Internet-based Cognitive Behavior Therapy for College Students with Symptoms of Depression

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Internet-based Cognitive Behavior Therapy for College Students with Symptoms of Depression

Submitted in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice at Eastern Kentucky University

By

Sandra D. Robertson

Louisville, KY

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Abstract

College students have high rates of depression, but do not always receive appropriate mental health care. Internet-based cognitive behavior therapy (ICBT) has the potential to provide students rapid access to an evidence-based treatment for depression. This project examined the acceptability and effectiveness of the ICBT program MoodGYM for college students with significant symptoms of depression. Nineteen college students with scores of 10 or higher on the Patient Health Questionnaire-9 (PHQ-9) depression scale were enrolled in the project. Attrition, defined as failing to complete any MoodGYM modules, was high at 31.6% (n=6). Only 26.3% of participants (n=5) completed all five modules. The mean baseline PHQ-9 score was 15.58 points out of a possible 27 points. The mean post-intervention score was 11.0. The mean change in PHQ-9 score of 4.467 points was statistically significant (p<.001) and the effect size was large (Eta² = 0.54). An ICBT program such as MoodGYM appears to be an effective treatment for depression and is acceptable to at least some students with symptoms of depression.

Keywords: Internet-based cognitive behavior therapy, computerized cognitive behavior therapy, college student depression
Internet-Based Cognitive Behavior Therapy for
College Students with Symptoms of Depression

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Internet-based Cognitive Behavior Therapy for College Students with Symptoms of Depression

College students face multiple academic, social, spiritual, and financial challenges. Students with the additional challenge of a mental health condition such as depression may suffer both short- and long-term consequences. Because of the potential negative outcomes of depression, early identification and timely treatment of students with symptoms of depression is vital. The purpose of this Doctor of Nursing Practice (DNP) project was to implement an evidence-based online cognitive behavior therapy program for college students experiencing symptoms of depression. The introductory section of this paper will first discuss the possible negative effects of depression on students and the prevalence of depression in the college student population followed by a description of the intervention.

Suicide was the second leading cause of death among people in both the 15- to 24- and 25- to 34-years age groups in 2015 (Centers for Disease Control and Prevention [CDC], 2017). Even though suicide does not occur exclusively among people with clinical depression, the severity of symptoms of depression is highly correlated with suicide risk (Oquendo et al., 2004). Even subclinical levels of depressive symptoms can increase the risk of suicidal ideation (Cukrowicz et al., 2011). Aside from the risk of suicide, depressive disorders create a significant emotional and economic burden for individuals, families, employers, insurance providers, and healthcare organizations as well as intangible losses such as missed opportunities and decreased quality of life (Byford, Barrett, Despiegel, & Wade, 2011; Greenberg, Fournier, Sisitsky, Pike, & Kessler, 2015; and, Mrazek, Hornberger, Altar, & Degtiar, 2014). This may be especially true for young adults.
A history of suicidal ideation, plans, and attempts in college students has been found to result in statistically significant declines in grade point average (GPA) (DeLuca, Franklin, Yueqi, Johnson, & Brownson, 2016; Mortier et al., 2015). Depression also affects exam scores (Andrews & Wilding, 2004), GPA (Eisenberg, Golberstein, & Hunt, 2009; Hysenbegasi, Hass, & Rowland, 2005), and retention in college (Eisenberg et al., 2009). Eisenberg, et al. estimated the mean probability of dropping out of college to be 8% for all students, but as high as 12.7% for students with severe depression. As many students rely on scholarships or financial aid to pay for college, a decrease in GPA or failure to make satisfactory academic progress can result in lost funding for tuition, increased loan burden, delayed graduation, or failure to complete a college degree.

The rate of suicidal ideation in college students is relatively high. Based on a longitudinal survey study conducted with 2337 undergraduate students at the University of Leuven in Belgium, Mortier et al. (2017) concluded that the rate of new onset suicidal thoughts and behaviors was 3.7% during the first year of college and 3.9% during the second year. About 1% of students reported making plans for suicide during the first year and 2.2% reported making suicide plans during the second year of college. The percentage of students reporting a suicide attempt was 0.2% for both years. Among college students in the U.S., the rate of non-fatal suicide attempts may be as high as 1.5% (American College Health Association [ACHA], 2016).

People in the 18- to 25-year age group had higher rates of past year major depressive episodes (9.3%) than either 26- to 49-year-olds (7.2%) and those over 50 years of age (5.2%) according to the 2014 National Survey on Drug Use and Health (Center for Behavioral Health Statistics and Quality, 2015). The younger age group also had a higher rate of severe impairment
related to depression (6.0%) than other age groups. Adults aged 26 to 49 had the second highest rate of past year major depressive episodes with severe impairment (4.6%).

Depressive symptoms are also quite pervasive among college students. Almost 37% of the 95,761 college students who participated in the Spring 2016 National College Health Assessment (NCHA) reported that within the past year they had felt so depressed it was difficult to function (ACHA, 2016). In the previous 12 months, 9.8% reported that they had seriously considered suicide and 1.5% had attempted suicide. However, only 13.9% of total respondents reported being diagnosed with or treated for depression by a health care provider or mental health professional.

Eisenberg, Golberstein, and Gollust, (2007) noted a significant disparity between perceived need for mental health services and use of counseling and/or medication on the campus of a large public university. The authors found that 30% of the students who responded to a web-based survey reported that they thought they needed help with mental health or emotional problems within the past year. Only half of those students had accessed either counseling or medical help for their problems. Since almost all of the students at the study site had health insurance coverage and the university provided basic health care and brief therapy at no additional cost to students, expense was not a factor in failure to access care. Even when students are screened for depression during primary care visits, those identified as having significant symptoms of depression and referred to treatment may choose to not engage in mental health treatment. Klein, Ciotoli, and Chung, (2011) found that only 35.7% of college students identified as having untreated clinically significant depression had entered treatment within one month of diagnosis.
Rates of depression and suicidal ideation may be even higher among those students accessing campus health services than in the general student population. Mackenzie et al. (2011) surveyed 1,622 university students seeking treatment at campus health services at four clinics and found that 26.4% of female and 24.7% of male respondents had scores on the Beck Depression Inventory-Primary Care (BDI-PC) screening tool that indicated clinical depression. In this study, 10% of female and 13% of male students reported having thoughts of suicide. Mackenzie et al. found that a majority (63.2%) of students utilizing campus health services who had clinically significant levels of depressive symptoms had seen a counselor. The low student utilization of mental health services reported in the NCHA survey and in the Eisenberg et al. (2007) study compared with the Mackenzie et al. study may suggest that students who use campus health clinic services are more likely to access mental health services than the general student population. The reason for this difference in accessing specialized care is unknown, but supports the practice of routine screening for depression in primary care as a way to increase appropriate treatment for students with mental health concerns.

Eisenberg, et al. (2007) identified a number of barriers to student utilization of mental health services including stigma, lack of time or resources, and concerns about privacy. Higher demand for services and increased identification of pathology may contribute to the lack of treatment availability. In the 2014 National Survey of College Counseling, 86% of the counseling center directors surveyed reported that they had seen an increase in the number of students starting college who were already taking psychotropic medications. The majority of directors (94%) also felt that there was a trend toward increasing numbers of students with severe psychological disorders over the previous five years (Gallagher, 2014). Unfortunately, data supporting the perceptions of these counseling center directors is not available.
Although initiation of treatment for mental health disorders is important, this does not guarantee that patients will receive sufficient treatment to achieve remission or significantly improve symptoms. Eisenberg and Chung (2012) applied the concept of minimally adequate depression treatment to data collected in the 2009 Health Minds Study survey of students enrolled at 15 colleges and universities. For the purposes of their research, Eisenberg and Chung defined minimally adequate care for depressed students as having taken a psychotropic medication for the treatment of depression for at least two months and having at least three discussions about their medication with a health care provider in the previous year or having at least seven sessions of psychotherapy within the previous year. Eisenberg and Chung found that 87% of students reporting significant symptoms of depression had at least some contact with a health care provider in the previous year, although not necessarily for treatment of depression. Only 22% of the students with a possible diagnosis of depression and 34% of students with both past-year depressive symptoms and suicidal ideation received minimally adequate treatment as defined above (Eisenberg & Chung, 2012).

While there has been a perceived increase in severity of student mental health issues and demand for mental health services, many college counseling centers restrict the number of sessions allowed per student client each semester due to limited therapist availability. Ideally counseling centers would be staffed at the recommended ratio of one counselor or therapist for every 1,000-1,500 students at the institution ("Statement Regarding Recommended Ratios," 2015). However, for the 275 schools represented by the counseling center directors responding to the National Survey of College Counseling, the average ratio was 1:2,018 (Gallagher, 2014). In order to improve access to care and to assure minimally adequate care, Eisenberg and Chung (2012) proposed increasing the number of mental health providers on campuses or coordinating
with community-based providers to improve access to treatment. Another possible solution to the problem of increasing demand for mental health treatment coupled with limited resources is to use technological approaches such as Internet-based interventions to improve efficiency and availability of care. Several meta-analyses have shown Internet-based or computer-assisted therapies such as cognitive behavior therapy (CBT) to be effective in treating depression with small to moderate effect sizes (Griffiths, Farrer, & Christensen, 2010; Twomey, O’Reilly, & Byrne, 2014) or moderate to large effect sizes (Andrews, Cuipers, Craske, McEvoy, & Titov, 2010; Saddichha, Al-Desouki, Lamia, Linden, & Krausz, 2014).

CBT focuses on how individuals perceive, think about, and respond to situations. According to cognitive theory, recognizing and changing unhelpful or distorted thinking patterns and the behaviors that occur in response to those thoughts can result in improvements in mood, anxiety, and general functioning (Beck Institute for Cognitive Behavior Therapy website, n.d.). CBT has been found to reduce the symptoms of depression both when compared with a waitlist or placebo control or treatment as usual and with antidepressant medication, interpersonal therapy, and psychotherapy (Farah et al., 2016). By offering CBT online, this evidence-based treatment for depression can be made more easily accessible to university students.

Free Internet access is widely available on most university campuses and many courses are conducted either partly or entirely online. Almost 100% of undergraduate students at one large public university reported having at least one personal computer or having access to a computer and 97% had Internet access at home (Kittinger, Correia, & Irons, 2012). Computer-based interventions have shown efficacy in preventing depression in college students (Braithwaite & Fincham, 2007; Cukrowicz & Joiner, 2007). Furthermore, Internet-based interventions have been successful in treating college students who have social phobia and fear
of public speaking (Tillfors et al., 2008) and preventing or treating depression and anxiety (Day, McGrath, & Wojtowicz, 2013; Lintvedt et al., 2013).

