemichi, T. K., & Hanzawa, L. (1994). The Telephone Interview for Cognitive Status (TICS): reliability and validity in a stroke sample. *International journal of geriatric psychiatry*, *9*(10), 803-807.

Dewan, M. C., Rattani, A., Gupta, S., Baticulon, R. E., Hung, Y. C., Punchak, M., ... & Park, K. B. (2018). Estimating the global incidence of traumatic brain injury. *Journal of neurosurgery*, *130*(4), 1080-1097.

Diamond, B. J., Shreve, G. M., Bonilla, J. M., Johnston, M. V., Morodan, J., & Branneck, R. (2003). Telerehabilitation, cognition and user-accessibility. *NeuroRehabilitation*, *18*(2), 171-177.

Diaz, A. P., Schwarzbold, M. L., Thais, M. E., Hohl, A., Bertotti, M. M., Schmoeller, R., ... & Walz, R. (2012). Psychiatric disorders and health-related quality of life after severe traumatic brain injury: a prospective study. *Journal of Neurotrauma*, *29*(6), 1029-1037.

Dieleman, J.L., Baral, R., & Birger, M. (2016). U.S. Spending on Personal Health Care and Public Health, 1996–2013. *JAMA*. doi:10.1001/jama.2016.16885

Donker, T., Blankers, M., Hedman, E., Ljotsson, B., Petrie, K., & Christensen, H. (2015). Economic evaluations of Internet interventions for mental health: a systematic review. *Psychological medicine*, *45*(16), 3357-3376.

Egan, J., Worrall, L., & Oxenham, D. (2005). An Internet training intervention for people with traumatic brain injury: Barriers and outcomes. *Brain Injury*, *19*(8), 555-568.

EuroQoL Group. (1990). EuroQol-a new facility for the measurement of health-related quality of life. *Health policy*, *16*(3), 199-208.

Faul, M., Wald, M. M., Xu, L., & Coronado, V. G. (2010). Traumatic brain injury in the United States; emergency department visits, hospitalizations, and deaths, 2002-2006.

Faux, S., Sheedy, J., Delaney, R., & Riopelle, R. (2011). Emergency department prediction of post-concussive syndrome following mild traumatic brain injury—an international cross-validation study. *Brain injury*, *25*(1), 14-22.

Feeny, D. (2005). and quality-adjusted life years. *Assessing Quality of Life in Clinical Trials: Methods and Practice*, 405.

Feng, Y., Parkin, D., & Devlin, N. J. (2014). Assessing the performance of the EQ-VAS in the NHS PROMs programme. *Quality of Life Research*, *23*(3), 977-989.

Field, A. (2009). Discovering statistics using SPSS, Third Edition.

Fleminger, S. (2008). Long-term psychiatric disorders after traumatic brain injury. *European journal of anaesthesiology*, *25*(S42), 123-130.

Freund, T., Gensichen, J., Goetz, K., Szecsenyi, J., & Mahler, C. (2011). Evaluating self-efficacy for managing chronic disease: psychometric properties of the six-item Self-Efficacy Scale in Germanyjep_1764.

Gandy, M., Karin, E., Fogliati, V. J., Mcdonald, S., Titov, N., & Dear, B. F. (2016). A feasibility trial of an Internet-delivered and transdiagnostic cognitive behavioral therapy treatment program for anxiety, depression, and disability among adults with epilepsy. *Epilepsia*, *57*(11), 1887-1896.

Gandy, M., Karin, E., Fogliati, V. J., Meares, S., Nielssen, O., Titov, N., & Dear, B. F. (2018). Emotional and cognitive difficulties, help-seeking, and barriers to treatment in neurological disorders. *Rehabilitation Psychology*, *63*(4), 563.

Gandy, M., Karin, E., McDonald, S., Meares, S., Scott, A. J., Titov, N., & Dear, B. F. (2020). A feasibility trial of an internet-delivered psychological intervention to manage mental health and functional outcomes in neurological disorders. *Journal of psychosomatic research*, *136*, 110173.

Gorman, J. M. (1996). Comorbid depression and anxiety spectrum disorders. *Depression and anxiety*, *4*(4), 160-168.

Gomez-Hernandez, R., Max, J. E., Kosier, T., Paradiso, S., & Robinson, R. G. (1997). Social impairment and depression after traumatic brain injury. *Archives of physical medicine and rehabilitation*, *78*(12), 1321-1326.

Gould, K. R., Ponsford, J. L., Johnston, L., & Schönberger, M. (2011). Predictive and associated factors of psychiatric disorders after traumatic brain injury: a prospective study. *Journal of neurotrauma*, *28*(7), 1155-1163.

Greenwood, R. (1997). Value of recording duration of post-traumatic amnesia. *The Lancet*, *349*(9058), 1041-1042.

Hadjistavropoulos, H. D., Alberts, N. M., Nugent, M., & Marchildon, G. (2014b). Improving access to psychological services through therapist-assisted, Internet-delivered cognitive behaviour therapy. *Canadian Psychology/Psychologie canadienne*, *55*(4), 303.

Hadjistavropoulos, H. D., Pugh, N. E., Nugent, M. M., Hesser, H., Andersson, G., Ivanov, M., ... & Austin, D. W. (2014a). Therapist-assisted Internet-delivered cognitive behavior therapy for depression and anxiety: translating evidence into clinical practice. *Journal of anxiety disorders*, *28*(8), 884-893.

Hadjistavropoulos, H. D., Schneider, L. H., Hadjistavropoulos, T., Titov, N., & Dear, B. F. (2018). Effectiveness, acceptability and feasibility of an Internet-delivered cognitive behavioral pain management program in a routine online therapy clinic in Canada. *Canadian Journal of Pain*, *2*(1), 62-73.

Hale, T. M., Cotten, S. R., Drentea, P., & Goldner, M. (2010). Rural-urban differences in general and health-related internet use. *American Behavioral Scientist*, *53*(9), 1304-1325.

Hansson, L., Stjernswärd, S., & Svensson, B. (2014). Perceived and anticipated discrimination in people with mental illness—An interview study. *Nordic Journal of Psychiatry*, *68*(2), 100-106.

Haydel, M. J., Preston, C. A., Mills, T. J., Luber, S., Blaudeau, E., & DeBlieux, P. M. (2000). Indications for computed tomography in patients with minor head injury. *New England Journal of Medicine*, *343*(2), 100-105.

Head, J. (1993). Definition of mild traumatic brain injury. *J Head Trauma Rehabil*, *8*(3), 86-7.

Helgeson, S. R. (2010). Identifying brain injury in state juvenile justice, corrections, and homeless populations: Challenges and promising practices. *Brain Injury Professional*, *7*(4), 18-20.

Hesdorffer, D. C. (2016). Comorbidity between neurological illness and psychiatric disorders. *CNS spectrums*, *21*(3), 230-238.

Hofmann, S. G., Asnaani, A., Vonk, I. J., Sawyer, A. T., & Fang, A. (2012). The efficacy of cognitive behavioral therapy: A review of meta-analyses. *Cognitive therapy and research*, *36*(5), 427-440.

Hyder, A. A., Wunderlich, C. A., Puvanachandra, P., Gururaj, G., & Kobusingye, O. C. (2007). The impact of traumatic brain injuries: a global perspective. *NeuroRehabilitation*, *22*(5), 341-353.

IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.

Iverson, G. L., Brooks, B. L., Ashton, V. L., & Lange, R. T. (2010). Interview versus questionnaire symptom reporting in people with the postconcussion syndrome. *The Journal of head trauma rehabilitation*, *25*(1), 23-30.

Jain, S. & Iverson, L.M. (2021) Glasgow Coma Scale. In: StatPearls. StatPearls Publishing. Available at: https://www.ncbi.nlm.nih.gov/books/NBK513298/

Johansson, O., Bjärehed, J., Andersson, G., Carlbring, P., & Lundh, L. G. (2019). Effectiveness of guided internet-delivered cognitive behavior therapy for depression in routine psychiatry: A randomized controlled trial. *Internet interventions*, *17*, 100247.

Johansson, P., Lundgren, J., Andersson, G., Svensson, E., & Mourad, G. (2022). Internet-Based Cognitive Behavioral Therapy and its Association With Self-efficacy, Depressive Symptoms, and Physical Activity: Secondary Analysis of a Randomized Controlled Trial in Patients With Cardiovascular Disease. *JMIR cardio*, *6*(1), e29926.

Jones, S. L., Hadjistavropoulos, H. D., & Soucy, J. N. (2016). A randomized controlled trial of guided internet-delivered cognitive behaviour therapy for older adults with generalized anxiety. *Journal of anxiety disorders*, *37*, 1-9.

Jorge, R. E., & Starkstein, S. E. (2005). Pathophysiologic aspects of major depression following traumatic brain injury. *The Journal of head trauma rehabilitation*, *20*(6), 475-487.

Juengst, S. B., Adams, L. M., Bogner, J. A., Arenth, P. M., O'Neil-Pirozzi, T. M., Dreer, L. E., ... & Wagner, A. K. (2015). Trajectories of life satisfaction after traumatic brain injury: Influence of life roles, age, cognitive disability, and depressive symptoms. *Rehabilitation psychology*, *60*(4), 353.

Juengst, S. B., Kumar, R. G., & Wagner, A. K. (2017). A narrative literature review of depression following traumatic brain injury: prevalence, impact, and management challenges. *Psychology research and behavior management*.

Kelders, S. M., Kok, R. N., Ossebaard, H. C., & Van Gemert-Pijnen, J. E. (2012). Persuasive system design does matter: a systematic review of adherence to web-based interventions. *Journal of medical Internet research*, *14*(6), e2104.

Kobak, K. A., Wolitzky-Taylor, K., Craske, M. G., & Rose, R. D. (2017). Therapist training on cognitive behavior therapy for anxiety disorders using internet-based technologies. *Cognitive Therapy and Research*, *41*(2), 252-265.

Königs, M., de Kieviet, J. F., & Oosterlaan, J. (2012). Post-traumatic amnesia predicts intelligence impairment following traumatic brain injury: a meta-analysis. *Journal of Neurology, Neurosurgery & Psychiatry*, *83*(11), 1048-1055.

Krishna, G., Bromberg, C., Connell, E. C., Mian, E., Hu, C., Lifshitz, J., ... & Thomas, T. C. (2020). Traumatic brain injury-induced sex-dependent changes in late-onset sensory hypersensitivity and glutamate neurotransmission. *Frontiers in neurology*, *11*, 749.

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2003). The Patient Health Questionnaire-2: validity of a two-item depression screener. *Medical care*, 1284-1292.

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*, *16*(9), 606-613.

Kroenke, K., Spitzer, R. L., Williams, J. B., Monahan, P. O., & Löwe, B. (2007). Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection. *Annals of internal medicine*, *146*(5), 317-325.

Kumar, V., Sattar, Y., Bseiso, A., Khan, S., & Rutkofsky, I. H. (2017). The effectiveness of internet-based cognitive behavioral therapy in treatment of psychiatric disorders. *Cureus*, *9*(8).

Kureshi, N., Erdogan, M., Thibault-Halman, G., Fenerty, L., Green, R. S., & Clarke, D. B. (2021). Long-term trends in the epidemiology of major traumatic brain injury. *Journal of community health*, *46*(6), 1197-1203.

Langlois, J. A., Rutland-Brown, W., & Wald, M. M. (2006). The epidemiology and impact of traumatic brain injury: a brief overview. *The Journal of head trauma rehabilitation*, *21*(5), 375-378.

Lawson Health Research Institute. (2019, September 9). An online approach to care. Retrieved from https://www.lawsonresearch.ca/news/online-approach-care

Lin, M. R., Chiu, W. T., Chen, Y. J., Yu, W. Y., Huang, S. J., & Tsai, M. D. (2010). Longitudinal changes in the health-related quality of life during the first year after

traumatic brain injury. *Archives of physical medicine and rehabilitation*, *91*(3), 474-480.

Lorig, K. R., Ritter, P. L., Stewart, A. L., Sobel, D. S., Brown, B. W.,Bandura, A., Gonzalez, V. M., Laurent, D. D. & Holman, H. R. (2001). Chronic disease self-management program – 2-year health status andhealth care utilization outcomes.Medical Care, 39 (11), 1217–1223.4.

Malec, J. F., Testa, J. A., Rush, B. K., Brown, A. W., & Moessner, A. M. (2007). Self-assessment of impairment, impaired self-awareness, and depression after traumatic brain injury. *The Journal of Head Trauma Rehabilitation*, *22*(3), 156-166.

Marshall, S., Bayley, M., McCullagh, S., Velikonja, D., & Berrigan, L. (2012). Clinical practice guidelines for mild traumatic brain injury and persistent symptoms. *Canadian Family Physician*, *58*(3), 257-267.

Marshall, S., Bayley, M., McCullagh, S., Velikonja, D., Berrigan, L., Ouchterlony, D., & Weegar, K. (2015). Updated clinical practice guidelines for concussion/mild traumatic brain injury and persistent symptoms. *Brain injury*, *29*(6), 688-700.

Martin, S., Armstrong, E., Thomson, E., Vargiu, E., Solà, M., Dauwalder, S., ... & Daly Lynn, J. (2018). A qualitative study adopting a user-centered approach to design and validate a brain computer interface for cognitive rehabilitation for people with brain injury. *Assistive Technology*, *30*(5), 233-241.

McCarthy, M. L., Dikmen, S. S., Langlois, J. A., Selassie, A. W., Gu, J. K., & Horner, M. D. (2006). Self-reported psychosocial health among adults with traumatic brain injury. *Archives of physical medicine and rehabilitation*, *87*(7), 953-961.

McCrea, M., Iverson, G. L., McAllister, T. W., Hammeke, T. A., Powell, M. R., Barr, W. B., & Kelly, J. P. (2009). An integrated review of recovery after mild traumatic brain injury (MTBI): implications for clinical management. *The Clinical Neuropsychologist*, *23*(8), 1368-1390.

Mehta, S., Peynenburg, V. A., & Hadjistavropoulos, H. D. (2018). Internet-delivered cognitive behaviour therapy for chronic health conditions: a systematic review and meta-analysis. Journal of behavioral medicine, 1-19.

Mehta, S., Hadjistavropoulos, H., Nugent, M., Karin, E., Titov, N., & Dear, B. F. (2020). Guided internet-delivered cognitive-behaviour therapy for persons with spinal cord injury: a feasibility trial. *Spinal Cord*, *58*(5), 544-552.

Mehta, S., Hadjistavropoulos, H. D., Earis, D., Titov, N., & Dear, B. F. (2019). Patient perspectives of Internet-delivered cognitive behavior therapy for psychosocial issues post spinal cord injury. *Rehabilitation psychology*, *64*(3), 351.

Mena, J. H., Sanchez, A. I., Rubiano, A. M., Peitzman, A. B., Sperry, J. L., Gutierrez, M. I., & Puyana, J. C. (2011). Effect of the modified Glasgow Coma Scale score criteria for mild traumatic brain injury on mortality prediction: comparing classic and modified Glasgow Coma Scale score model scores of 13. *The Journal of trauma*, *71*(5), 1185.

Menon, D. K., Schwab, K., Wright, D. W., & Maas, A. I. (2010). Position statement: definition of traumatic brain injury. *Archives of physical medicine and rehabilitation*, *91*(11), 1637-1640.

Meyer, D. L., Davies, D. R., Barr, J. L., Manzerra, P., & Forster, G. L. (2012). Mild traumatic brain injury in the rat alters neuronal number in the limbic system and increases conditioned fear and anxiety-like behaviors. *Experimental neurology*, *235*(2), 574-587.

Michaels, A. J., Michaels, C. E., Smith, J. S., Moon, C. H., Peterson, C., & Long, W. B. (2000). Outcome from injury: general health, work status, and satisfaction 12 months after trauma. *Journal of Trauma and Acute Care Surgery*, *48*(5), 841-850.