The purpose of this capstone project was to implement an Internet-based cognitive behavior treatment (ICBT) intervention for university students experiencing symptoms of depression. If this intervention is effective and acceptable, online CBT could reduce the time to initiation of evidence-based treatment and offer another option to help increase the number of students receiving minimally adequate depression care as defined by Eisenberg and Chung (2012; see above). Additionally, some students who are identified as being at risk and who decline treatment in traditional settings may be more comfortable using self-guided ICBT than traditional face-to-face talk therapy due to concerns about time constraints, confidentiality, or perceived stigma.

The site chosen is a metropolitan university with an enrollment of over 22,000 students. Campus Health Services (CHS) provides routine depression screening for patients once a semester. Students who are identified as experiencing significant symptoms of depression may be referred to Student Psychiatric Services (SPS) at CHS, the Counseling Center (CC), the Psychological Services Center (PSC; the clinical psychology department doctoral training center), or community providers for treatment. For at least the past three years, CC intake appointments for the semester have been filled as early as mid-semester and students seeking services are offered the option of signing up for the wait-list. Because of this, students who are unwilling or unable to pay for therapy or to seek treatment off campus and those who are not interested in psychopharmacological management of depression might not receive treatment.

The specific ICBT program selected for implementation in this project was MoodGYM, an online CBT program developed by the National Institute for Mental Health Research at the
Australian National University. MoodGYM was originally intended to prevent depression in young people, but has been used with adolescents and adults for treatment of depression as well as prevention. MoodGYM has been studied extensively in terms of effectiveness, efficacy, and acceptability.

MoodGYM consists of five modules, each requiring between 30 to 45 minutes to complete (Christensen, Griffiths, & Korten, 2002). Module 1 provides an introduction to the program and concepts of CBT. Module 2 focuses on identifying and changing dysfunctional thinking patterns. The third module includes behavioral strategies for managing feelings associated with depression, improving self-esteem, and increasing activities. In Module 4 the emphasis is on stress reduction and relaxation techniques. The final module focuses on problem-solving and interpersonal relationships (Christensen, Griffiths, Mackinnon, & Brittliffe, 2006). Goldberg Depression and Anxiety Scales are administered at the beginning of each module.

Users also have access to a personal workbook containing 29 exercises and assessments (Christensen et al., 2002). MoodGYM has been implemented in schools (Calear, Christensen, Mackinnon, Griffiths, & O’Kearney, 2009; Lillevoll et al., 2014; and O’Kearney et al., 2009), in clinical settings (Christensen et al., 2004; Gilbody et al., 2015; Hickie et al., 2010; and Høifødt et al., 2013), and as a self-help intervention (Batterham, Neil, Bennett, Griffiths, & Christensen, 2008; Christensen et al., 2002; Christensen et al., 2004; and Farrer et al., 2011).

**Conceptual Framework**

Depressive disorders can be chronic conditions with periods of remission and exacerbation. The Collaborative Care Model (CCM) was chosen as the conceptual framework for this project because it addresses both the chronic nature of depressive disorders and the
collaborative approach necessary to effectively treat depression and other mental health disorders in the primary care setting.

The CCM, originally known as the Chronic Care Model, identifies six main elements for successful management of chronic illnesses: (a) the community, (b) the healthcare system, (c) delivery system design, (d) decision support, (e) clinical information systems, and (f) self-management support (Wagner et al., 2001). The CCM has been used extensively in research on management of illnesses such as diabetes (Stellefson, Dipnarine, & Stopka, 2013) and coronary artery disease in persons with Type 2 diabetes (Parchman, Zeber, Romero, & Pugh, 2007; Vargas et al., 2007). It has also been used to improve management of depression and anxiety disorders (Archer et al., 2012; Holm & Severinsson, 2012; Knight & Houseman, 2008; Roy-Byrne et al., 2005).

The elements of the CCM make it an appropriate framework for implementing computer-assisted therapy for depression in the primary care setting. In particular, the CCM emphasizes partnership between the community, community resources, and the health care system; collaboration between care providers at all levels; collaboration between care providers and patients; and self-management support (Wagner et al., 2001). Active involvement and self-management by the patient are crucial for successful treatment with ICBT.

**Review of Literature**

Computer-assisted cognitive behavioral therapy (CCBT) has been studied since 1990 when the results of the first randomized controlled trial of a computer-administered cognitive-behavioral intervention for depression were published by Selmi, Klein, Greist, Sorrell, and Erdman. Selmi, et al. found that face-to-face CBT and CCBT were not significantly different
from each other and both resulted in greater improvement in depression scale scores than the wait-list control condition with weekly researcher contact.

In CCBT research the role of computers in providing CBT may be as limited as having a downloadable text to be used at home or may be much more complex and include multiple forms of teaching or individualized interactions. In addition to research projects demonstrating efficacy of CCBT or ICBT in treating mental health disorders under controlled conditions, there have been several effectiveness studies evaluating CCBT initiated in the primary care or community setting (Mewton & Andrews, 2015; Mewton, Sachdev, & Andrews, 2013). Efficacy (or explanatory) trials evaluate an intervention under highly controlled research settings whereas effectiveness (or pragmatic) trials apply the intervention in less strictly controlled clinical or community settings (Gartlehner, Hansen, Nissman, Lohr, & Carey, 2006). The CCBT or ICBT interventions range from having patients use self-help CBT modules with no clinician involvement (Meyer et al., 2015; Twomey, et al., 2014) to protocols in which clinician or nonclinical staff involvement is an integral component (Paxling, et al, 2011; Perini, Titov, & Andrews, 2009; Wright et al., 2005).

Attrition rates in CCBT studies tend to be high except when incentives are offered for completion (Batterham et al., 2008; Phillips et al., 2014; Twomey, et al, 2014). In one study, fewer than 10% of participants assigned to the ICBT intervention ever signed on to the program (Lillevoll et al., 2014). Adherence is typically higher when there is some clinician involvement or researcher contact (Calear et al., 2013; Farrer et al., 2011; Hickie et al., 2010; Høifødt et al., 2013).

The review of literature for this project first presents results of systematic reviews and meta-analyses of computer-assisted or Internet-delivered CBT interventions followed by
discussion of individual research studies utilizing MoodGYM. The discussion of results will focus on the effects of interventions on MDD, dysthymia, or sub-clinical depression symptoms even when other disorders such as generalized anxiety disorder were included in the research. Appendix A contains a table of research studies included in the reviews and meta-analyses discussed here listed by first author’s surname and year of publication to show where a study is included in more than one review or meta-analysis. Most studies using ICBT or CCBT interventions excluded persons diagnosed with bipolar disorder, psychosis, or substance abuse and those experiencing severe depression or suicidal ideation. When such conditions were identified in prospective participants or during the course of the study research staff made contact with the applicants to refer them to appropriate care.

**Computer-assisted Cognitive Behavior Therapy: Systematic Reviews and Meta-analyses**

Cognitive behavior therapy is considered an effective treatment modality for mental health disorders. However, the cost of traditional CBT may be prohibitive and therapists adequately trained in the technique are often in short supply. As a consequence, different methods for making CBT more affordable and available have been considered. Twomey, O’Reilly, and Byrne (2014) reported on the results of 29 randomized controlled trials of various CBT delivery methods used in primary care settings to treat depression and anxiety disorders. These delivery methods included guided self-help, telephone CBT, computerized CBT, and face-to-face CBT. Studies were divided into 3 categories: comparing CBT with no treatment, comparing CBT with primary care treatment as usual (TAU), and comparing CBT plus TAU with primary care TAU alone. Across all delivery methods, CBT was more effective overall than no treatment for reduction in symptoms of depression and demonstrated a medium effect size ($d=0.57$, 95% CI=0.15-1.03). There was also a medium effect size for the three studies
comparing CCBT with no treatment ($d=0.69$, $95\% \text{ CI}=0.44-0.99$). CCBT and face-to-face CBT were more effective than primary care TAU, but the effect sizes were small to moderate ($d=.30$, $95\% \text{ CI}= 0.06-0.66$ and $d=0.45$, $95\% \text{ CI} = 0.28-0.62$, respectively). Comparisons of CBT+TAU and TAU yielded similar results with small effect sizes.

Other meta-analyses and systematic reviews have found more robust effects of CCBT. Griffiths, Farrer, and Christensen (2010) evaluated 29 peer-reviewed articles reporting on the results of 26 different randomized controlled trials of Internet interventions utilizing cognitive behavior therapy for depression and/or anxiety. The studies included were selected on the basis of three main criteria: being either wholly or partially a self-help web-based intervention, incorporating an outcome measure for the targeted symptom(s), and not using any active intervention in the control group. Some studies included used a psychoeducational control condition. Both effectiveness and efficacy studies were evaluated. Two interventions that were guided or partly delivered by a therapist were included. Of the 26 trials evaluated, eight focused on depression alone and two focused on both depression and anxiety. The remainder focused on anxiety disorders. Sample sizes varied widely with a minimum of 23 participants to a maximum of 786 with a median sample size of 300 participants. Two studies included follow-up at six months post intervention. Interventions ranged from one to 13 weeks in duration. All but three of the trials were community-based. Only five of the programs were available in English (Griffiths et al., 2010). Some studies limited participants to those with a clinical diagnosis of a depressive disorder, some used a cut-off score on self-report measures, and some included participants with sub-clinical symptomatology or those who self-selected for participation.

Griffiths et al. (2010) calculated effect size differences (ESDs) between intervention groups and controls based on Cohen’s $d$ effect sizes. As might be expected, ESDs were highest
(0.42 to 0.65) for studies using participants with clinically significant symptoms or those with formal diagnoses of depressive disorders. When symptoms were at subclinical levels or participants had not been formally diagnosed, ESDs ranged from 0.30 to 0.53. It must be noted that three of the trials targeting depression used a psychoeducational intervention for the control group and only one of these showed a statistically significant difference in outcomes between the control and intervention arms (Griffiths et al.).

Andrews, Cuipers, Craske, McEvoy, and Titov (2010) analyzed the results of 22 randomized controlled trials of CCBT versus no treatment or treatment as usual for major depressive disorder, social phobia, panic disorder, or generalized anxiety disorder. According to Andrews et al. (2010), CCBT resulted in a significant improvement in symptoms compared to TAU or no treatment and demonstrated large effect sizes (Hedges g=0.88, p<0.001 across all four disorders). For studies focusing on MDD the effect size for CCBT compared with control conditions was also large (Hedges g=0.78, 95% CI=0.59-0.96). This analysis included five studies comparing CCBT with face-to-face CBT for the treatment of depression and panic disorder and found no significant difference in outcomes. Andrews et al. found a slight but nonsignificant difference in effect size favoring face-to-face CBT over CCBT for depression based on the results of two studies. Although it might be assumed that patients would prefer face-to-face therapy, participants reported satisfaction with the CCBT intervention.