Migliorini, C., Tonge, B., & Sinclair, A. (2011). Developing and piloting ePACT: A flexible psychological treatment for depression in people living with chronic spinal cord injury. *Behaviour Change*, *28*(1), 45-54.

Miller, G. F., Kegler, S. R., & Stone, D. M. (2020). Traumatic brain injury–related deaths from firearm suicide: United States, 2008–2017. *American journal of public health*, *110*(6), 897-899.

Mishra, P., Pandey, C. M., Singh, U., Gupta, A., Sahu, C., & Keshri, A. (2019). Descriptive statistics and normality tests for statistical data. *Annals of cardiac anaesthesia*, *22*(1), 67.

MoodGym. (n.d.). moodgym CBT training program. Retrieved from https://moodgym.com.au/info/faq

Moore, E. L., Terryberry-Spohr, L., & Hope, D. A. (2006). Mild traumatic brain injury and anxiety sequelae: a review of the literature. *Brain injury*, *20*(2), 117-132.

National Center for Injury Prevention and Control (US). (2003). *Report to Congress on mild traumatic brain injury in the United States: Steps to prevent a serious public health problem*. Centers for Disease Control and Prevention.

National Institute for Health and Care Excellence (NICE). (2009). Depression in adults with a chronic physical health problem: recognition and management, in: Clinical Guideline 91. National Institute for Health and Care Excellence: London.

Newby, J. M., Mewton, L., Williams, A. D., & Andrews, G. (2014). Effectiveness of transdiagnostic internet cognitive behavioural treatment for mixed anxiety and depression in primary care. *Journal of Affective Disorders*, *165*, 45-52.

Nolin, P., Villemure, R., & Heroux, L. (2006). Determining long-term symptoms following mild traumatic brain injury: Method of interview affects self-report. *Brain Injury*, *20*(11), 1147-1154.

Osman, A., Bagge, C. L., Gutierrez, P. M., Konick, L. C., Kopper, B. A., & Barrios, F. X. (2001). The Suicidal Behaviors Questionnaire-Revised (SBQ-R): validation with clinical and nonclinical samples. *Assessment*, *8*(4), 443-454.

Ouellet, M. C., Beaulieu-Bonneau, S., Sirois, M. J., Savard, J., Turgeon, A. F., Moore, L., ... & Laviolette, V. (2018). Depression in the first year after traumatic brain injury. *Journal of neurotrauma*, *35*(14), 1620-1629.

Pearson, C., Janz, T., Ali, J. (2013). Mental and substance use disorders in Canada. Health at a Glance 2013;1(September). Available: https://www150.statcan.gc.ca/n1/en/pub/82-624-x/2013001/article/11855-eng.pdf?st=prEwOLnA

Pickelsimer, E. E., Selassie, A. W., Sample, P. L., Heinemann, A. W., Gu, J. K., & Veldheer, L. C. (2007). Unmet service needs of persons with traumatic brain injury. *The Journal of head trauma rehabilitation*, *22*(1), 1-13.

Ponsford, J., Lee, N. K., Wong, D., McKay, A., Haines, K., Alway, Y., ... & O'Donnell, M. L. (2016b). Efficacy of motivational interviewing and cognitive behavioral therapy for anxiety and depression symptoms following traumatic brain injury. *Psychological medicine*, *46*(5), 1079-1090.

Ponsford, J. L., Spitz, G., & McKenzie, D. (2016a). Using post-traumatic amnesia to predict outcome after traumatic brain injury. *Journal of neurotrauma*, *33*(11), 997-1004.

Public Health Agency of Canada. (2020). Injury in review, 2020 edition: Spotlight on traumatic brain injuries across the life course.

Quintiliani, L. M., Mann, D. M., Puputti, M., Quinn, E., & Bowen, D. J. (2016). Pilot and feasibility test of a mobile health-supported behavioral counseling intervention for weight management among breast cancer survivors. *JMIR cancer*, *2*(1), e5305.

Rao, V., Bertrand, M., Rosenberg, P., Makley, M., Schretlen, D. J., Brandt, J., & Mielke, M. M. (2010). Predictors of new-onset depression after mild traumatic brain injury. *The Journal of neuropsychiatry and clinical neurosciences*, *22*(1), 100-104.

Rapoport, M. J. (2012). Depression following traumatic brain injury. *CNS drugs*, *26*(2), 111-121.

Rees, L., Marshall, S., Hartridge, C., Mackie, D., & Weiser, M. (2007). Cognitive interventions post acquired brain injury. *Brain injury*, *21*(2), 161-200.

Ritter, P. L., & Lorig, K. (2014). The English and Spanish self-efficacy to manage chronic disease scale measures were validated using multiple studies. *Journal of clinical epidemiology*, *67*(11), 1265-1273.

Roy, C. W., Thornhill, S., & Teasdale, G. M. (2002). Identification of rehabilitation problems after head injury. *Brain injury*, *16*(12), 1057-1063.

Rozental, A., Andersson, G., Boettcher, J., Ebert, D. D., Cuijpers, P., Knaevelsrud, C., ... & Carlbring, P. (2014). Consensus statement on defining and measuring negative effects of Internet interventions. *Internet interventions*, *1*(1), 12-19.

Ruwaard, J., Lange, A., Schrieken, B., & Emmelkamp, P. (2011). Efficacy and effectiveness of online cognitive behavioral treatment: a decade of interapy research. *Annual Review of Cybertherapy and Telemedicine 2011*, 9-14.

Salottolo, K., Levy, A. S., Slone, D. S., Mains, C. W., & Bar-Or, D. (2014). The effect of age on Glasgow Coma Scale score in patients with traumatic brain injury. *JAMA surgery*, *149*(7), 727-734.

Sander, A. M., Lequerica, A. H., Ketchum, J. M., Hammond, F. M., Gary, K. W., Pappadis, M. R., ... & Bushnik, T. (2018). Race/ethnicity and retention in traumatic brain injury outcomes research: a traumatic brain injury model systems national database study. *The Journal of head trauma rehabilitation*, *33*(4), 219.

Scholten, A. C., Haagsma, J. A., Cnossen, M. C., Olff, M., Van Beeck, E. F., & Polinder, S. (2016). Prevalence of and risk factors for anxiety and depressive disorders after traumatic brain injury: a systematic review. *Journal of neurotrauma*, *33*(22), 1969-1994.

Schønning, A., & Nordgreen, T. (2021). Predicting Treatment Outcomes in Guided Internet-Delivered Therapy for Anxiety Disorders—The Role of Treatment Self-Efficacy. *Frontiers in psychology*, *12*.

Seel, R. T., Macciocchi, S., & Kreutzer, J. S. (2010). Clinical considerations for the diagnosis of major depression after moderate to severe TBI. *The Journal of head trauma rehabilitation*, *25*(2), 99-112.

Simon, G. E., Rutter, C. M., Peterson, D., Oliver, M., Whiteside, U., Operskalski, B., & Ludman, E. J. (2013). Does response on the PHQ-9 Depression Questionnaire

predict subsequent suicide attempt or suicide death?. *Psychiatric services*, *64*(12), 1195-1202.

Sinclair, C., Holloway, K., Riley, G., & Auret, K. (2013). Online mental health resources in rural Australia: clinician perceptions of acceptability. *Journal of medical Internet research*, *15*(9), e2772.

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*, *166*(10), 1092-1097.

Stalder-Lüthy, F., Messerli-Bürgy, N., Hofer, H., Frischknecht, E., Znoj, H., & Barth, J. (2013). Effect of psychological interventions on depressive symptoms in long-term rehabilitation after an acquired brain injury: a systematic review and meta-analysis. *Archives of physical medicine and rehabilitation*, *94*(7), 1386-1397.

Stålnacke, B. M. (2007). Community integration, social support and life satisfaction in relation to symptoms 3 years after mild traumatic brain injury. *Brain injury*, *21*(9), 933-942.

Sussman, E. S., Pendharkar, A. V., Ho, A. L., & Ghajar, J. (2018). Mild traumatic brain injury and concussion: terminology and classification. *Handbook of clinical neurology*, *158*, 21-24.