In a systematic review of Internet-based interventions for mood and anxiety disorders, Arnberg, Linton, Hultcrantz, Heintz, and Jonsson (2014) attempted to determine if such treatments are efficacious, safe, and cost-effective and if they are not less effective than more traditional treatments (i.e., noninferior). The authors also evaluated the quality of evidence and risk of bias for each study examined. For the purposes of the review, randomized controlled trials
had to include participants diagnosed with a specific anxiety or mood disorder via a structured clinical interview. The interventions had to be delivered via the Internet without any face-to-face support. Technician assistance or therapist guidance could be supplied by telephone, email, or some form of messaging. Control conditions could be wait-list, treatment as usual, or any established psychological treatment. Trials judged to have a high risk of bias were excluded from further consideration. Arnberg et al. (2014) found 40 trials meeting inclusion criteria with low or moderate risk of bias. Of these, eight focused on depressive disorders only and all of these were judged to have moderate risk of bias. Five of the eight trials compared CCBT with a wait-list control, with a wait-list control plus weekly symptoms ratings, or a wait-list control plus an online discussion group. The difference in scores between intervention and control groups on the Beck Depression Inventory was used. The pooled results of these trials showed a standardized mean difference of 0.83 (95% CI 0.59, 1.07) in favor of CCBT. Arnberg et al. were not able to make any determinations about safety, noninferiority to conventional treatments, or cost effectiveness of ICBT for depression.

Another systematic review of literature regarding Internet-based interventions for depression and anxiety included 33 studies (Saddichha, Al-Desouki, Lamia, Linden, & Krausz, 2014). Twenty-nine of these were RCTs and 26 used CBT or CBT techniques (e.g., cognitive restructuring). All but two of the studies reviewed reported a significant decrease in depression scores with ICBT. In general, interventions with therapist guidance resulted in moderate to large effect sizes (0.6 to 1.9) compared with small to moderate effect sizes (0.3-0.7) in purely self-guided ICBT (Saddichha et al., 2014).
**MoodGYM Research**

MoodGYM has been used in both efficacy and effectiveness research, with and without clinical guidance, and in clinical populations as well as in the general population. It has also been studied for the treatment of depression in persons with health issues such as fibromyalgia (Menga et al., 2014) and traumatic brain injury (Topolovec-Vranic et al., 2010). The studies discussed here have been divided into three categories: MoodGYM without clinician or researcher guidance, MoodGYM used in institutional settings (schools), and MoodGYM with clinician or researcher contact ranging from reminder emails to face-to-face contact.

**MoodGYM alone.** Christensen, Griffiths, and Korten (2002) looked at site usage, visitor demographics, and effects on depression and anxiety for public visitors in the first six months MoodGYM was available to the public. Two thousand nine hundred and nine visitors registered on the site and 1503 completed at least one of the online assessments. Women made up 60% of the users and the mean age was 35.5 years (SD=13.0, range 10 to 80 years). About one third of the users were from Australia, where MoodGYM was developed, and slightly over one third were from the United States. In addition, 71 university students participated in the MoodGYM program as part of an abnormal psychology class. The intervention resulted in a statistically significant \( p < .001 \) decrease in GDS scores. The average decrease in GDS score for participants completing all five MoodGYM modules was 2.7 points. Baseline GDS scores for the university students participating were initially lower than those of the public participants (2.56 for women and 3.83 for men) and did not change significantly.

The BlueMood study was a three-armed RCT that compared MoodGYM and a psychoeducational website (BluePages) with an attention placebo control (Christensen, Griffiths, and Jorm, 2004). The outcome measures were Center for Epidemiological Studies-Depression
(CES-D) scores, dysfunctional thoughts, and depression literacy. The control condition consisted of weekly contact with a nonclinical interviewer to discuss exercise, education, and health habits. A total of 525 adults between the ages of 18 and 52 were recruited via survey. The average age was 36.43 years (SD=9.4). More than twice as many women as men participated (375 vs 150). Those accepted into the trial scored 22 or higher on the Kessler Psychological Distress Scale (K-10), were not currently receiving treatment from a psychologist or psychiatrist, and had access to the Internet. Statistical analyses were performed using both intention-to-treat (i.e., all participants including those who dropped out) and “completer” (those who completed the study) groupings. In the intention-to-treat (ITT) analyses the baseline CES-D score was used as the post-intervention score for those who did not complete the study. A separate analysis was run for a subgroup of participants with CES-D baseline scores of 16 or higher, indicating clinical depression.

The BlueMood study showed a moderate effect size (Cohen’s $d=0.4$) for both the MoodGYM and BluePages interventions in the ITT analyses compared with an effect size of 0.1 for the control condition (Christensen et al., 2004). When analyses were run on only those who completed the interventions, effect sizes rose slightly to 0.6 for the MoodGYM group and to 0.5 for the BluePages group. However, for the subgroup of participants who started with elevated CES-D scores, the effect sizes for the intervention arms were large at 0.9 for MoodGYM and 0.75 for BluePages compared with 0.25 for the control group. Overall completion rates for this study were fairly high with 83% of participants completing the post-intervention questionnaires and 79% completing all components of the intervention. The dropout rate was significantly higher for MoodGYM than for BluePages (25% vs.15%, $p=.02$).
Mackinnon, Griffiths, and Christensen (2008) followed up with participants in the BlueMood trial at six and 12 months post intervention to see if improvements from the active interventions were maintained. At the end of the intervention period both the MoodGYM and BluePages interventions reduced scores on the CES-D significantly more than the control condition ($p<.001$ and $p<.005$, respectively). Scores on the CES-D for the MoodGYM group were still significantly improved compared with the control group at the 6-month follow-up, but the difference for the BluePages group was not significant. However, at 12 months both intervention groups demonstrated a statistically significant reduction in CES-D scores when compared with the control ($p=.044$ for MoodGYM and $p=.024$ for BluePages). Effect sizes were small at 0.27 for MoodGYM and 0.29 for BluePages at 12 months post intervention.

Building on the BlueMood study described above, Christensen, Griffiths, Korten, Brittliffe et al. (2004) compared the adherence and results obtained by public visitors to the MoodGYM site with those of individuals participating in a clinical trial. Goldberg Depression and Anxiety Scales (GDS and GAS) were used as the outcome measures. Of the 19607 visitors to MoodGYM who were not part of the BlueMood trial, 3176 completed both the initial and final depression scales. Only 138 were shown to have completed all five MoodGYM modules. Of the non-trial registrants, 61.9% completed at least one GDS, but only 15.6% completed the GDS on at least two occasions compared with 86.3% and 66.5% of trial participants. Christensen et al. (2004) found that improvement in GDS scores was correlated with the number of modules completed up to four of the five modules, but there was no significant additional gain for participants who completed all five modules. There were no statistically significant differences in the changes in GDS and GAS scores between the trial and non-trial participants.
Christensen, Griffiths, Mackinnon, and Brittiffe (2006) compared six different MoodGYM program versions with respect to the effects on depression and retention in a partially-randomized, non-controlled trial. The different versions consisted of between one and five modules of MoodGYM. Three versions were considered brief CBT and three were considered extended CBT. The purpose of the study was to determine if brief CBT was as effective as extended CBT and if completion rates were higher in the shorter versions of MoodGYM. During the 19 weeks of the trial in 2005, 15412 users registered on the MoodGYM website. Seventy-four percent chose to participate in the study and completed informed consents. Participants ranged in age from 25 to 44 years and 66% were women. The 2434 users of the MoodGYM website who reported that they had been referred by a clinician were directed to the full MoodGYM (5 module) version of the intervention. Of the remaining 9,217 users, 70% chose which version of the program they wanted to use and 30% were randomly assigned to a version.

Christensen et al. (2006) found that the effect sizes were largest for two of the extended CBT versions, but not for the full MoodGYM program. Version 4, consisting of Modules 1, 2, and 5 (see above for module descriptions) had the largest effect size (0.40) compared with Module 1 alone. Version 5 (Modules 1, 2, 3, and 5) had the next largest effect size at 0.34. Version 6, the full MoodGYM program, resulted in significantly poorer outcomes than Versions 4 and 5 in both the intention-to-treat analysis and the completer analysis.

MoodGYM has also been used as a stand-alone intervention in a university setting to decrease the symptoms of depression in Norwegian students reporting psychological distress. Lintvedt et al. (2013) recruited participants from the University of Trømso and the University College of Trømso. Three hundred seventy of about 10,000 students consented to participate in the RCT comparing MoodGYM plus access to BluePages to a waitlist control group. Of those
who consented, 163 students met inclusion criteria (score of 20 or higher on the Kessler Psychological Distress Scale and access to the Internet). The mean age of participants was 28.3 years (SD=7.4). Women constituted 76.7% of participants, but only 61% of the university population. There were significantly more men in the intervention arm than in the control group, which is worth noting since other studies have found that men are more likely than women to drop out of a MoodGYM study or complete fewer modules (Batterham et al., 2008; Neil et al., 2009; and Twomey, et al., 2014).

Lintvedt et al. (2013) analyzed data using the ITT approach as well as separate analyses for completers and compliers. Completers were participants who returned the post-intervention questionnaire, regardless of actual use of the MoodGYM/BluePages intervention. For this study, compliers were participants who reported at least some use of MoodGYM/BluePages and those who could be identified as using the intervention through the website. The dropout rate from the study was quite high with 46.9% of the intervention group and 28% of the control group failing to return the post-intervention questionnaire administered eight weeks after study enrollment.

Full-time students were significantly more likely to dropout than part-time students. Almost three-quarters of the intervention group reported using the MoodGYM and BluePages websites. Older students and those who felt a need for help were more likely to be compliers. For the ITT analysis, there was a highly significant interaction between group and time ($p<.001$) for CES-D scores. The post-intervention CES-D scores for the MoodGYM/BluePages group were significantly lower at the post-intervention assessment than pre-intervention ($p<.05$) while the control group had significantly higher CES-D scores post intervention ($p<.05$). The between group effect size for CES-D was large (Cohen’s $d=.57$). Results of the completer and complier analyses were similar to the ITT analysis, but the between group effect size was larger (Hedge’s
Because Lintvedt et al. were interested in preventing depression, they also analyzed completer and complier subgroups based on severity of symptoms prior to the intervention. The three subgroups were “subclinical” (CES-D score 0-15), “mild/moderate” (CES-D score 16-23), and “moderate/severe” (CES-D score ≥ 24). Effect sizes for the subclinical and mild/moderate subgroups in the complier analysis were quite high (Hedges $g=1.64$ and $.90$), suggesting that the intervention may be effective in preventing development of clinical depression.