Teasdale, T. W., & Engberg, A. W. (2001). Suicide after traumatic brain injury: a population study. *Journal of Neurology, Neurosurgery & Psychiatry*, *71*(4), 436-440.

Thiese, M. S. (2014). Observational and interventional study design types; an overview. *Biochemia medica*, *24*(2), 199-210.

Thompson, L., & McCabe, R. (2012). The effect of clinician-patient alliance and communication on treatment adherence in mental health care: a systematic review. *BMC psychiatry*, *12*(1), 1-12.

Thornicroft, G. (2008). Stigma and discrimination limit access to mental health care. *Epidemiology and Psychiatric Sciences*, *17*(1), 14-19.

Tiersky, L. A., Anselmi, V., Johnston, M. V., Kurtyka, J., Roosen, E., Schwartz, T., & DeLuca, J. (2005). A trial of neuropsychologic rehabilitation in mild-spectrum traumatic brain injury. *Archives of physical medicine and rehabilitation*, *86*(8), 1565-1574.

Tipton, E., Hallberg, K., Hedges, L. V., & Chan, W. (2017). Implications of small samples for generalization: Adjustments and rules of thumb. *Evaluation review*, *41*(5), 472-505.

Titov, N., Andrews, G., Davies, M., McIntyre, K., Robinson, E., & Solley, K. (2010). Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. *PloS one*, *5*(6), e10939

Topolovec-Vranic, J., Cullen, N., Michalak, A., Ouchterlony, D., Bhalerao, S., Masanic, C., & Cusimano, M. D. (2010). Evaluation of an online cognitive behavioural therapy program by patients with traumatic brain injury and depression. *Brain Injury*, *24*(5), 762-772.

Truitt, W. A., Johnson, P. L., Dietrich, A. D., Fitz, S. D., & Shekhar, A. (2009). Anxiety-like behavior is modulated by a discrete subpopulation of interneurons in the basolateral amygdala. *Neuroscience*, *160*(2), 284-294.

Tsaousides, T., D'Antonio, E., Varbanova, V., & Spielman, L. (2014). Delivering group treatment via videoconference to individuals with traumatic brain injury: a feasibility study. *Neuropsychological rehabilitation*, *24*(5), 784-803.

Uebelacker, L. A., German, N. M., Gaudiano, B. A., & Miller, I. W. (2011). Patient health questionnaire depression scale as a suicide screening instrument in depressed primary care patients: a cross-sectional study. *The primary care companion for CNS disorders*, *13*(1), 27081.

Valente, S. M., & Fisher, D. (2011). Traumatic brain injury. *The Journal for Nurse Practitioners*, *7*(10), 863-870.

Verwer, J. H., Van Leeuwen, C. M. C., Bolier, L., & Post, M. W. M. (2016). Feasibility of an online well-being intervention for people with spinal cord injury: a pilot study. *Spinal cord*, *54*(6), 473-477.

Waldron, B., Casserly, L. M., & O'Sullivan, C. (2013). Cognitive behavioural therapy for depression and anxiety in adults with acquired brain injury. What works for whom?. *Neuropsychological Rehabilitation*, *23*(1), 64-101.

Webb, C. A., Rosso, I. M., & Rauch, S. L. (2017). Internet-based cognitive behavioral therapy for depression: current progress & future directions. *Harvard review of psychiatry*, *25*(3), 114.

Whelan-Goodinson, R., Ponsford, J., Johnston, L., & Grant, F. (2009). Psychiatric disorders following traumatic brain injury: their nature and frequency. *The Journal of head trauma rehabilitation*, *24*(5), 324-332.

Whelan-Goodinson, R., Ponsford, J. L., Schönberger, M., & Johnston, L. (2010). Predictors of psychiatric disorders following traumatic brain injury. *The Journal of head trauma rehabilitation*, *25*(5), 320-329.

Williamson, M. L., Elliott, T. R., Berry, J. W., Underhill, A. T., Stavrinos, D., & Fine, P. R. (2013). Predictors of health-related quality-of-life following traumatic brain injury. *Brain Injury*, *27*(9), 992-999.

Wolfson, C., Fereshtehnejad, S. M., Pasquet, R., Postuma, R., & Keezer, M. R. (2019). High burden of neurological disease in the older general population: results from the Canadian Longitudinal Study on Aging. European journal of neurology, 26(2), 356-362.

World Health Organization. (1996). Ad Hoc Committee on Health Research Relating to Future Intervention Options & World Health Organization. Special Programme for Research and Training in Tropical Diseases. Investing in health research and development: report of the Ad Hoc Committee on Health Research Relating to Future Intervention Options. https://apps.who.int/iris/handle/10665/63024

Yehene, E., Lichtenstern, G., Harel, Y., Druckman, E., & Sacher, Y. (2020). Self-efficacy and acceptance of disability following mild traumatic brain injury: A pilot study. *Applied Neuropsychology: Adult*, *27*(5), 468-477.

Appendices

Appendix A: Ethics Approval Form

Western Research

Date: 7 April 2021

To: Dr Swati Mehta

Project ID: 116271

Study Title: Internet delivered cognitive behavioural therapy for persons with mild traumatic brain injury: Pilot Phase 2

Application Type: HSREB Initial Application

Review Type: Full Board

Meeting Date: 23/Feb/2021

Date Approval Issued: 07/Apr/2021

REB Approval Expiry Date: 07/Apr/2022

Dear Dr Swati Mehta

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. **All other required institutional approvals and mandated training must also be obtained prior to the conduct of the study**.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
Patient Health Questionnaire-PHQ-9; Kroenke et al. 2001	Online Survey	Received March 25, 2021	
Generalized Anxiety Disorder- GAD-7; Spitzer et al. 2006	Online Survey	Received March 25, 2021	
Quality of Life- EQ5D; EuroQol Research, 2015	Online Survey	Received March 25, 2021	
Program Credibility_ICBTForPers	Online Survey	Received March 25, 2021	
Program Satisfaction_ICBTForPer	Online Survey	Received March 25, 2021	
Working Alliance_ICBTForPersons	Online Survey	Received March 25, 2021	
Brief Pain Inventory Short Form_IC	Online Survey	Received March 25, 2021	
Self-Efficacy For Managing Chronic Condition	Online Survey	Received March 25, 2021	
Online screening consent-ICBT for persons with mTBI	Online Survey	Received March 25, 2021	1
Updated-Online Screen-ICBT for mTBI	Online Survey	07/Mar/2021	2
ICBT For mTBI Protocol v2 clean copy	Protocol	25/Mar/2021	2
ICBT consent v3 clean copy	Written Consent/Assent	25/Mar/2021	3

Documents Acknowledged:

Document Name	Document Type	Document Date
Budget ICBT-mTBI	Study budget	Received March 25, 2021

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB , except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Karen Gopaul , Ethics Officer on behalf of Dr. Philip Jones, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Appendix B: Online Screening Consent Form

Online Screening Consent

Letter of Informed Consent for Online Screen

Project Title: Internet delivered cognitive behaviour therapy course for persons with mild traumatic brain injury

Investigator: Dr. Swati Mehta, Scientist, Parkwood Institute Research,

Lawson Health Research Institute,

Phone: [redacted]

Sponsor: Lawson Health Research Institute

The purpose of this study is to examine the acceptability and feasibility of Online-CBT for assisting clients who have been diagnosed with a mild traumatic brain injury.

Please take the time to carefully read the following information. If any information is unclear, please email the researcher, Dr. Swati Mehta, [redacted] for clarification. You may also phone [redacted]

Purpose of the Screening: The purpose of the screening is to assess your present concerns and determine whether you are eligible for ICBT course.

Overview: The courses provide education on depression and anxiety and also discuss cognitive, behavioural and physical strategies for managing symptoms. The courses are short-term and typically require clients to review the materials presented online on a weekly basis as well as to practice skills that are taught in the courses. All clients who receive courses from us are asked to complete brief questionnaires before, during and after participating the courses in order to help us evaluate the courses. The courses sessions take approximately 1-2 hours of a participants time a week, with additional self-learning assignments that can take another 1 hour. The screening takes approximately 30 minutes. The weekly questionnaires take 5 minutes.

Format of the Screening

Pre-Online Screening: Once you consent to the screening, you will be asked some basic eligibility questions. If you are not eligible for the course, the Online Screening will terminate and you will be given information about why you are not eligible. You can contact the researcher to discuss your eligibility further if you wish. This first part of the Online Screening will likely take 5 minutes.

Full Online Screening: If you meet basic eligibility for the course you will be asked to provide basic personal information such as name, address, telephone number, and email address before continuing. This information is necessary for Research team to contact you to discuss the results of the Online Screening. In the screening, you will be presented with questions asking about your background, symptoms of anxiety and depression, other mental health concerns, health, relationships, occupation, and treatment history. Additionally, at this time we request the name and contact information for a medical contact, such as your physician. Once you have consented to participate in the study, the research team will send a Physician Notification Form to the medical contact you provided so that he or she is aware of your participation, and has the opportunity to express any concerns he or she may have regarding your participation in ICBT. Additional contact may occur between the research team and your medical contact as needed in the case of an emergency and the purpose of continuity of care. Lastly, you will also be asked some questions about your perceptions of the Online Screening process. We anticipate that this Online Screening will likely take 15-35 minutes to complete, depending on the responses you provide.

Telephone Screening: Following the completion of the Online Screening a staff member will contact you by phone to discuss the results of the Online Screening with you and let you know if you are eligible for one of our studies. It typically takes us 2 to 3 business days to arrange this phone call. We anticipate that this Telephone Screening will likely take 20 minutes to complete, depending on the responses you provide. The 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. Please note: The ICBT course is not for everyone. Individuals that are experiencing high levels of distress may benefit from traditional face to face programs. Participation in the Online Screening does not guarantee participation in ICBT courses.

Voluntary Participation & Ability to Withdraw:

Participation in the screening is entirely voluntary. Should you choose not to participate, or if you wish to stop the screening at any time after starting, you may do so without any consequences to your present or future health care. However, once the data has been pooled for analysis after the course has been completed, withdrawal from the study will no longer be possible. The information you have provided will be retained by researchers.

Limits of Confidentiality:

The responses you provide are confidential although there are certain limits to confidentiality that every participant must be aware of:

If you pose an immediate threat to your life, or another individual's life, confidentiality may be broken in order to prevent harmIf you disclose information suggesting that any child is at risk of abuse, the appropriate authorities will have to be notifiedIf you become involved in a legal case, the judge has the right to subpoena any information relevant to the legal problemThere are unique risks that may compromise your privacy that exist with any Internet-based service. A description of these risks follows:1. Any computer connected to the Internet will store information about visited websites on the Internet in the browser's history list and the browser's cache. The responses to the questionnaires are only temporarily stored on your computer until you close down your browser window. In other words, after you complete and submit your responses, your computer will discard this information, although some of this information may remain in your browser's cache. You may delete this information by clearing your history list and browser's cache.

2. After you complete the Online Screening, the information you provide will be sent directly to the survey software website over a secure connection. The information will then be encrypted and securely stored in the database at which point it is only accessible by the staff.

Methods Used to Protect Your Information:

The staff has taken precautions to protect the security of your information. The REDcap servers at Lawson Health Research Institute 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).

In addition to these security precautions, 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 their information.

There are 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. 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 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 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. Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable 3rd party software, such as ZoneAlarm. Firewalls protect your computer and information from network attacks and threats.

5. 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.

6. 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 3rd parties.

Use of Information Collected through the Screening:

Information gathered through the screening will be used for three purposes.

1. To determine eligibility for participation in the ICBT course:

If in the process of the follow-up telephone discussion of your online screening with a staff it is determined that participation in the ICBT course would be appropriate, your screening will become part of your file. If in the process of the follow up telephone discussion of your online screening with the staff it is determined that you do not meet criteria, the Staff member will attempt to provide you with options available to you in your community.2. To better assist with the education you receive with the ICBT course.

3. To be used in de-identified form (identifying information removed) by researchers to evaluate the Online Screening and ICBT Course and to help guide the development of future screening tools and courses offered. Any publications stemming from the evaluation of this information will examine all 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 their secure server housed at Lawson Health Research Institute until we retrieve this information. This server is located in Canada and information on that server is covered by the Canadian Privacy Act.

2. All information will be kept securely on REDcap servers at Lawson Health Research Institute for a period of ten years.

Questions about the Study

If you have any questions or concerns with the course, contact the Swati Mehta at [redacted] or [redacted]

Screening start time:	_____

We recommend that you download a copy of this consent form for your records by pressing the button below.

[Attachment: "Online screening consent v2.pdf"]

I have read the study information above and have had any questions answered to my satisfaction.	◯ Yes ◯ No
I am aware that I can contact the Researcher, Dr. Swati Mehta, at swati.mehta@sjhc.london.on.ca or call 519-685-4292x42359.	◯ Yes ◯ No
I am aware that any questions regarding my rights as a participant may be addressed to the committee through the University of Western Ontario Office of Research Ethics (519) 661-3036, email: ethics@uwo.ca.	◯ Yes ◯ No
I understand that the information I give through the online screening will only be shared with appropriate research staff and will be kept confidential unless I pose an immediate threat to my life, or another individual's life, or if I disclose information suggesting that any child is at risk of abuse.	◯ Yes ◯ No
I understand that my participation is voluntary and that I am free to withdraw at any time.	◯ Yes ◯ No
I understand that when the results of the study are published, I will not be personally identifiable.	◯ Yes ◯ No
I understand that this course is not right for everyone. After I complete the online screening, I will be contacted at the phone number I provide to the research team to discuss the results.	◯ Yes ◯ No
Do you freely and voluntarily consent to take part in this Online Screening? That is, do you consent to completing the Online Screening to the best of your ability, providing your contact information, and being contacted by a research staff member to discuss the results.	◯ Yes ◯ No

The screening can only be completed by individuals who consent to the conditions in the screening.

At this time, we suggest you contact the researcher, Dr. Swati Mehta, at swati.mehta@sjhc.london.on.ca, to ask any questions that you may have regarding online screening for this study.

Thank you for consenting to take part in the Online Screening. As mentioned in the consent form, in this part of the screening, you will be asked some basic eligibility questions. If your responses indicate that you do not meet the basic eligibility requirements to take part in one of our courses, you will receive an immediate computer generated response informing you that you are not eligible and you will not be asked any further questions.

Appendix C: ICBT Letter of Information and Consent Form.

ICBT consent form

Letter of Information and Consent

Project Title: Internet delivered cognitive behaviour therapy course for persons with mild traumatic brain injury: Pilot Phase 2

Investigator: Dr. Swati Mehta, Scientist, Parkwood Institute Research,
Lawson Health Research Institute, Phone: [redacted]

Sponsor: Lawson Health Research Institute

Invitation to Participate

You are being invited to participate in this research study because of your mild traumatic brain injury (mTBI). The goal of the study is to determine the acceptability and feasibility of an internet delivered cognitive behaviour therapy (ICBT) course designed specifically for individuals with mTBI.

Background/Purpose

Canadians living with neurological conditions, which stem from brain injury or stroke, face many long-term challenges with reduced functioning and activity limitations. In addition, it has been found that physical and mental conditions are more common in individuals with a neurological condition. Research suggests that some mental conditions among those with neurological conditions may have negative effects on rate of recovery and success of rehabilitation.

Cognitive Behavioural Therapy (CBT) has been shown in several studies to improve an individual's psychological health by modifying emotional, behavioural, and cognitive responses that would otherwise not adjust well to certain environments or situations.

Resource limitations can restrict the ability of service providers to deliver CBT in the community, and the study team believes that internet-delivered CBT (ICBT) may offer an alternative approach.

Procedures

Approximately twenty participants will be invited to participate in this study. Participants will be recruited from Outpatient clinic at Parkwood.