MoodGYM has been tested as an intervention for people whose access to mental health care is delayed. Twomey, O’Reilly, Byrne, Bury, et al. (2014) evaluated the effectiveness of MoodGYM for reducing general psychological distress, distress, depression, anxiety, and functional impairment of 149 adults on waiting lists to receive mental health services from three rural and three urban public health clinical sites in Ireland. Participants were randomly assigned to MoodGYM or to a wait-list control group. Online assessments for both groups were conducted at baseline, at the conclusion of the 32-day MoodGYM intervention, and at 12 weeks post intervention. Automated emails were used to remind participants to complete modules. The short intervention time and automated emails were intended to reduce study attrition and increase completion rates.

Twomey, O’Reilly, Byrne, Bury, et al. (2014) used the Depression, Anxiety, and Stress Scale-21 (DASS-21) to measure general psychological distress. The DASS-21 has subscales for depression, anxiety, and stress, which were used to measure these secondary outcomes. Higher scores indicate higher levels of symptom severity or impairment. There was not a significant effect on symptoms of depression, but there was a statistically significant decrease in DASS-21 overall scores ($p < .05$) and in the stress subscale ($p < .05$) in the MoodGYM group compared
with the wait-list control group. Effect sizes were small for the between groups comparison (Cohen’s $d = 0.14$ for psychological distress and $d = 0.15$ for stress). For the pre-treatment/post-treatment comparison, effect sizes for psychological distress and stress were larger (Cohen’s $d = 0.48$ and 0.64, respectively).

There was a very high dropout rate for MoodGYM participants (56%) in the Irish study with males dropping out at a rate of 85% compared with 58.3% of females (Twomey, O’Reilly, Byrne, Bury, et al., 2014). Of those who remained in the study and responded to optional questions about the acceptability of MoodGYM, two out of 22 did not complete any sessions and just over half completed three or more sessions. These rates of attrition and failure to complete the program may have contributed to the small effect size noted above. Twomey, O’Reilly, Byrne, Bury, et al. suggested that since there was no regular clinician contact, the lack of a therapeutic alliance might have decreased the motivation for participants to complete the program. Although not mentioned as a contributing factor by Twomey, O’Reilly, Byrne, Bury, et al., the pressure to complete all five modules within a month might have resulted in some of the attrition. The authors commented that further research is needed to determine the length of time best suited to keep the interest of participants without adding additional pressure by requiring them to complete the program within a certain time frame.

Powell et al. (2013) examined the effects of MoodGYM on the mental well-being of participants self-selected from the general population in the United Kingdom. Depression scores on the CES-D were included as a secondary outcome. In this study 3070 individuals consented to participate and were randomized to the MoodGYM intervention or the wait-list control. The mean age of participants was 41, 76.86% were female, and 57.7% were treated for a mental health problem prior to enrolling in the study. Assessments were performed at baseline, 6 weeks
after baseline, and 12 weeks after baseline. CES-D scores for the MoodGYM group were significantly lower than for the control group at 6 and 12 weeks \((p < .0001\) for both time points). The attrition rate for the MoodGYM group was almost three times higher than for the control group \((73.5\% \text{ vs. } 26.9\%)\).

MoodGYM was used as a comparison condition in a noninferiority trial conducted by Donker et al., (2013) to evaluate online interpersonal therapy (IPT) and a new online cognitive behavior therapy intervention. For this study Module 5 of MoodGYM was eliminated to make it more comparable to the other two interventions in length. Participants were recruited from spontaneous users of a website known as “e-couch” who expressed interest in the trial. Potential participants were given an online screening survey to complete. Those who had very high CES-D scores (over 27) and those who were judged to have suicidal intent were immediately provided with information about treatment resources, but were not excluded from the study. Eligible participants had to be 18 years of age or older and not currently receiving treatment for depression. Randomization to treatment condition was stratified based on age, gender, and symptom severity. Participants were mostly female \((72.38\%)\) and about a third were between the ages of 25 and 29 years. Participation in the program lasted for four weeks and weekly email reminders were sent to participants in all three treatment conditions. Depression symptoms were measured at baseline, immediately after the intervention, and at a 6-month follow-up.

Donker et al. (2013) used ITT analysis, but they also performed analyses based on three subgroups: completers \((\text{participants who returned post intervention and 6-month follow-up surveys, } n = 336)\), adherent completers \((\text{those who completed two or more of the treatment modules and returned surveys, } n = 294)\), and those who were considered clinical cases at baseline \((\text{i.e., scores } \geq 22 \text{ on CES-D; } n = 1,737)\). For the four-module MoodGYM intervention within
group effect sizes (Cohen’s $d$) were moderate to large for all subgroups except the clinical case group. In the ITT analysis, the MoodGYM effect size was 0.60 at the conclusion of the intervention and 0.66 at six months post intervention. Effect sizes for the completer group were 0.82 and 1.04 post intervention and at six months. For the adherent completer subgroup, effect sizes were 0.90 and 1.21. The effect size was small for the MoodGYM clinical case subgroup at the post-intervention assessment ($d=0.56$) and moderate at the six-month follow-up assessment ($d=0.61$).

**MoodGYM in institutional settings.** Several studies have examined the application of MoodGYM in secondary school settings. Despite having structured time to access MoodGYM when it was implemented in school settings, the compliance was not as high as might be expected.

A small controlled trial of MoodGYM was conducted with 15- and 16-year-old boys at a secondary school in Canberra, Australia (O’Kearney, Gibson, Christensen, & Griffiths, 2006). The 78 students who participated were randomly assigned to the MoodGYM intervention or to a control condition consisting of the usual personal development program employed by the school. Students in the MoodGYM group were allowed access to the program during a weekly tutor group meeting lasting 45 minutes. The Year 9 coordinator for the school selected which tutor groups would be assigned to the intervention and which would be assigned to the control condition. The CES-D was the primary outcome measure and scores were obtained at baseline, immediately after completion of the 5-week program, and at 16 weeks post intervention. There was no significant difference between groups in the change in the CES-D scores at the completion of the program or at the 16-week follow-up assessment. However, it was noted that
for participants who completed at least three MoodGYM modules there was a moderate effect size (0.34) on CES-D score at completion of the intervention.

O’Kearney et al. (2009) conducted a controlled, non-randomized study of the effects of MoodGYM on depressive symptoms, risk of depression, depression literacy, and attitudes toward depression when the ICBT program was integrated into the personal development curriculum at an Australian girls’ school. A sample of 157 girls aged 15 and 16 participated. Assignment to the intervention or control condition was done by class at the discretion of the school administration. Classes in the control condition followed the usual curriculum. The main outcome measure was the CES-D. Analyses were conducted based on the group as a whole, as well as on subgroups based on high (initial CES-D score ≥ 24) and low (CES-D score < 24) depression status. At the beginning of the intervention 25% of the participants were considered high depression status. The intervention lasted for six weeks and depression was evaluated at baseline, post-treatment, and at 20 weeks after the intervention.

O’Kearney et al. (2009) found no significant difference in CES-D scores post-intervention, but the decline in CES-D scores over time was significantly greater for participants in the MoodGYM group compared with the control. At the 20-week follow-up the decrease in CES-D scores was significantly different from the control group for students in the high depression status subgroup, but not the low depression status subgroup. At the 20-week follow-up effect sizes for MoodGYM were moderate (d = .46) for the intervention group overall and large (d = .92) for the high depression subgroup. Adherence to MoodGYM was significantly lower (i.e., fewer modules completed) for students initially reporting high levels of depression (p = .009). Overall, less than a third of the participants assigned to MoodGYM completed three or more modules.
The YouthMood Project, conducted in 2006 and 2007, was intended to evaluate the effectiveness of MoodGYM for reducing symptoms and preventing the development of clinical levels of anxiety and depression (Calear, Christensen, Mackinnon, Griffiths, & O’Kearney, 2009). Thirty Australian high schools participated in the cluster, stratified RCT incorporating MoodGYM into the schools’ curricula. Participating schools were a mixture of public, private, single-sex, and coeducational institutions. Schools were stratified according to type and rural or urban location, then randomly assigned to the intervention group or wait-list control. While MoodGYM was used with all students in the intervention schools, participation in the study was not required. A total of 1477 students consented to participate. The mean age of participants was 14.34 year (range 12 to 17 years) and 55.9% of the participants were female. Participants in the intervention group were assigned one module of MoodGYM per week for five weeks and class time was allocated for completion of modules, but teachers were not able to access student data and were not able to monitor student progress through the modules. Sixty-two percent of the MoodGYM participants completed three or more modules and 32.7% completed all five modules (Calear et al., 2009). Fifteen percent of participants completed at least 20 of the 29 exercises accompanying the modules (Calear et al., 2013).

Calear et al. (2009) found no significant effects of the MoodGYM intervention overall on the CES-D scores of participants at the post-intervention point or at the 6-month follow-up. However, when gender was factored into the analysis there was a statistically significant difference in CES-D scores between the MoodGYM group and the control group for males overall ($p = .02$). Post-intervention CES-D scores were 2.64 points lower for male students in the MoodGYM group than in the control group ($d = .43$, 95% CI [.20, .66]). At the 6-month follow-up the scores were 2.15 points lower ($d = .31$, 95% CI [.07, .55]) for the intervention group.
Calear et al. (2009) also found that for males only there were significantly more participants in the control group than in the MoodGYM group who met the criterion for depression caseness (CES-D ≥ 24) at both the post-intervention (p=.01; 8.9% vs. 2.0%) and 6-month follow-up (p=.03; 9.6% vs. 4.0%) assessments.

**MoodGYM with support.** MoodGYM was designed as a stand-alone intervention, but several studies incorporated different levels of support or guidance from research staff or clinicians. Farrer et al. (2011) recruited persons calling an Australian helpline for a randomized controlled trial of MoodGYM with and without weekly telephone support on the CES-D scores, dropout rate, and adherence of participants. Over 3000 callers to the help line were invited to participate and 155 English-speaking adults met eligibility criteria and were enrolled in the trial. In order to be eligible, helpline users had to score 22 or above on the K-10 and have access to the Internet for at least 30 minutes per week. Persons diagnosed with suicidal ideation, schizophrenia or bipolar disorder, or a reading impairment were excluded from participation. Block randomization was used to assign participants to one of four treatment arms: Internet intervention only (one week of BluePages and five weeks of MoodGYM), Internet intervention plus tracking (weekly 10-minute phone calls from a volunteer counselor), tracking only, and a wait-list control.