If you decide to participate in this study, you will be asked to participate in ICBT sessions, as well as complete additional self-learning assignments, and complete weekly questionnaires at the beginning of each session. To fully understand whether this course is effective, you will be asked to complete additional questions about your symptoms and quality of life. These questionnaires will be completed before you start the study, after you complete the study, and again 3-months after study completion. These questionnaires should take roughly 15-30 minutes to complete.

In addition to the above questions, you will also answer questions at the end of intervention regarding your relationship with your Guide, Randy Upper, and your satisfaction with the service at the end of the Course.

Sessions will take approximately 1-2 hours of your time per week. Some courses may also include additional self-learning assignments that can take another 1 hour. The screening takes approximately 30 minutes. The weekly questionnaires take 5 minutes. You will have 10 weeks to complete the ICBT course. It is recommended that you spend 1 week on lessons 1 and 3, and 2 weeks on lessons 2, 4, 5, and 6. You will be contacted three months after you complete the study for a follow-up. Please inform the study team of any changes in your physical or mental

health status that may have an impact on your ability to participate in the Course.

ICBT Course: The ICBT Course for persons with mTBI includes 6 core lessons. Lessons consist of materials that are accessed and read online and printable materials that you can retain for longer term use. With each lesson, you will be asked to complete various exercises to assist you in applying these new skills in your daily life.

Your course will cover the following information:

Lesson 1: Introduction to the purpose and content of the course; education about anxiety, low mood and depression; and an opportunity to learn about the 3 primary symptoms and the cycle of symptoms.

Lesson 2: Education about unhelpful thoughts and practical strategies to learn to manage them.

Lesson 3: Education about the physical symptoms associated with anxiety and depression and skills for managing them.

Lesson 4: Education about problematic behaviours associated with anxiety and depression and practical skills for overcoming these symptoms.

Lesson 5: Education about strategies for improving memory and attention

Lesson 6: Summary of the key messages, preparation to end the course, planning for after intervention, and relapse prevention.

Guidance: In the course, you will receive emails from your Guide to provide brief but important reminders from the research team. These emails will provide you with guidance regarding the weekly lessons. The emails will also ask you to complete questionnaires that are important to understanding how you are doing in the course. In addition to these emails, you will be assigned to a trained Guide located at Lawson Health Research Institute, Parkwood Institute based on availability of the Guide.

Guide contact is primarily by email using the online platform. Using the message system that exists on this website, you may message your Guide to receive assistance with the lessons and exercises. You are free to contact your Guide when it is convenient for you. Please note that your Guide will aim to respond to your emails on the check-in day provided. If for some reason a Guide is unavailable, he/she will email you to explain the delay.

Most contact with the Guide is by email, however, if your Guide notices that there has been a large increase in your depressive symptoms and/or you are having frequent thoughts about death or hurting yourself, then your Guide will contact you by telephone to gain more information and to provide support. The telephone call will be used to gain additional information about your situation. If the Guide determines that you are at high risk, then confidentiality will need to be broken. The Guide will have to contact either: your family physician, or 911 depending on the situation.

If the Guide is unable to make contact with you directly and significant concerns exist about your psychological status and safety, the Guide may utilize the emergency contact you provided during the screening interview (Family Physician) to ensure your safety.

The Course is not a crisis service and may not be able to respond immediately. In the event that your circumstances change during your participation in ICBT and 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.

Other times your Guide may call you, is if the need arises to discuss clinical issues with you in more detail.

At the end of the 10 week intervention, you will no longer have contact with your Guide, but you will continue to have

access to the lesson material. In total, you will have access to the ICBT course for 6 months from when you begin intervention. You will also be able to message the Researchers, Dr. Swati Mehta at swati.mehta@sjhc.london.on.ca with any questions during that follow-up time.

Voluntary Participation

Participation in ICBT is voluntary. Should you choose to not participate, or if you wish to withdraw from intervention at any time after starting, you may do so without any consequences to your present or future health care. However, once the data has been pooled for analysis after the course has been completed that is 3 months after the start of the program, withdrawal from the study will no longer be possible. The information that you have already provided will be retained by researchers.

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

Withdrawal from Study

You may withdraw from participation in the study at any time. Otherwise, study will be complete when you have completed the course. If you would like to refer to the lessons after study, you may do so by printing off the desired materials prior to your account being deactivated. If you do decide to discontinue ICBT, please inform the research team. If you do not communicate your withdrawal, the Research team will be required to continue attempting to contact you until the end of the study period.

Once you let the team know that you wish to withdraw from ICBT, you will be given the option to return to the site and provide your feedback on your experience and answer the same questionnaires that you would have answered if you had completed study.

In the event your participation is terminated (e.g., your withdrawal of participation from the course), your physician or medical clinic may be notified for the purpose of continuity of care.

Potential Benefits & Challenges

There are potential benefits and challenges associated with ICBT.

Potential Benefits Potential Challenges

You do not need to schedule an appointment for ICBT

You avoid having to visit an office if things like transportation, stigma, or your own availability are of concern

You can have more control when you work on the activities

You can access the online material from the location of your choice at your convenience. If you would like to continue referencing materials after the course, you can print off the pages.

You can e-mail your Guide through our secure website

You may feel more comfortable disclosing personal information online than in person

ICBT may require more self-motivation than face-to-face programs

Without non-verbal cues, there is a greater potential for misinterpretation of e-mail messages between you and your Guide

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 Guide· ICBT is a newer form of intervention, so there has been less research conducted when compared to face-to-face programs

Alternatives to Being in the Study

Before consenting to this type of intervention, you should consider the alternatives to ICBT, including in-person intervention, confiding in friends or family, taking part in community programs that may be available to you, written self-help resources, visiting a family physician, or not seeking intervention at all. It is also possible that during the course of ICBT, the we may determine that in-person programs 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 present, if you require specialized medical intervention, or if you need support that is more long-term, interactive, or intensive. ICBT may also not be suitable for you if you are unable to keep up with the suggested timeline of one to two weeks per lesson. If in-person program is more suitable for you, we will assist you in finding appropriate in-person services in your area, with your consent.

Confidentiality

The information collected in the study will be used for research purposes only, and neither your name nor any information which could identify you will be used in any publication or presentation of the study results. Information collected in this study will be stored for up to 15 years and only those involved in the study will have access.

For the purpose of evaluating the ICBT, your responses to questionnaires will be extracted from the website and kept in a computer file that will be available to the research team. This file will not contain any of your identifying information. The de-identified data will be kept on the PI's St. Joseph's Health Care London, hospital network drive.

Representatives of The University of Western Ontario Health Sciences Research Ethics Board and/or Quality Assurance and Education (QAEP) Officers from Lawson Health Research Institute (Lawson) may audit this research study for quality assurance purposes. Thus, by agreeing to participate in this research trial, you consent to give representatives of The University of Western Ontario Research Ethics Board and Lawson Health Research Institute's QAEP access to your research-related medical records to ensure the proper conduct of the research and verify the accuracy of the collected data. Participants' privacy will be protected to the maximum extent allowable by law.

In addition, as an internet-based study, there are unique risks that may compromise your privacy that exist with any internet-based service. The following is a description of these potential risks:

Data from this study will be stored on REDCap servers at Lawson Health Research Institute. The online file consists of the e-mails you exchange with your Guide, notes your Guide takes related to your case, forms you complete online, the email address that you provided to the unit in the screening interview, and the telephone screening interview (e.g., personal information, questions about depression and anxiety). The REDcap servers at Lawson Health Research Institute are protected with generally available security technologies, including firewalls and data encryption. Access to the server will be strictly controlled. This means that limits are in place for who has access to the server. The only people with access are the researchers and the server administrators.

When submitting information to your Guide through the internet, including questionnaires and e-mail messages, there is a possibility your information will be intercepted by unauthorized third parties using sophisticated tools. In order to limit this risk, the web platform system, housed in secure facilities at Lawson Health Research Institute, utilizes encryption in the form of HTTPS to transmit the data both to and from yourself and your Guide. The data that is stored within the web system, such as messages to your Guide and responses to questionnaires, are encrypted with AES encryption. Furthermore, the system itself uses strict access controls whereby users of this system are only able to access their own information.