Farrer et al. (2011) found a significant occasion by treatment interaction for depression symptoms (p=.01). Both Internet intervention groups had a significantly greater decline in CES-D scores from the baseline to the post-intervention assessment than the control group. There was no significant difference between the tracking-only group and any other group on any measure examined. Effect sizes at the post-intervention assessment were large for both Internet intervention groups when compared with the control group (Hedges g=.76 for Internet only,
$g=1.04$ for Internet plus tracking). At the 6-month follow-up effect sizes increased for the Internet interventions compared with the control group ($g=1.19$ and 1.26). Participants in the Internet intervention plus tracking group were significantly less likely to complete the post-intervention survey ($p=.013$) than those in the control group. Since the control group was waiting to gain access to the Internet intervention, those participants may have had more incentive to complete the assessment at 6 weeks than those who had already accessed the intervention. There were no significant differences between the two Internet intervention groups on CES-D scores, completion rates, or adherence. Adherence for both Internet intervention groups was fairly low with only 15.8% of the Internet-only and 17.8% of the Internet-plus-tracking group completing all five MoodGYM modules. Approximately one third of participants in the Internet-only group and 37.7% in the Internet-plus-tracking group completed three or four MoodGYM modules. A large percentage of both groups did not complete any modules at all (50% and 31.1%, respectively).

Høifødt et al. (2013) combined MoodGYM with brief therapist support and evaluated the effectiveness and acceptability of this intervention when compared with a delayed-access control group. The sample for this randomized controlled trial included 106 Norwegian adult patients age 18 to 65 years (average age 36.1) with mild to moderate symptoms of depression (Beck Depression Inventory II scores between 10 and 40) recruited from primary care offices. Depressive symptoms were measured using the Beck Depression Inventory-II (BDI-II) and the Hamilton Anxiety and Depression Scale (HADS). Other outcomes were measured, but will not be included in this discussion. Participants who were taking antidepressant medication had to be stabilized for at least one month prior to entering the study. There was no restriction placed on either the intervention group or the control regarding access to treatment through primary care or
mental health services during the duration of the study. It should be noted that data from the delayed-access control group was pooled with the initial intervention group, possibly introducing bias into the results. Sixty percent of participants in the original treatment group and 37% in the delayed-access group completed the trial protocol. Total nonadherence was 40%. Statistical analysis was performed on an ITT basis. Participants in the intervention arm of the study were encouraged to complete one module of MoodGYM per week and were expected to meet face-to-face for 15 to 30 minutes weekly for the seven weeks of the intervention. Participants also received tailored emails between sessions to introduce the next module, to provide information or advice, and to motivate participants to continue using the program. Total therapist time spent per participant ranged from 70 to 506 minutes with a mean of 242.1 minutes (SD 96.6). Both the intervention group and control group experienced significant decreases in BDI-II scores during the intervention period with the MoodGYM group showing significantly more improvement than the control group ($p=.002$). The between group effect sizes for the BDI-II and the depression subscale of the HADS from pre- to post-intervention were large (Cohen’s $d=0.65$ and $1.10$). By the 6-month follow-up, the delayed-access group had completed the MoodGYM intervention so between group effect sizes were very small. The original intervention group did maintain gains at the 6-month follow-up. There was no significant effect of amount of time spent with a therapist on any of the outcome measures.

Hickie et al. (2010) conducted a feasibility study comparing the outcomes of mental health care provided by general practitioners with advanced mental health training (enhanced GP) with enhanced GP care plus MoodGYM (enhanced GP+MG). The design was a cluster randomized trial where GP practices were randomly assigned to the enhanced GP or enhanced GP+MG condition. There was no control condition. Eligibility was based on age (16 to 50 years)
and psychological distress as measured by the Kessler Psychological Distress Scale (K10; score of 20 or higher). Participants were required to speak English as a first language, to have Internet access and to have had symptoms of depression not attributable to grief for less than two years. Potential participants were excluded if they were enrolled in any other research project; were receiving psychological or pharmacological treatment; or had a major medical illness, neurological impairment, head trauma, drug or alcohol abuse or dependence, or a mixed depressive episode. Psychological distress was measured using the Somatic and Psychological Health Report (SPHERE-12) and the K10. Self-reported disability was measured using the Brief Disability Questionnaire (BDQ). The interventions lasted approximately eight weeks and assessments were made at baseline, immediately after the interventions ended, and six and 12 months after the intervention. Although this feasibility study did not measure the effects of MoodGYM on depression directly, it has been included here as an example of clinician-supported MoodGYM. The mean age of participants was 33.7 years and 70% were female. Sixty-five percent of participants received enhanced GP care and 35% received enhanced GP + MG. As in other studies, attrition was higher for the MoodGYM condition than for the comparison condition (41% vs. 28%). Although the authors did not report statistically significant results, possibly owing to the small sample size and high rates of attrition, there was a pattern of more rapid resolution of symptoms for the enhanced GP+MG group. The effect size for enhanced GP+ MG compared with enhanced GP alone on the SPHERE-12 was moderate ($d=0.40$) immediately after the intervention and small ($d=0.29$) for both the SPHERE-12 and K10 at six months.
Adherence and Attrition

Getting patients with depression into appropriate treatment is often a problem, but keeping them in treatment can also be very difficult. The number of participants completing the MoodGYM intervention was very low in many of the studies discussed above, but the low completion rates should be put into context. It has long been recognized that a significant percentage of patients undergoing mental health treatment discontinue therapy before the provider recommends. Estimates of early discontinuation of treatment range from 19.7% (Swift & Greenberg, 2012) to 26.5% (Wells et al., 2013). Premature discontinuation has been reported to be higher among those receiving mental health care in a general medical setting (32%) and lower among those receiving treatment from psychiatrists (15%) or other mental health professionals (19%) (Olfson, Mojtabai, Sampson, Hwang, & Kessler, 2009). Swift and Greenberg (2012) found that about 30% of people treated at university-based clinics stopped treatment early.

Public or spontaneous visitors to the MoodGYM site were not highly likely to begin using the intervention even after creating an account and agreeing to participate in research. Batterham et al. (2008) found that 63% of community users failed to complete any MoodGYM modules. In the study described previously comparing six different versions of MoodGYM, Christensen et al. (2006) found that 70% of registered participants did not complete any MoodGYM modules. Adherence in some school-based settings was also very low. Over 91% of Norwegian high school students who agreed to participate in a MoodGYM study never signed on to the site and only 0.57% completed all five modules (Lillevoll et al., 2014).

Several MoodGYM studies have looked at attributes associated with increased compliance, but the results have been contradictory. Calear et al. (2013) reported on adherence to
MoodGYM in the YouthMood project described above and found that younger students and those with higher levels of depression were more likely to be adherent than older students or those with lower initial CES-D scores. In contrast, O’Kearney et al. (2009) found that high school girls who had higher initial CES-D scores were less likely to complete three or more modules than those with lower scores.

Neil et al. (2009) compared the adherence to MoodGYM of school-based users with community-based adolescent users in Australia. Neil et al. found that female gender and being in the school-based setting predicted better adherence. For students in the school-based setting, living in a rural location and having lower baseline anxiety scores were associated with better adherence. In contrast to the findings of O’Kearney et al (2009), community-based participants with higher baseline depression scores were more likely to be adherent to MoodGYM than those with lower baseline scores.

Batterham, Neil, Bennett, Griffiths, and Christensen (2008) examined demographic and other characteristics of voluntary MoodGYM users who registered on the site between January 2006 and April 2007 in order to identify variables which might predict adherence to MoodGYM in community users. Demographic information including age, gender, education level, country of origin, and urban or rural location was collected from users prior to accessing MoodGYM modules. Users were also asked about a history of significant depression and if they had been referred to the site by a mental health professional. The GDS and GAS were used to measure levels of depression and anxiety at baseline and at the completion of each module. The MoodGYM website tracked module completion and users were separated into three groups for the purpose of data analysis: those who did not complete any modules (63%), those who completed one module (27%), and those who completed two or more modules (10%). Using chi-
square and F statistics for individual independent variables, Batterham et al. found that the number of modules completed was significantly positively associated with younger age; higher level of education; female gender; residing in Europe or Oceania (predominantly Australia); having higher baseline scores for depression, anxiety, and dysfunctional thinking; history of depression; and being referred to the site by a mental health professional. Participants whose GDS score decreased or remained the same after completion of the first module had significantly higher odds of continuing to use MoodGYM than those whose score increased (16% and 20%, respectively).

One approach to encouraging adherence and completion of self-guided programs is to incorporate automated email reminders in a CCBT intervention. Titov et al. (2013) examined the effects of automated email reminders on adherence and outcomes of an online self-help course (The Wellbeing Course) intended to treat multiple anxiety disorders and depression. Use of automated emails appears to have been effective in decreasing attrition (defined as terminating the program before the third lesson) and increasing completion of all five lessons within eight weeks (Titov, et al., 2013). Fifty-eight per cent of participants assigned to the treatment plus email group completed all lessons and only 11.0% ended participation early. In the treatment-only group, 35.8 % completed all lessons and 34% terminated early. However, the number of lessons completed did not appear to have any effect on the primary outcome measures as there was no statistically significant difference between treatment groups. In a different study, adding telephone support increased the percentage of participants accessing MoodGYM compared with those who did not have telephone support (68.9% vs. 50%), but did not have much effect on the number of participants who completed all five modules (17.8% vs. 15.8%) (Farrer et al., 2011).
Incorporating brief face-to-face therapy with MoodGYM resulted in participants completing an average of 3.8 modules (Høifødt et al., 2013).

**Discussion of Literature**

Results from the literature reviews and meta-analyses discussed here support the efficacy and effectiveness of CCBT for treatment of depression and anxiety disorders. CCBT had a significant effect on depression scores compared with control conditions, especially when the control was a waitlist or placebo rather than an active treatment. Effect sizes (Cohen’s $d$) ranged from 0.3 to 1.9. In general, effect sizes were smaller when CCBT was compared with primary care treatment as usual and tended to be larger when CCBT was compared with a wait-list control. CCBT effect sizes were also larger in studies where initial levels of depression symptoms were clinically significant. There are indications that CCBT is not appreciably inferior to face-to-face CBT in the treatment of depression.

Attrition rates in randomized controlled trials of CCBT tended to be high unless there was an incentive to complete the studies. Attrition can introduce bias into research, as can some methods intended to minimize attrition such as payments for completing assessments. It is not clear if demographic characteristics or baseline symptom severity have a consistent effect on attrition, but incorporating some sort of contact such as email reminders, telephone calls, or face-to-face meetings appears to improve adherence to CCBT. Other bias can be attributed to the inability to blind participants to treatment assignment.

MoodGYM studies had attrition rates as high as 90%. As in other CCBT studies, attrition was lower when participants had some sort of contact with research staff or therapist support. Participants who completed three or more MoodGYM modules generally had a statistically significant decrease in depression scale scores when compared with those in the control group.
Efforts to improve initiation of treatment and adherence resulted in improved outcomes. Effect sizes may be modest in ITT analyses, but are larger when analyses are run on treatment-adherent subgroups.