Methods Used to Protect Your Information

There are participant variables that cannot be controlled by the researcher. For example, the type of computers used by participants and the settings in which they are used cannot be controlled by the researcher. Examples include using a shared computer, using a computer that has been compromised, or transmitting data on an unsecured network (e.g., public computers). However, there are also various things that you can do to protect your information:

Use your home computer instead of a computer in a shared space, such as a library or office.Make sure the computer you are sending emails from is secure.Do not share your login information with anyone. In the event you were contacted and asked for your password please contact the unit directly to report it.Do not use a password that is easily guessed by others, or a password that you have used before.When you leave your computer, or are done working with the web application ensure you have logged out.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.Enable either the firewall software that came with your operating system (e.g. Windows firewall), or install a reputable 3rd party firewall program.Use anti-virus software to both prevent and recover from virus programs.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 3rd parties.Guide Communications: As a client, you agree not to share your Guide's communications with anyone else unless your Guide's written and informed consent is first obtained. You also agree not to give advice based on the Guide's communications, or show Guide communications to others, out of context.

For the purposes of understanding the process of care in an online format, email exchanges between Guide and client may be examined by researchers. If email exchanges are examined, we will ensure that identifying information is not revealed.

For Your Safety:

In event of an emergency, such as high suicide risk, we will contact your family physician or medical clinic whose information you provided to us in the screening interview in order to discuss intervention options. In communication with your physician or medical clinic, the Research staff will include your name, heath card number, and your birth date to identify you.

Costs

The program is offered free of costs to participants.

Compensation

Participants will receive an honorarium as an Amazon e-gift card in the amount of $25 for completing the post-intervention questionnaires and $25 for completing the 3-month follow up questionnaires. Compensation is not dependent on completing the course itself. Once participants complete the post-intervention and 3-month follow-up questionnaires they will receive email with their gift card information.

Questions about the Study

If you have any questions or concerns with the course, contact the Researcher, Dr. Swati Mehta at [redacted] or [redacted]

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics [redacted], email: [redacted] The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential.

Or

St. Joseph's Health Care London Patient Relations Consultant at [redacted]

Screening start time: _____	
We recommend that you download a copy of this consent form for your records by pressing the button below. [Attachment: "ICBT consent v3.2.pdf"]	
I have read the study information above and have had any questions answered to my satisfaction.	◯ Yes ◯ No
I am aware that I can contact the researcher, Dr. Swati Mehta at swati.mehta@sjhc.london.on.ca	◯ Yes ◯ No
I am aware that any questions regarding my rights as a participant may be addressed to the committee through the University of Western Ontario Office of Research Ethics (519) 661-3036, email: ethics@uwo.ca.	◯ Yes ◯ No
I understand that when the results of the study are published, I will not be personally identifiable.	◯ Yes ◯ No
Do you freely and voluntarily consent to take part in this Study?	◯ Yes ◯ No
The program is only available to individuals who consent to the conditions. At this time, we suggest you contact the Researcher, Dr. Swati Mehta at swati.mehta@sjhc.london.on.ca, to ask any questions that you may have regarding this study.	
Thank you for consenting to take part in the study.	

Appendix D: Pre-analysis: Test of Assumptions for Paired Sample T-tests.

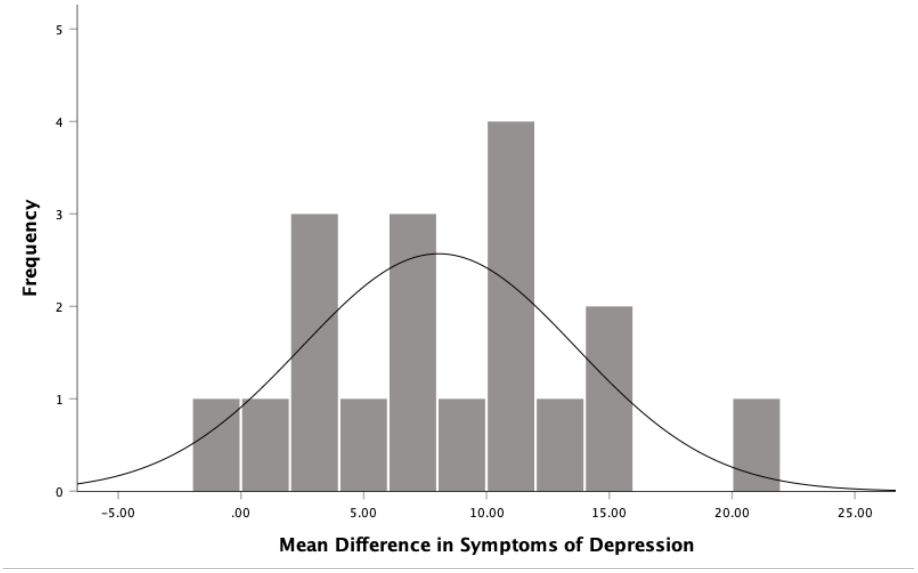

Figure 4. Histogram demonstrating the normal distribution of the mean difference in symptoms of depression (PHQ-9).

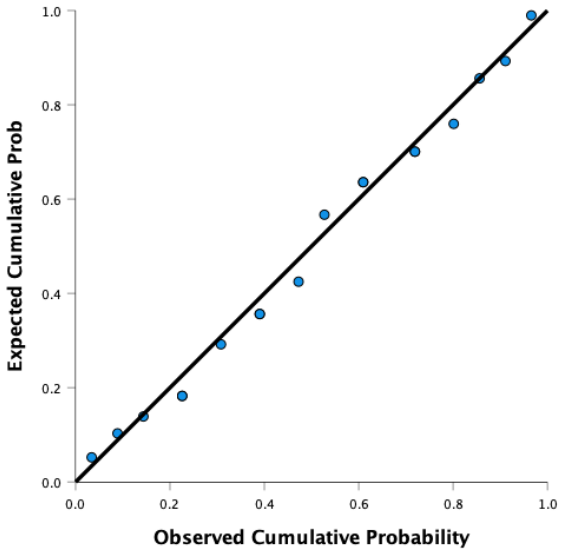

Figure 5. Probability-Probability plot of the mean difference in symptoms of depression (PHQ-9).

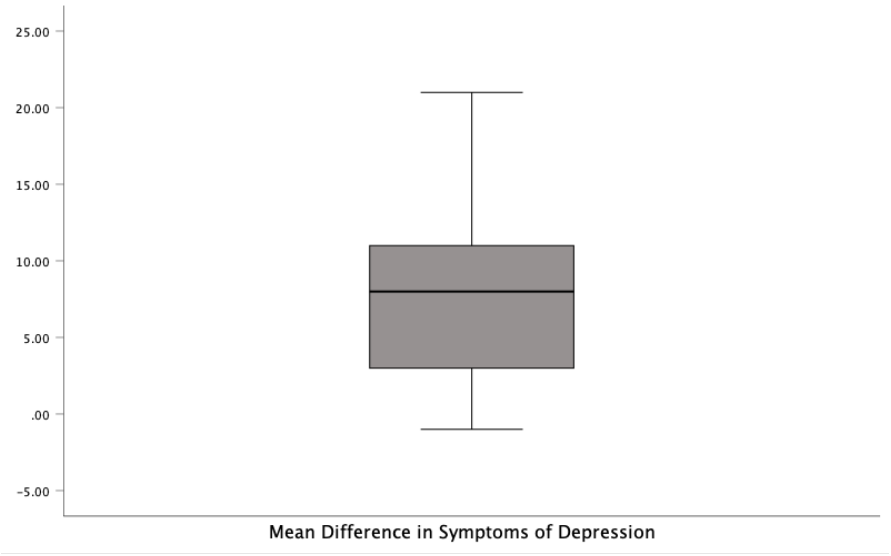

Figure 6. Boxplot of the mean difference in symptoms of depression (PHQ-9).