**Agency Description: Campus Health and Counseling Center**

The site selected for the proposed CCBT project was the University of Louisville (U of L) Campus Health Services Cardinal Station clinic. U of L is located in the largest city in Kentucky and is home to 12 colleges and schools, including Law, Medicine, Dentistry, Nursing, and Engineering. In the Fall 2016 semester U of L had a total enrollment of 22,640 with 16,033 undergraduate, 5,808 graduate, 155 post-doctoral students, and 655 medical house staff. The number of male and female students is roughly equal (the number of gender-non-conforming students is not tracked). Students who self-identify as ethnic and racial minorities make up 22.9% of the university population while 72.3% identify as White.

**Services and Fees.** Campus Health Services (CHS) at the University of Louisville provides primary health care to students enrolled in at least six credit hours of class. Students enrolled in 6.5 or more credit hours are required to pay a Primary Care Health Fee (PCHF) unless they have proof of insurance. The PCHF is used in part to cover the costs of psychiatric care at CHS and counseling services provided by the U of L Counseling Center (CC). This has the advantage of making mental health services available to all students at no additional charge, regardless of insurance status. This system also allows students to keep the fact that they are in treatment private from their families if they prefer. Mental health services are available to all students taking at least 6 hours of classes regardless of whether or not they have paid the PCHF.

There is currently no limit on the number of visits a student may have at CHS for psychiatric care. Students seeking treatment at the CC are limited to eight sessions per semester.
unless approved for extra appointments due to severity of symptoms. Students may self-refer for treatment at the CC, but must be referred for treatment with Student Psychiatric Services (SPS). Referrals may come from primary care, the CC, community therapists or physicians, or from entities within the University such as the Office of the Dean of Students, the Disability Resource Center, and Student Support Services.

Campus Health Services has made depression screening and treatment a priority. From 2012 to 2015 Campus Health Services participated in a quality improvement project known as the National College Depression Partnership (NCDP). NCDP promoted routine depression screening in the primary care setting and tracking students identified as having significant symptoms of depression as well as impairment in daily functioning in order to ensure that such students would receive minimally adequate depression care. As part of the NCDP, Campus Health started using the PHQ-2 and PHQ-9 to perform routine depression screening for students presenting for primary care. The goal is to screen each patient at least once per semester. The PHQ-2 consists of two questions asking if respondents have had little interest or pleasure in usual activities and if they have been feeling down, depressed, or hopeless in the past two weeks. Any student who answers “yes” to either of these questions is given the full PHQ-9. Students who score 11 or above on the PHQ-9 (moderately severe depression) and who report they are finding it very difficult or extremely difficult to perform activities of daily living are entered into a patient registry where their follow-up appointments and subsequent PHQ-9 scores are tracked. Primary care or psychiatric providers may add students reporting suicidal ideation to the registry regardless of PHQ-9 scores.

Students who meet inclusion criteria for the depression registry and who are not currently in treatment may be referred to the Counseling Center, Psychological Services Center, or to
Student Psychiatric Services for mental health care or may be treated by the primary care provider. The goal is to have students with significant levels of depression begin treatment within two weeks of being identified and to remain in treatment until they have received an adequate trial of medication or show subclinical levels of depression symptoms as measured by repeat PHQ-9 assessments. Students who have significant symptoms of depression sometimes decline referral to a mental health provider or choose not to schedule if they are not able to get an appointment quickly.

**Organizational Structure and Levels of Staffing.** CHS currently employs one primary care physician who serves as the Executive Director of Campus Health. There are also three full-time primary care nurse practitioners, one part-time primary care nurse practitioner, three part-time psychiatrists, and two full-time psychiatric nurse practitioners (including this author) on staff. CHS serves as a clinical site for medical students and nurse practitioner students, including psychiatric nurse practitioners. In addition to the main clinic located in the Cardinal Station (CS) building there is a smaller satellite office located on the Health Sciences Campus in downtown Louisville for the convenience of medical, dental, nursing, and public health students.

The Executive Director of CHS reports to the University Provost and the Vice President for Health Affairs. The director of Student Psychiatric Services is a member of the U of L psychiatry faculty and reports to the Executive Director and the chair of the Department of Psychiatry. The Health Sciences Campus (HSC) office has an additional counselor funded by the School of Medicine. His services are exclusively for health professions students in the medical, dental, nursing, dental hygiene, public health, and audiology/speech pathology programs. Health professions students have the option to obtain treatment through the Counseling Center or through CHS at Cardinal Station as well as at HSC.
The Counseling Center currently employs five doctoral-level psychologists, one licensed clinical social worker, two licensed marriage and family therapists, one licensed psychological associate, and one licensed art therapist. One of the psychologists is the Counseling Center Director and functions primarily in an administrative role. In addition, graduate trainees in counseling psychology and social work from local universities provide therapy under the supervision of senior staff. The Counseling Center is under the direct administration of the Vice President of Student Affairs via the Dean of Students Office.

CHS and the CC use different electronic records systems. The Counseling Center uses Titanium while CHS uses AllScripts as its electronic health record. These systems are not compatible with each other and there is no secure way for therapists and health care providers to communicate with each other electronically about mutual patients. However, CHS psychiatric providers meet with CC staff weekly to discuss mutual patients. Mental health providers may communicate via telephone when necessary. Email is not used for sharing patient information. AllScripts does have the capability for patients and providers to communicate securely via the Patient Portal, but not all students register for the Patient Portal. The Patient Portal meets the requirements for confidentiality set forth in the Health Insurance Portability and Accountability Act (HIPAA).

The CC clinical staff has more than doubled in the past eight years, but even when CHS psychiatric providers are included in calculations of the staff to student ratio, U of L does not meet the recommendation of the International Association of Counseling Services recommendation for a permanent staff to student ratio of 1:100 or 1:1500. At the current level of staffing, the U of L Counseling Center often has a wait of three weeks or more before a student can be seen for an evaluation. The wait for an initial appointment can be as long as 2 months and
there are times during the year when the Counseling Center stops accepting new patients and goes to a wait-list protocol which includes telephone triage by CC staff. By the first week in November 2016, there was a wait list with 65 names on it (Aesha Uqdahl, U of L Counseling Center Director, personal communication). There is always a counselor assigned to assess students in crisis who walk in without an appointment during regular office hours, but a crisis session does not count as an initial evaluation and follow-up can be delayed. As noted above, staffing levels affect access to treatment which in turn can affect retention in school and academic performance of students. Access to treatment may also affect university risk and liability. Sup-optimal staffing levels can decrease the availability of mental health staff to provide outreach and education to the campus community at large ("Statement Regarding Recommended Ratios," 2015).

Students often seek help with mental health issues from primary care providers at CHS, where an appointment is usually available within 24 to 48 hours. A primary care provider may choose to treat the student or to make a referral to one of the psychiatric providers or to the CC. Except during times of very high demand, students can usually get an evaluation appointment with psychiatric staff within 2 weeks. Patients with severe symptoms or suicidal ideation may be referred to psychiatric staff for one of the three urgent appointment slots reserved each week. Students who are disinclined to take medication and who cannot schedule an evaluation at the CC in a timely manner may choose to forego treatment for mental health problems.

**Organizational Mission and Goals**

The mission of U of L Campus Health Services is “…to support and enhance students’ educational experience by providing clinically excellent, affordable and confidential integrated medical, mental, health promotion and violence prevention services as well as specialized
healthcare services to the general University community. Utilizing an ecological health model, we assist the University community in achieving academic and life goals” ("Mission, values, goals," n.d., para. 1). Adoption of MoodGYM or a similar ICBT program at CHS supports this mission by providing timely access to evidence-based mental health treatment to students experiencing symptoms of depression. The Executive Director of CHS and the Director of Student Psychiatric Services are open to quality improvement projects and evidence-based practices. See Appendix B for the Statement of Mutual Agreement with CHS. The DNP project presented here builds on the NCDP depression screening quality improvement project that CHS has already implemented and provides another avenue for providing minimally adequate depression treatment.

Stakeholders in this endeavor include students and their families, university medical and mental health clinical staff, administrators, faculty, staff, and the Louisville community as a whole.

**Project Design**

**Description of the Intervention**

MoodGYM was selected as the online CBT program for this project for a number of reasons. There is an extensive body of research using MoodGYM and most of it has shown a positive effect on various mental health problems. Furthermore, MoodGYM is listed on the National Registry of Evidence-based Programs and Practices maintained by the Substance Abuse and Mental Health Services Administration (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012). When this DNP project was initiated, MoodGYM was available at no charge to users. However, in early 2017 the program was updated and access was restricted. It is still available free of charge to users in Australia, but organizations in other
countries must subscribe to MoodGYM to make it available to their members. Individual users may also purchase access. The organization eHub Health, founded by The Australian National University to manage MoodGYM, permitted up to 35 users to sign up for MoodGYM through this project free of charge.

Aside from the current limit on access to MoodGYM, the disadvantages of the program are that it is heavily dependent on text and it is not as technologically advanced as other online therapy programs. MoodGYM may not be seen as relevant or inclusive to same-sex attracted people or the gender-diverse population (Rozbroj, Lyons, Pitts, Mitchell, & Christensen, 2015). However, the advantage of MoodGYM being thoroughly tested outweighed these disadvantages for the purpose of this project.

**Procedures**

**IRB approval.** The proposal was submitted to the University of Louisville Institutional Review Board (IRB) via the Integrated Research Information System (iRIS) and approved by means of an expedited review by the IRB Chair. The IRB number assigned was 17.1312 (see Appendix C). Once the project was approved by the U of L IRB, an Internal Authorization Agreement was obtained from the Eastern Kentucky University IRB (see Appendix D.).

**Measurements and instruments.** The main outcome measure was the PHQ-9. The PHQ-9 is an open-source, self-report scale that does not require special training to administer or interpret. It is already in use at CHS for routine depression screening and follow-up assessments by psychiatric staff. This instrument has been used extensively in research and clinical settings and is considered to have good reliability and validity. Kroenke, Spitzer, & Williams (2001) tested the PHQ-9 in a primary care study ($n=3000$) and an obstetrics-gynecology study ($n=3000$). Chronbach’s alpha, a measure of internal reliability, was 0.89 for the primary care study and 0.86
for the obstetrics-gynecology study. Test-retest reliability was also very high (the correlation of scores on the PHQ-9 administered 48 hours apart was 0.84). Criterion, construct, and external validity were found to be very strong (Kroenke, et al, 2001).

The secondary outcomes were number of modules and exercises completed, time spent using MoodGYM, and participant satisfaction with the intervention. All outcome measures were recorded in an Excel spreadsheet stored on an encrypted, password-protected USB drive stored in the project leader’s office at CHS. Patient names were coded and were not attached to the spreadsheet. Patient names and codes were entered into a separate document and stored in a locked cabinet in a CHS office with restricted access.

**Implementation.** Participants were recruited from multiple sources. Informational flyers were posted in the CHS waiting rooms, exam rooms, and psychiatric provider offices. A flyer was also posted in the waiting room of the Counseling Center. The project was described to Counseling Center staff members and a synopsis of the enrollment procedure was given to them. Patients who had already established treatment with one of the psychiatric providers and who met the inclusion criteria were also invited to participate in the ICBT program.

In order to be included in the program, patients had to have a PHQ-9 score of 10 or above at the time of enrollment. Students with a primary diagnosis of an eating disorder, substance abuse disorder, post-traumatic stress disorder, or psychosis were not included in the ICBT program. Students diagnosed with bipolar depression were not excluded from participation. Suicidal ideation was not part of the exclusion criteria because the frequency of follow-up appointments was as high or higher than for treatment as usual.

Students who expressed interest in the program and who were not currently in treatment with a psychiatric provider were scheduled for an intake appointment with the project leader to
establish a diagnosis and assess for exclusion criteria. The 90-minute intake appointment included the standard psychosocial evaluation used at CHS. At the conclusion of the evaluation, students meeting inclusion criteria were offered the option of enrolling in the ICBT program, regardless of whether or not they wished to pursue use of medication or individual therapy. Students who were already in treatment with a psychiatric provider at CHS were scheduled with for a 30-minute appointment with the project leader to enroll in the program. Potential risks and benefits of the program and the contents of the informed consent were explained to potential participants. All participants were given a copy of the informed consent and were allowed time to review the document and to ask questions. Based on the recommendations of Wilhelmsen et al. (2013), participants were given information about the effectiveness of MoodGYM and allowed flexibility regarding time to complete modules and number of modules to complete in order to promote adherence to the program. Students were encouraged to try to complete at least four of the five modules within 6 weeks, but were told that they could have longer if necessary. The target of four modules was selected because several MoodGYM studies indicated that completing fewer than five modules was as least as effective as completing all five for reducing symptoms of depression.

A representative from eHub Health, the website hosting MoodGYM, provided individual codes allowing participants to register on the website. Participants were given folders containing their copies of the informed consent document and worksheets to use for recording time spent on each module and exercise (Appendix E). The participant satisfaction survey (Appendix F) was given to participants who completed MoodGYM at their final follow-up appointment. The satisfaction survey consisted of four statements about the helpfulness of MoodGYM, ease of use, the likelihood of using what was learned through MoodGYM, and the likelihood of
recommending a program such as MoodGYM to someone else. Participants were asked to indicate how much they agreed with each statement with answers ranging from “Strongly Agree” to “Strongly Disagree.” A space was also provided for participants to write in comments about MoodGYM.

After enrollment in the program, participants were scheduled for follow-up appointments with the project leader every two or three weeks. The purpose of these appointments was to discuss progress, complete PHQ-9 forms, assess for worsening symptoms or significant suicidal ideation, and encourage adherence. If a student had expressed suicidal ideation with a plan and intention, the usual CHS protocol would have been followed (i.e., transportation to Emergency Psychiatric Services at the University of Louisville Hospital via the U of L campus police). Participants also kept their regular appointments with their psychiatric provider or therapist. There were no restrictions on starting face-to-face therapy or medication or making medication changes.

Data analysis. The MoodGYM project utilized a pre-post intervention design. Data were analyzed using Statistical Package for the Social Sciences (SPSS). Paired t tests were used to compare depression scores on the PHQ-9 before and after completion of the intervention. Descriptive statistics were performed on demographic data and secondary outcomes. Effect size was calculated using Eta².

Results

A total of 19 students agreed to participate in the project. The participant ages ranged from 20 to 35 with a mean of 24.8 years. The majority of participants were female (89.5%). Only one participant was not already established as a patient of one of the two PMHNPs at Campus Health. Although there were no direct referrals from the Counseling Center, one
Participant already in treatment saw the recruitment poster in the Counseling Center waiting room and contacted the project leader.

Six participants (31.6%) did not complete any MoodGYM modules. Four of these failed to keep their follow-up appointments and did not respond to messages asking them to reschedule. Two participants who did not complete any MoodGYM modules did return for follow up. One of these two reported that she did not feel she had time to do MoodGYM while classes were in session, but planned to try the program over winter break. The other was a patient with trichotillomania who felt that she engaged in hair-pulling more when she was on her computer. Three participants (15.6%) completed one module, five (26.3%) completed two modules, and five (26.3%) completed all five modules. For those who completed all modules, the time from enrollment to the final follow-up appointment averaged 7.05 weeks (range 6.5 to 8.5 weeks). The average number of modules completed for all participants was 2. Although participants were asked to estimate the amount of time spent on each module and exercise, only three returned the worksheet used to track time spent and two of these had missing data. Time spent on modules and exercises was not included in the final analyses.

The mean pre-intervention PHQ-9 score was 15.58 (range 9-27, S.D. 3.834). The range included a PHQ-9 score below 10 because one participant had a high PHQ-9 score when recruited, but scored lower on the day of enrollment and the decision was made to include this student. For participants who kept at least one follow-up appointment but did not complete all five MoodGYM modules, the last PHQ-9 score recorded was carried forward and used as the post-intervention score. The mean post-intervention PHQ-9 score was 11 (n=15, range 2-18, S.D. 4.408). The mean decrease in PHQ-9 scores after participants completed one or more MoodGYM modules was 4.467 points (S.D. 4.257; 95% CI [2.109-6.824]) and the change was
statistically significant ($p < .001$). The effect size for the intervention was large ($\eta^2 = 0.54$). For participants who completed all five modules, the mean decrease in PHQ-9 score was 6 points compared with 4.4 points for the eight participants who only completed one or two modules. One participant had a 2-point increase in PHQ-9 score, but this occurred after the end of a romantic relationship and the student did not return for further follow-up appointments.

Seven participants completed the patient satisfaction survey and all seven stated that they agreed or strongly agreed with the statements on the survey regarding the usefulness of MoodGYM, ease of use, likelihood of incorporating CBT techniques in their lives, and likelihood of recommending an ICBT program such as MoodGYM to someone who was having problems with depression. One participant commented that MoodGYM was “too foreign” and another one said that she had difficulty understanding the Australian slang. Two participants thought that the fictional characters were “corny” and juvenile, but otherwise liked the program. Other comments were generally positive.

**Discussion**

Internet-based CBT appears to be an acceptable and effective treatment for college students with symptoms of depression. The mean change in PHQ-9 score post intervention was both statistically and clinically significant. For this study, participants who completed all five modules had larger reduction in PHQ-9 scores than those who only completed one or two modules.

The rate of attrition, defined for the purpose of this project as failure to complete any MoodGYM modules, was almost one third of participants. It was expected that the attrition rate would be high based on rates reported in the literature. Even with poor adherence, the difference between pre- and post-intervention PHQ-9 scores was significant.
This intervention was acceptable to at least some of the participants. Those students who filled out satisfaction surveys reported that they thought the MoodGYM website was both useful and easy to use and that they would recommend a program such as MoodGYM to someone else having problems with depression. Since most of the participants who did not complete all modules were lost to follow-up and did not fill out the patient satisfaction survey, the opinions of those who did not like the program were not available.

Limitations of the project include a small sample size, limited recruitment from primary care, the lack of a 6 or 12 week post-intervention reassessment, and potential bias introduced by participants wishing to please the project leader. Due to schedule constraints it was not possible to recruit for a longer period of time and the limited time frame of the project made a 6-week or later post-intervention assessment impractical. It is possible that greater improvements in PHQ-9 scores would be evident as students continue to practice skills learned through MoodGYM.

All but one of the participants was an established patient of either the project leader or the other PMHNP working at Campus Health. More patients not already in treatment might have been enrolled in the MoodGYM project if a more focused effort had been made to recruit patients when they filled out the PHQ-9 during primary care appointments. Phone calls made to primary care patients eligible for inclusion in the project after their appointments were not answered except in one case.

It is possible that some of the students agreed to participate in the project because of the therapeutic relationship they had with the project leader or the other PMHNP at CHS. They may have also under-reported the severity of their symptoms in order to “help” the project demonstrate a positive effect on depression. Using a disinterested party such as a medical assistant or nurse to meet with students biweekly while they were participating in the MoodGYM
project might have decreased the possibility of bias, but was not practical given the levels of staffing at the study site.

There were no referrals from the Counseling Center over the course of the project. Appointments for initial evaluations at the Counseling Center were available for most of the recruitment period for the MoodGYM project. Continuing recruitment later into the semester when there was a wait list at the Counseling Center might have resulted in some direct referrals from the Counseling Center.

Implications

Online CBT programs such as MoodGYM have the potential to allow rapid access to evidence-based treatment for students with symptoms of depression and to help meet the high demands for mental health treatment. Self-guided CBT may be particularly attractive to students who are uncomfortable with traditional face-to-face talk therapy or those who do not wish to take antidepressant medication. Minority and international students may also find online CBT more acceptable than usual mental health treatment due to cultural biases against psychotherapy and medications. Giving students who are on a wait list for student counseling services access to an online CBT program could help reduce the negative effects of depression on attendance, grades, and retention in school.

When this project was first proposed MoodGYM was available at no charge to anyone who wished to use it. However, in the spring of 2017 MoodGYM was updated and access was restricted. It is still free to users in Australia, but those outside of Australia must pay for access. As of the conclusion of this DNP project, there were no colleges or universities in the United States that were using MoodGYM. The project leader corresponded with a representative of eHub Access regarding the costs for a higher education institution to have access to MoodGYM
for students. The first estimate quoted was based on a price per enrolled student and while that appeared to be very low at the outset, it would have amounted to enough money to hire another therapist for the Counseling Center. After some negotiation, the fee was substantially reduced. If it can be demonstrated that students will use such a program, university administration may be willing to underwrite the cost. At the University of Louisville, the 2017-2018 academic year in-state undergraduate tuition is just over $11,000 and over twice that amount for out-of-state students. If two in-state students or one out-of-state student who might otherwise drop out of school due to depression were retained for one year because of MoodGYM, the cost of the program would be more than covered.

Other online or computer-administered CBT programs are available, but were not chosen for this project because they did not have the extensive research history of MoodGYM. Newer programs that are more technologically sophisticated and interactive than MoodGYM or ones that are developed as smartphone apps might be more acceptable to college students and the attrition rate with one of these programs might be lower.