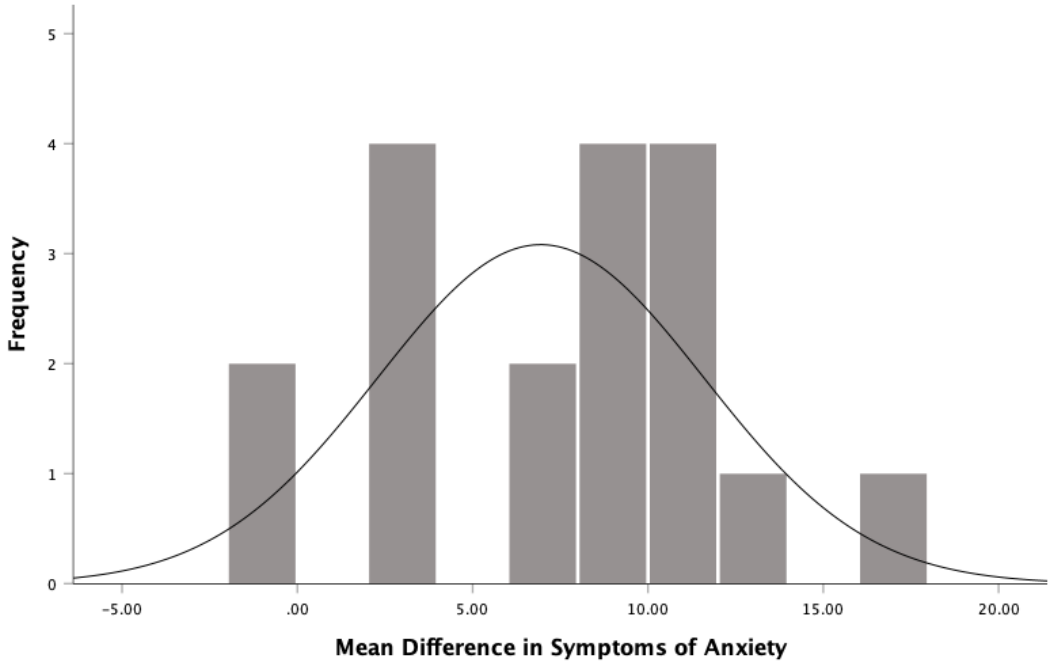

Figure 7. Histogram demonstrating the normal distribution of the mean difference in symptoms of anxiety (GAD-7).

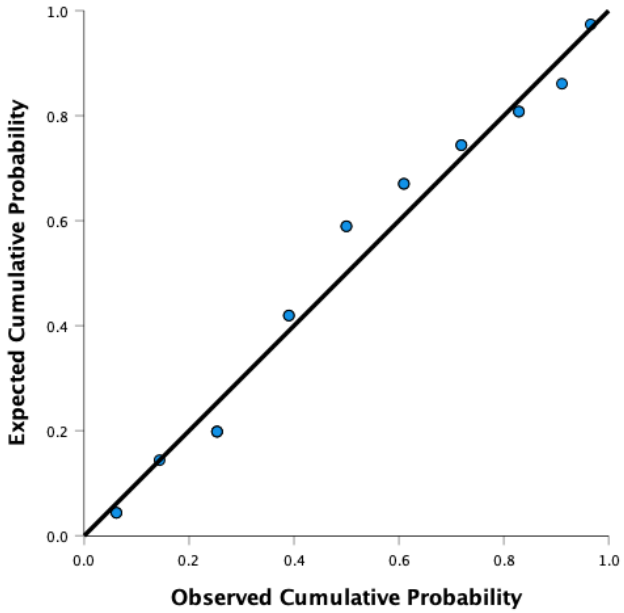

Figure 8. Probability-Probability plot of the mean difference in symptoms of anxiety (GAD-7).

Figure 9. Boxplot of the mean difference in symptoms of anxiety (GAD-7).

Curriculum Vitae

Name: Ujjoyinee France Barua

Post-secondary Education and Degrees:

B.Sc. Double Major in Psychology and Biology
University of Western Ontario
London, Ontario, Canada
2015 – 2020

M.Sc. Health and Rehabilitation Sciences
The University of Western Ontario
London, Ontario, Canada
2020 – Present

Related Work Experience

Research Assistant
Relationships Decisions Lab, Dr. Samantha Joel
The University of Western Ontario
2018 – 2021

Graduate Teaching Assistant
The University of Western Ontario
2020

Research Assistant
Parkwood Institute, St. Joseph's Hospital
Dr, Swati Mehta
2020 – Present

Graduate Teaching Assistant
The University of Western Ontario
2021

Publications:

Barua, U., Ahrens, J., Shao, R., Loh, E., MacKenzie, H., Sequiera, K., Wolfe, D., Mehta, S. (Under Peer-review). Cognitive Behavioural Therapy for Managing Depressive and Anxiety Symptoms after Brain Injury: A Meta-Analysis. *Brain Injury*.

Barua, U., Mehta, S., & Loh, E. (2021). Internet-delivered Cognitive Behavioural Therapy for Persons with Mild Traumatic Brain Injury: A Multi-Method Feasibility Trial. *Archives of Physical Medicine and Rehabilitation*, *102*(10), e85-e86.

Barua, U., Ahrens, J., Mehta, S., & Shao, R. (2021). Treating Psychological Symptoms After Brain Injury Using Cognitive Behavioural Therapy: A Meta-Analysis. *Archives of Physical Medicine and Rehabilitation*, *102*(10), e121-e122.

Peer-reviewed Conferences:

Barua U. Internet-delivered Cognitive Behavioural Therapy for Persons with Mild Traumatic Brain Injury: A Multi-Method Feasibility Trial. 2021 Feb 3rd, Health and Rehabilitation Sciences Graduate Research Conference 2021, London, Ontario,

Barua U. Internet-delivered Cognitive Behavioural Therapy for Persons with Mild Traumatic Brain Injury: A Multi-Method Feasibility Trial. 2021 May 12th, Rehabilitation Science Research Colloquium 2021, Virtual.

Barua U. Internet-delivered Cognitive Behavioural Therapy for Persons with Mild Traumatic Brain Injury: A Multi-Method Feasibility Trial. 2021 September 28th, American Congress of Rehabilitation Medicine, Dallas, Texas, USA.

Barua U, Ahrens J, Shao R, Mehta S. Treating Psychological Symptoms After Brain Injury Using Cognitive Behavioural Therapy: A Meta-Analysis. 2021 September 28th, American Congress of Rehabilitation Medicine, Dallas, Texas, USA.

Barua U, Borad S, Courten E, Upper R, Wolfe D, Charlifue S, Sequeira K, Loh E, Mehta S. Development of an Online Cognitive Behaviour Therapy Program for Caregivers of Persons with Spinal Cord Injury. February 2nd, 2022, Health and Rehabilitation Sciences Graduate Research Conference 2022, London, Ontario.

Barua U, Borad S, Courten E, Upper R, Wolfe D, Charlifue S, Sequeira K, Loh E, Mehta S. Development of an Online Cognitive Behaviour Therapy Program for Caregivers of Persons with Spinal Cord Injury. May 6th, 2022, Best Practices Day 2022. Toronto, Ontario.

Mehta S, Loh E, Upper R, Cornell S, Duong Y, Morrison O, **Barua U**, Ahrens J, Marrocco S, Wolfe D. Improving Activity Engagement among persons with SCI during COVID-19: Virtual Physical Activity Program Feasibility Study. May 6th, 2022, Best Practices Day 2022. Toronto, Ontario.

Barua U. Internet-delivered Cognitive Behavioural Therapy for Persons with Mild Traumatic Brain Injury: A Multi-Method Feasibility Trial. 2021 May 12th – May 13th, The 12th Annual Canadian Association of Cognitive Behavioural Therapy Research Conference, Vancouver, British Columbia.

Barua U, Borad S, Courten E, Upper R, Wolfe D, Charlifue S, Sequeira K, Loh E, Mehta S. Development of an Online Cognitive Behaviour Therapy Program for Caregivers of Persons with Spinal Cord Injury. September 15th – September 18th, International Society of Spinal Cord Injury Research Conference 2022, Vancouver, British Columbia.