**Summary/Conclusions**

Online CBT with therapist support was an acceptable treatment modality to about 2/3 of the students who agreed to participate in this project. PHQ-9 scores decreased for most participants over the course of the intervention, although it cannot be determined if this was entirely the result of the intervention or other factors such as medication changes. Use of online CBT could be a cost-effective and efficacious treatment for university students with symptoms of depression.
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## Appendix A. Studies Included in Meta-analyses and Systematic Reviews

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Appendix B. Statement of Mutual Agreement

Campus Health Services
Office of the Vice-President for Health Affairs
Phillip F. Bressoud, MD, FACP
Executive Director and
Associate Professor of Medicine

April 26, 2017

Clinic Support Letter

Sandra D. Robertson, MSN, APRN, PMHNP-BC
Doctor of Nursing Practice Student, Eastern Kentucky University
215 Central Ave, Ste 110
Louisville, KY 40292

Dear Ms. Robertson,

I am writing in support of your capstone project entitled Internet-based Cognitive Behavior Therapy for College Students with Symptoms of Depression. I understand that as part of your project you will be offering University of Louisville Campus Health Services patients who are experiencing symptoms of depression the opportunity to participate in an Internet-based cognitive behavior therapy program called MoodGYM. As part of this intervention, primary care providers at Campus Health will give an informational handout about the project to students who have positive scores for depression on the Patient Health Questionnaire-9 (PHQ-9). Established patients being treated for depression by either primary care providers or psychiatric providers may be referred to the program as well. I understand that as part of the screening process to determine eligibility for inclusion in the project you may need to access PHI for PHQ-9 scores and for diagnoses that would exclude a student from participating in the project. Informed consent will be obtained from all student participants.

I understand that this research will be carried out following sound ethical principles and that participant involvement in this project is strictly voluntary. All results will be reported in the aggregate. Demographic data will be de-identified and all data will be stored in a secure location.

I look forward to you starting your project once IRB approval is obtained. As the Executive Director of the University of Louisville Campus Health Services, I agree that your capstone project may be conducted at our facility.

Sincerely,

[Signature]

Phillip F. Bressoud, MD, FACP
Executive Director and
Associate Professor of Medicine

CC: File
Tony Logsdon, Program Manager

A: Health Sciences Center
401 East Chestnut Street Suite 110
Louisville, KY 40202
P: 502-852-6446
F: 502-852-6649
W: www.louisville.edu/campushealth

A: Cardinal Station Center
201 Central Avenue Suite 110
Louisville, KY 40208
P: 502-852-6479
F: 502-852-6660
Appendix C. Internal Review Board Approval

This study was reviewed by the Chair of the Institutional Review Board and approved through the Expedited Review Procedure, according to 45 CFR 46.110(b), since this study falls under Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

The following items have been approved:

<table>
<thead>
<tr>
<th>Submission Components</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Submission Form</td>
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<tr>
<td>Form Name</td>
<td></td>
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<tr>
<td>Submit for Initial Review</td>
<td>Approved</td>
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<tr>
<td>Review Response Submission Form</td>
<td>Approved</td>
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<tr>
<td>IRB Study Application</td>
<td>Approved</td>
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<table>
<thead>
<tr>
<th>Study Document</th>
<th>Version #</th>
<th>Version Date</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>17.1312 Roberston signed IAA UL is IOR for EKU</td>
<td>Version 1.0</td>
<td>05/26/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT MoodGYM User Satisfaction Survey</td>
<td>Version 1.0</td>
<td>05/21/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT MoodGYM worksheet</td>
<td>Version 1.0</td>
<td>05/13/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT PHQ-9</td>
<td>Version 1.0</td>
<td>05/13/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT Recruitment flyer</td>
<td>Version 1.0</td>
<td>05/13/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT General information handout</td>
<td>Version 1.0</td>
<td>05/13/2017</td>
<td>Approved</td>
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<tr>
<td>ICBT Clinic support letter</td>
<td>Version 1.0</td>
<td>05/13/2017</td>
<td>Reviewed</td>
</tr>
<tr>
<td>ICBT Robertson Protocol</td>
<td>Version 1.1</td>
<td>06/03/2017</td>
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<tr>
<td>ICBT Robertson HIPAA Partial Waiver</td>
<td>Version 1.0</td>
<td>06/04/2017</td>
<td>Approved</td>
</tr>
<tr>
<td>Robertson ICBT Subject Informed Consent Document</td>
<td>Version 1.1</td>
<td>06/06/2017</td>
<td>Approved</td>
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</tbody>
</table>

This study now has final IRB approval from 6/9/17 through 6/8/17.

For guidance on using IRIS, including finding your approved stamped documents, please follow the instructions at https://louisville.edu/research/humansubjects/IRISSubmissionManual.pdf
If this study will take place at an affiliated research institution, such as KentuckyOne Health, Norton Healthcare or University of Louisville Hospital, permission to use the site of the affiliated institution is necessary before the research may begin. If this study will take place outside of the University of Louisville Campuses, permission from the organization must be obtained before the research may begin (e.g. Jefferson County Public Schools). Failure to obtain this permission may result in a delay in the start of your research.

Privacy & Encryption Statement
The University of Louisville’s Privacy and Encryption Policy requires such information as identifiable medical and health records: credit card, bank account and other personal financial information; social security numbers; proprietary research data; dates of birth (when combined with name, address and/or phone numbers) to be encrypted. For additional information: http://security.louisville.edu/PolStds/ISO/PS018.htm.

Implementation of Changes to Previously Approved Research
Prior to the implementation of any changes in the approved research, the investigator will submit any modifications to the IRB and await approval before implementing the changes, unless the change is being made to ensure the safety and welfare of the subjects enrolled in the research. If such occurs, a Protocol Deviation/Violation should be submitted within five days of the occurrence indicating what safety measures were taken, along with an amendment to revise the protocol.

Unanticipated Problems Involving Risks to Subjects or Others (UIRTSOS)
In general, these may include any incident, experience, or outcome, which has been associated with an unexpected event(s), related or possibly related to participation in the research, and suggests that the research places subjects or others at a greater risk of harm than was previously known or suspected. UIRTSOS may or may not require suspension of the research. Each incident is evaluated on a case by case basis to make this determination. The IRB may require remedial action or education as deemed necessary for the investigator or any other key personnel. The investigator is responsible for reporting UIRTSOS to the IRB within 5 working days. Use the UIRTSO form located within the IRIS system to report any UIRTSOS.

Continuation Review Requirements
You are responsible for submitting a continuation review 30 days prior to the expiration date of your research study. Investigators who allow their study approval to expire have committed significant non-compliance with federal regulations. Such lapses may require reporting to federal agencies, a program audit by compliance auditors to ensure that subjects were not enrolled during the expired period, and may lead to findings of serious and continuing non-compliance if expiration were to occur a second time.

1099 Information (If Applicable)
As a reminder, in compliance with University policies and Internal Revenue Service code, all payments (including checks, pre-paid cards, and gift certificates) to research subjects must be reported to the University Controller’s Office. Petty Cash payments must also be monitored by the issuing department and reported to the Controller’s Office. Before issuing compensation, each research subject must complete a W-9 form. For additional information, please contact the Controller’s Office at 852-8237 or control@louisville.edu

The committee will be advised of this action at a regularly scheduled meeting.

If you have any questions, please contact the IRB analyst listed above or the Human Subjects Protection Program office at hsppofc@louisville.edu.

Full Accreditation since June 2005 by the Association for the Accreditation of Human Research Protection Programs, Inc.
Peter M. Quesada, Ph.D., Chair

Social/Behavioral/Educational Institutional Review Board

PMQ/qsp
Appendix D. Internal Authorization Agreement

**IRB Authorization Agreement**

*University of Louisville IRB is IRB of Record*

<table>
<thead>
<tr>
<th>Name of Institution or Organization Providing IRB Review (Institution/Organization A):</th>
<th>University of Louisville</th>
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<tbody>
<tr>
<td>OHRP Federal-wide Assurance (FWA) Number</td>
<td>FWA00002211</td>
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<tr>
<td>IRB Registration #:</td>
<td>IRB00000251, IRB A Biomedical IRB IRB00000252 IRB B</td>
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<tr>
<th>Name of Institution or Organization Relying on the IRB Review Above (Institution/Organization B):</th>
<th>Eastern Kentucky University</th>
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<tr>
<td>OHRP Federal-wide Assurance (FWA) Number</td>
<td>FWA00003332</td>
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<tr>
<th>Name of Research Project</th>
<th>Internet-based Cognitive Behavior Therapy for College Students with Symptoms of Depression</th>
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| Principal Investigator(s): | Institution A: A: Sandra Robertson  
B: Sandra Robertson/Donna Corley |
| IRB Protocol Number: | 17.1312 |
| Sponsor or Funding Agency: | |

The Officials signing below agree that Institution B may rely on the above IRB for initial review, approval and continuing oversight by the University of Louisville under its Assurance for the project identified above. This agreement applies only to the project named above and to no other research projects in which Institution B may be engaged in at present or in the future.

The initial review, approval and continuing oversight performed by the relied-upon IRB satisfies the requirements of the HHS regulations for the protection of human subjects at 45 CFR 46, as well as the requirements of University of Louisville’s OHRP-approved Assurance. Institution B retains the obligation to comply with all other requirements of 45 CFR 46 and as otherwise required by the FWA, or other applicable laws or regulations.

This document should be kept on file at both institutions and must be provided to OHRP upon request.

**Signature of Signatory Official (Institution A):**  
Christy LaDuke MA, BS, CCRP  
Assistant Director, Human Subjects Protection Program  
University of Louisville  
MedCenter One – Suite 200  
501 E. Broadway  
Louisville, KY 40202-1798  
Office: (502) 852-5188  
Fax: (502) 852-2164  
Email: clpeppp01@louisville.edu

**Signature of Signatory Official (Institution B):**  
Dr. Gerald J. Pogatsnir  
Title: Associate Vice President for Research  
Institution: Eastern Kentucky University  
SSB CPO 68  
521 Lancaster Avenue  
Richmond, KY 40475-3102  
Office: (859) 622-1744  
Fax: (859) 622-6610  
Email:jerry.pogatsnir@eku.edu
Appendix E. MoodGYM Worksheet

MoodGYM Worksheet

Please record the date you do each module and exercise and estimate how much time you spent on it.

<table>
<thead>
<tr>
<th>Modules</th>
<th>Exercises</th>
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## Appendix F. MoodGYM Satisfaction Survey

MoodGYM Satisfaction Survey

<table>
<thead>
<tr>
<th>Rate how much you agree with each statement</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neither agree nor disagree</th>
<th>Disagree</th>
<th>Strongly disagree</th>
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</thead>
<tbody>
<tr>
<td>1. I found the information on the MoodGYM website helpful.</td>
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<td>2. I found the MoodGYM website easy to use.</td>
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<td>3. I think I will apply what I learned through MoodGYM to my life.</td>
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<td>4. I would recommend a program such as MoodGYM to someone else having problems with depression.</td>
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Comments: