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Computerized Behavioral Activation Treatment for Major Depressive Disorder and the Effects on Sexual Desire

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COMPUTERIZED BEHAVIORAL ACTIVATION TREATMENT FOR MAJOR DEPRESSIVE DISORDER AND THE EFFECTS ON SEXUAL DESIRE

by

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The present study was designed to examine the effects of a computerized behavioral activation treatment program on sexual desire, sexual behavior, and depression symptoms. Seven adults who met criteria for either major depressive disorder or dysthymic disorder were recruited from Kalamazoo, Portage, and surrounding areas in Southwestern Michigan. All participants completed at least five sessions of behavioral activation treatment, and six out of seven participants completed all ten sessions. Symptoms of depression, sexual desire, and sexual behavior were assessed at pretreatment and before each treatment session through a combination of the Beck Depression Inventory – II (BDI-II), the Revised Hamilton Rating Scale for Depression (RHRSD), the Structured Clinical Interview for DSM-IV Axis I disorders (SCID-I), and the Sexual Desire Inventory (SDI). It was hypothesized that participants would report an improvement in overall depression. It was further hypothesized that participants would report an increase in sexual desire and sexual behavior frequency after completing the depression treatment program. Results were explored statistically using Pearson Product Moment Correlations of variables, paired two sample *t*-tests of pretest and posttest treatment data, and visual inspection of individual participant scores over the course of treatment. Results indicated a significant improvement in depression that is both

statistically and clinically significant. Additionally, no significant improvement to sexual desire, nor an increase in sexual behavior frequency, was noted as a result of completing treatment.

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CHAPTER I

INTRODUCTION

Historically, sexual desire has been labeled as and studied as different names: libido, sexual drive, sexual motivation, sexual interest, and sexual appetite. Several of those terms have a mix of cognitive, affective, and behavioral connotations. In order to separate the terms for research purposes, it has been suggested that sexual desire be used to describe the thoughts, fantasies, and interest in sexual activity. "Sexual desire refers to *interest in sexual activity*. It is primarily a cognitive variable, which can be measured through the amount and strength of thought directed toward approaching or being responsive to sexual stimuli" (p. 178; Spector, Carey, & Steinberg, 1996). Sexual desire is not a behavior and as such should not be quantified behaviorally by measuring frequency of sexual activity. A person can have strong sexual desire, but not engage in any sexual behavior. Similarly, a person can engage in sexual behavior even if they have low sexual desire (Santtila, Wager, Witting, Harlaar, Jern, Johansson, Varjonen, & Sandnabba, 2008). Impaired sexual desire can also have negative effects on relationships as sexual desire and marital satisfaction are related to one another (Trudel & Goldfarb, 2010).

Major depressive disorder is a significant public-health concern across the world. Recent research has calculated the average lifetime prevalence of a major depressive episode at 14.6%, and the 12-month prevalence to be 5.5%, and it affects women more than men at a 2:1 ratio (Bromet et al., 2011). Major depression is not only defined by

sadness, low mood, or irritability. It also is known to have a number of symptoms that can affect a person cognitively, emotionally, and physically.

Low or loss of sexual desire has long been associated as a symptom or side effect of major depressive disorder (Trudel, 1991; Trudel, Landry, & Larose, 1997). It has also been associated with anxiety, depression, and insufficient physical activity (Martin, Atlantis, Wilson, Lange, Haren, Taylor, & Wittert, 2012), along with other disturbances of functioning like disrupted sleeping patterns, changes in appetite, and loss of energy or fatigue (American Psychological Association, 2000; Beck, 1996). Men who experience symptoms of major depressive disorder often report a lack of sexual desire, decreased interest in sex (Kennedy, Dickens, Eisfeld, & Begby, 1999), decreased sexual frequency, erectile dysfunction, and anorgasmia (Thase, Reynolds, Jennings, Frank, 1988). These sexual symptoms span the range of problems that are diagnostically considered sexual dysfunctions (with the exception of sexual pain; American Psychological Association, 2000).

A diagnosis of hypoactive sexual desire disorder (HSDD) would be an appropriate if a person persistently shows a deficiency or lack of sexual fantasy and sexual desire but only if these symptoms are not better accounted for by an Axis I disorder like major depressive disorder. If a person experiences a lack or loss of sexual desire after they developed symptoms of major depressive disorder, then it is more appropriate clinically for that person's diagnosis and treatment to be centered on the major depressive disorder and the sexual desire is considered a symptom of the depression (American Psychological Disorder, 2000). The clinical and diagnostic

information for depression and sexual desire each include information about the other which further establishes the link between the two.

Behavioral activation has shown promise for treatment of other psychological conditions that share symptoms and presentations with major depressive disorder. Behavioral activation has been used with a client with comorbid depression and posttraumatic stress disorder (Mullick & Naugle, 2005), with people who are depressed and are obese who showed improvement in depression and showed weight loss (Pagoto, Bodenlos, Schnieder, Olendzki, & Spates, 2008), it showed effectiveness in a case study decreasing both depression and anxiety when the symptoms presented comorbidly, (Hopko, Luejez, & Hopko, 2004), and a randomized control trial showed that behavioral activation was effective in reducing and maintaining smoking abstinence and lowering depressive symptoms in people who were depressed and were smokers (MacPherson, Tull, Matusiewicz, Rodman, Strong, Kahler, Hopko, Zvolensky, Brown, & Lejuez, 2010). Using aerobic exercise, researchers documented an improvement in sexual functioning when compared to a placebo pill (Hoffman, Babyak, Sherwood, Hill, Patidar, Doraswamy, Blumenthal, 2009) supporting alterative treatment methods for sexual problems. It is not yet clear how sexual desire changes as a result of a change in depression after treatment for depression. Behavioral activation may be an efficacious treatment package that improves sexual desire along with depressive symptoms that occur with depressive disorders, even though the behavioral activation does not directly address sexual desire.

CHAPTER II

LITERATURE REVIEW

Sexual Desire

Sexual desire is a different process from sexual arousal, which refers to the physiological response to sexual arousal in the form of vasocongestion. However, like sexual desire, sexual arousal is also affected by depression. Men with major depressive disorder not only report loss of interest in sex, a cognitive variable, but also a lack of penile tumescence (erection) during waking and sleeping hours (Thase, Reynolds, Jennings, Frank, 1988). Sexual arousal can be considered the more biological aspect of human sexuality as it involves vascular and muscular functioning for male erection and ejaculation. The link between depression and impaired nocturnal tumescence is especially interesting because of the presumed lack of awareness and overt control over physical arousal, especially while asleep. This suggests the experience of depression has an involuntary effect on a basic, biological level. The biological connection between sexual desire and depression is not only found in men. Low sexual desire, depression, and anxiety were linked in women being treated for symptoms related to menopause (Schnatz, Whitehurst, & O'Sullivan, 2010).

Two of the most commonly used measures of depression, the Beck Depression Inventory (BDI-II; Beck et al., 1996) and the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960) both include items that inquire about change in sexual functioning in people experiencing depression. The HRSD, which is an interview

completed by a practitioner, includes an item to record genital symptoms like the loss of libido, impaired sexual performance, or changes in menstruation in women. The BDI-II, a self report questionnaire, asks the person to rate changes in their sexual interest, ranging from "I have not noticed any recent change in my interest in sex" to "I have lost interest in sex completely." The inclusion of sexual desire, which is similar to other somatic (pain) and appetitive (e.g., hunger and sleep) symptoms, further reflects the connection between depression and decreased sexual desire. However, the sexual desire item from the BDI-II is documented to have low predictive validity when compared to overall depression scores (Beck, 1996). Low sexual desire is not enough to predict major depression, but the connection between low or a loss of sexual desire with depression is common.

A common treatment for major depressive disorder is prescription medication. Selective serotonin reuptake inhibitors (SSRIs) like fluoxetine (Prozac), citalopram (Celexa), sertraline (Zoloft), and peroxetine (Paxil) have been shown to reduce sexual desire in men as a side effect (Montejo-Gonzales et al., 1997). In a double-blind, placebo-controlled study, 30-40 percent of the men in the SSRI treatment group experienced a decrease in sexual desire, compared to only six percent of the placebo group (Harrison et al., 1986). Bupropion (Welbutrin), which is a selective norepinephrine reuptake inhibitor (SNRI) is also common anti-depressant, is known to have the lowest amount of sexual side effects compared to the other SSRIs (Phillips & Slaughter, 2000), and the television commercials advertise this fact as one of the "benefits" of taking bupropion for depression. Part of the problem in the treatment of depression is that if men are reporting decreased sexual desire along with depression, and they experience an improvement to

depression with the use of an SSRI or SNRI, they may still have decreased sexual desire. For some men, the antidepressants may cause the loss of sexual desire, even if it wasn't a problem associated with their depression before taking the medication (Corona, Ricca, Bandini, Mannucci, Lotti, Boddi, Rastrelli, Sforza, Faravelli, Forti, & Maggi, 2009). A relationship between depression symptomatology and sexual desire was established in a psychiatric sample, however a high percentage of the patients were taking pharmacological treatment for their depression (84.3%), making it difficult to determine if low sexual desire was due to the depression or due to the medication (Lourenço, Azevedo, & Gouveia, 2010). This sexual side effect of medication could lead to people discontinuing their prescription regimen or dropping out of pharmacotherapy treatment. Some may discontinue treatment altogether, and others may seek non-pharmacological means of treatment for depression in hopes of finding an effective treatment with fewer side effects. Difficulty with low sex drive can remain even after depression treatment is completed (Taylor, Walters, Vittengl, Krebaum & Jarrett, 2010) which suggests that additional attention to this area may be warranted for a more comprehensive treatment package to reduce relapse.

Treatments for Depression

Several empirically supported psychotherapy-based treatments for depression exist (Chambless et al., 1998). Beck's Cognitive Therapy (Beck, Rush, Shaw, & Emery, 1979) for depression is a comprehensive treatment package that has theoretical bases in behavioral and cognitive psychology. The treatment package begins with an activation component which includes daily activity monitoring, assessment of pleasure and mastery

while engaged in activities, assignment of tasks of increasing difficulty to encourage approach behaviors, cognitive rehearsal and discussion of scheduled activities to identify potential problems that would limit participation, and teaching problem solving skills and social skills if needed to overcome obstacles. The cognitive component of the package involves monitoring and changing of automatic thoughts related to depression, and includes the use of the "downward arrow" technique which guides the client to identify their core beliefs. Many controlled trials have been conducted which have tested cognitive therapy compared to waitlist control and pharmacotherapy, and meta analyses of these studies conclude that cognitive therapy demonstrates a greater degree of change in those experiencing symptoms of depression (Dobson, 1989). Beck's Cognitive Therapy package was analyzed in a component analysis to identify the critical aspects of the treatment which could help determine the mechanism of change, and it was determined that the behavioral activation component which occurs in the beginning of the cognitive therapy treatment package yielded similar results to the comprehensive cognitive therapy package (Jacobson, Dobson, Truax, Addis, Koerner, Gollan, Gortner, & Prince, 1996). This dismantling research showed that the behavioral activation component, on its own, if cross-validated, could be an effective treatment for depression

Behavioral Activation

Behavioral activation, as a treatment for depression, can be defined as "A therapeutic process that emphasizes structured attempts at engendering increases in overt behaviors that are likely to bring the patient into contact with reinforcing environmental contingencies and produce corresponding improvements in thoughts, mood, and overall

quality of life" (p. 700; Hopko, Lejuez, Ruggiero, & Eifert, 2003). The treatment is centered around the idea that people who are depressed may be experiencing a loss or lack of positive reinforcement from behaving in their own environment (for a variety of reasons including poorly developed skill sets, negative environmental contexts not of their creation, or changes in life patterns, to name a few), or an environment is dominated by aversive control or punishers. This lack of positive reinforcement or presence of punishment may cause the onset of depression (Lewinsohn, 1973), and the person may engage in several behaviors that temporarily offer positive reinforcement through escape from aversive conditions or through avoiding potentially aversive conditions (Ferster, 1973). This pattern of avoidance and escape keeps the person feeling and acting depressed through negative reinforcement. Behavioral activation, based on this conceptualization, was developed to target this absence of reinforcement and/or behavioral escape and avoidance by attempting to increase the frequency of positive reinforcement, decrease aversiveness or punishment, and target avoidance and escape (Jacobson, Martell, & Dimidjian, 2001).

Behavioral activation was written as a 16 session therapy that took place between a client and a therapist who served as a "coach" or "consultant." The components of the treatment include focused activation, goal setting, teaching and using functional analysis. Focused activation, involves the client monitoring and tracking their activity on a daily and weekly basis. These constitute initial homework assignments. Several tools can be used here as the client does their homework outside of session. Activity logs can be worksheets or charts to record the activity at the time it occurred, while also including a measure of how masterful the client felt when performing the activity, and how much

pleasure the client experienced. Activities are chosen by the client, but can be prompted by the therapist and tied to established goals of the client. Activities that the client would like to include in their schedule should be ordered from the easiest to perform to most difficult. The easiest activity is the first chosen to be implemented because it has the lowest threshold of difficulty as perceived by the client and is likely to experience positive reinforcement. The successful accomplishment of a new activity may also prove rewarding, which in turn encourages the client to incorporate the next activity. A meta-analysis of 16 randomized controlled trials showed that activity scheduling showed significant effects in the treatment of depression (Cuijpers, van Straten, & Warmerdam, 2007).

Activity scheduling continues throughout treatment and the therapist teaches the client to use functional analysis to examine their own behavior. This can help the client to determine if they are choosing behavior that is avoiding aversiveness, which although seemingly beneficial in the short term could worsen problems in the long term. Or they may be choosing approach behavior which could bring them into contact with positive reinforcement even after confronting a difficult activity. The therapist's role begins to fade out as treatment moves toward maintenance and termination stages. If successful and the intervention works as hypothesized, the client is now activated at this point and has learned the tools to aid in reversing the pattern that can cause and maintain depression.

Research support for behavioral activation. Behavioral activation is considered a "well –established treatment" with efficacious research support according to the American Psychological Association list of empirically supported treatments (Chambless

et al., 1998). The component analysis (Jacobson et al., 1996) helped establish the evidence base for behavioral activation compared to cognitive therapy (Beck et al., 1979). Since then, several other studies have tested the efficacy of behavioral activation in a growing body of literature supporting its use in the treatment of depression. Behavioral activation was later compared to cognitive therapy and antidepressant medication (paroxetine) in a large scale randomized control trial that was structured to mimic methods used in pharmaceutical research to test effectiveness of drug treatments (Dimidjian, Hollon, Dobson, Schmaling, Kohlenberg, Addis, Gallop, McGlinchey, Markley, Gollan, Atkins, Dunner, & Jacobson, 2006). The results from this study showed that behavioral activation performed similarly to cognitive therapy and to the drug treatment although when dropout rates were considered, BA was found to be superior to all of the alternatives. Furthermore, a post experimental analysis based on this study revealed that BA worked for patients who were extreme non-responders to CT (Dimidjian et al., 2006).This helped further establish behavioral activation as a treatment for depression. It is regarded as comparatively easy to implement, shorter duration, and as effective as longer treatment packages or antidepressant medication, without the harmful side effects. A follow up study (Dobson, Hollon, Dimidjian, Schmaling, Kohlenberg, Gallop, Rizvi, Gollan, Dunner, & Jacobson, 2008) compared results after treatment and showed behavioral activation had long lasting effects at a much lower cost for treatment, even two years after treatment had ended.

Additional applications of behavioral activation. In addition to the large component analysis and randomized controlled trials of behavioral activation, additional research has been conducted that continues to show support for the use of behavioral

activation for depression. A small (N = 25) randomized-controlled trial with depressed inpatients showed that a modified version of behavioral activation that met three times weekly for brief (20 minute) sessions with a token economy rewarding activity levels between sessions was an effective treatment for depression compared to standard practice (Hopko, Lejuez, LePage, Hopko, & McNeil, 2003). A small-sample pilot study found behavioral activation to be effective with male and female teens, and included adaptations to the protocol including parental involvement in therapy (Ritschel, Ramirez, Jones, Craighead, 2011). A randomized controlled trial of a modified behavioral activation treatment with one treatment session was found to be significantly better at reducing depression scores in college students compared to a control group (Gawrysiak, Nicholas, & Hopko, 2009). A four-week protocol used with geriatric patients with mild to moderate cognitive impairment found behavioral activation to be more helpful when compared to a control group of similar patients (Snarski, Scogin, DiNapoli, Presnell, McAlpine, & Marcinak, 2011).

Computerized Treatment for Psychological Disorders

Psychotherapy treatments have been translated for delivery via computer terminals so that a patient interacts with a computer-guided treatment program rather than with a live psychotherapist. From a broader or administrative standpoint, these technologies can increase access to effective treatment and can also reduce the costs of delivering treatment (Cavenaugh & Shapiro, 2004). The use of computerized treatments could help bridge the gap between the millions who are affected by psychiatric conditions like depression, and the minority of people who can afford or get access to treatment.

Randomized-controlled trials that compare computerized versions of cognitive-behavioral therapies to treatment as usual for depression show symptoms of both depression and anxiety decreased after completing treatment in a clinically and statistically significant way (Proudfoot, Ryden, Everitt, Shapiro, Goldberg, Mann, Tylee, Marks, & Gray, 2004). In addition to treatment effects, participants who used the computerized treatment rated their satisfaction with treatment experience higher than those who received treatment as usual. A recent systematic review and meta-analysis of research on computer-based psychological treatments for depression reviewed 68 published papers on computer-based treatments for depression, and concluded that the current research supports the efficacy of treatment delivered by a computer (Richards & Richardson, 2012).

A majority of the work that takes place in behavioral activation takes place outside of the therapy room. Clients learn about activation and how that relates to the reversal of the conceptualized cause of depression from the therapist, and they are taught functional analysis of their own avoidance behavior to prevent relapse from occurring, but the real "work" that is done involves the client choosing activities that get them into contact with positive reinforcement and also reduces their likelihood of avoiding negative or punishing aspects of their life. The "coach" metaphor is recommended for behavioral activation (Jacobson, Martell, & Dimidjian, 2001) to empower the client, to decrease reliance on the therapist as the agent of change, and to help maintain treatment gains after therapy discontinues. If the learning takes place in therapy, and the implementation takes place in the client's natural environment, behavioral activation could be delivered to the

client in a way that does not involve a therapist at all, through the use of multimedia computer programs.

One such computerized treatment package is called Building a Meaningful Life through Behavioral Activation (BAML; Spates, Kalata, Ozeki, Stanton, & Peters, 2013). With this software, clients participate in treatment by coming to a therapy room with a computer instead of a live therapist. They are guided through each of the ten, 35 minute to 1-hour-long modules that teach and monitor the components of behavioral activation treatment for depression. This program, in contrast to some recent developed models, is not a static 'text on a computer screen'; nor is it considered "self-help" or bibliotherapy. Instead it is multimedia-rich software that uses videos and interactions to actively involve the participants in their own therapy. Clients perform weekly activities and homework on their own, and they report information on the computer which is tracked and monitored over the course of treatment. The use of this software opens opportunities not only for therapy, but for research as well, and serves as a direct link between science and practice.

Problem Statement

The present study seeks to build on previous literature in three primary ways. First, previous data regarding possible association of depression and side effects of depression, including sexual desire, is limited. This is especially true as pertains to the possible therapeutic effects of depression treatment on improving sexual desire. Multiple measures of sexual desire and depression symptoms allow for exploration of relationship between variables before, during, and after treatment. This investigation will add to and clarify whether improvement in depression is also associated with any positive change in sexual desire. Second, no studies have examined the efficacy of a computerized behavioral activation treatment for depression to measure its effects on sexual desire. The present study aims to provide preliminary data about the efficacy of this program on sexual desire to see if this symptom will be changed along with other depression symptoms. Third, the present study seeks to build on previous research that suggests behavioral activation is an efficacious treatment for depression and computerized behavioral activation *may* be an efficacious treatment for depression, but only a limited open trial investigation has examined the efficacy of the computerized behavioral activation treatment for depression used in this study. The overall design of the present study aimed to provide initial data from a controlled investigation about the efficacy of this program.

CHAPTER III

METHOD

Sample

Seven participants experiencing symptoms of depression were recruited from Western Michigan University and businesses in the Kalamazoo and Portage area of Southwest Michigan. Recruitment was conducted through the use of informational flyers posted at local businesses and universities, and recruitment speeches were made at Western Michigan University classrooms with prior granted permission.

All participants had a score of 14 or higher on the Beck Depression Inventory (BDI-II), in addition to meeting criteria for a diagnosis of major depressive disorder or dysthymic disorder based on the results of a Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I) and receiving a score of eight or higher on the Revised Hamilton Rating Scale for Depression (RHRSD). The SDID-I and the RHRSD were administered and scored by trained independent assessors.

Potential participants were excluded from participation in the study if they were determined to meet criteria for bipolar disorder, psychotic disorder, active substance abuse, mental retardation and/or dementia during the pretreatment assessment phase of the study. Additionally, participants were excluded if they were receiving current psychotherapy services for their depression or if they had recently started treatment with antidepressants and had been taking the antidepressants for less than eight weeks. One

participant was excluded from participation after already starting treatment because of a suicide attempt and subsequent hospitalization.

Setting

All informational, assessment, and treatment sessions were conducted in private laboratory rooms located on the campus of Western Michigan University. This laboratory space has three separate rooms with doors to ensure privacy and confidentiality. Sessions took place on an IBM computer terminal held within one of the laboratory rooms.

Treatment

The depression treatment for this study was delivered via a computer-based multimedia therapy program for behavioral activation. The program, entitled "Building a Meaningful Life through Behavioral Activation," (BAML) proposes to teach the participant information about depression, gives a description and rationale for behavioral activation treatment for depression, and uses videos of client and therapist interactions to model typical behavioral activation treatment. The participants used a designated computer terminal that had the behavioral activation software installed. In between the weekly computer guided sessions, the participants were assigned homework that guided and monitored their activity involvement during treatment.

Measures

Symptoms of depression were monitored throughout the present study through the use of a variety of measures. The *Beck Depression Inventory* (Appendix A; BDI-II; Beck, 1996) is a twenty-one question survey completed by the participant designed to assess and monitor symptoms of depression. The BDI-II was administered to participants during both pretreatment assessment appointments (initial and comprehensive), prior to starting

each treatment session, and at each post-treatment assessment appointment for follow up. Each of the 21 items can be reported on a scale of zero to three, with three being most severe. A total score of 0 to 13 indicates minimal depression, a score of 14 to 19 suggests mild depression, 20 to 28 is moderate depression, and a score 29 or higher indicates severe depression. The BDI-II shows high internal consistency for outpatients (α = .92) and for college students (α = .92) using Cronbach's alpha coefficient. Test-retest reliability has also been shown to be significant (r = .93, p < .001). The BDI-II has been shown to be significantly correlated with other measures of depressive symptoms such as the Hamilton Psychiatric Rating Scale for Depression (r = .71) and the Beck Hopelessness Scale (r = .68).

Item 21 on the BDI-II specifically asks about sexual desire, as indicated by a "Loss of interest in sex". The item to total correlation (r^2) for this item is .39 for the original psychiatric outpatient sample, and .27 for the college sample. Intercorrelation scores between loss of interest in sex were highest with items that recorded tiredness or fatigue (.40), loss of interest (.37), and indecisiveness (.32) for the psychiatric outpatient sample, and irritability (.36), punishment feelings, agitation, and loss of interest (.29 for each) for the college sample.

The Revised Hamilton Rating Scale for Depression (RHRSD; Warren, 1994; Appendix C) is a clinician-rated scale, intended to be completed after a clinical interview, which provides a quantitative measure of the clinician's assessment of a patient's level of symptoms of depression and the impact of these symptoms on the patient's everyday functioning. The RHRSD was completed by a research team member at the conclusion of the second pretreatment assessment, and was included in each post-treatment follow

up assessment appointment. The RHRSD consists of 22 items, 17 of which may be scored. Nine of these items are rated on a five-point scale, from zero to four, and eight of these items are rated on a three-point scale, from zero to two. These scores are then added together to yield a total score. Total scores from zero to six suggest that the individual is in the non-depressed range, scores between seven and 17 suggest the individual is experiencing mild levels of depression, scores between 18 and 24 suggest the individual is experiencing moderate levels of depression, and scores above 25 suggest the individual is experiencing severe levels of depression. The RHRSD displays adequate reliability and has a mean correlation of .67 with a wide variety of other measures of symptoms of depression, which demonstrates acceptable construct validity (Burnett, 1998).

The Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First, Gibbon, Spitzer, & Williams, 1996; Appendix E) is a semi-structured interview used to diagnose major DSM-IV disorders. The SCID-I was administered by trained research team members with each participant during the second pretreatment assessment and during each post-treatment assessment. The SCID-I consists of six major modules, including Mood Episodes, Psychotic Symptoms, Psychotic Disorders, Mood Disorders, Substance Use Disorders, and Anxiety and Other Disorders. For the present study, the Mood Episodes module was used in determining if participants' current symptoms reached clinical criteria for a diagnosis. The reliability of the SCID has been adequately demonstrated previously (Segal, Hersen, & Van Hasselt, 1994).

The Sexual Desire Inventory (Appendix D; SDI; Spector, Carey, & Steinberg, 1996) is a 14-item, self-report questionnaire designed to measure sexual desire in men

and women. Participants completed the SDI before beginning each treatment session. It was not administered at the intake or qualifying assessment appointments because low sexual desire was not required to qualify for this study. Responses to the 14 questions of the SDI load onto two factors, dyadic sexual desire and solitary sexual desire. Internal consistency values were found to be high for the dyadic scale ($\alpha = .86$) and the solitary scale ($\alpha = .96$). Test-retest reliability was found to be .76 over a one-month period, which is the period of time that the original instructions ask the participants to use as reference when responding to the instrument.

The Sexual Behavior Inventory (Appendix E; SBI) was created for this project. The SBI is a 2-item, self report questionnaire that is designed to measure sexual behavior. Participants respond to the two Likert-style questions to report their behavior over the last week indicating a 1 (Zero times) to 9 (More than two times a day). Items include, "How many times did you masturbate," "How many times did you engage in partnered sexual activity (beyond kissing and petting)."

In addition to the standardized outcome and symptom monitoring measures used in the present study, additional measures were used to gather demographic information and assess consumer satisfaction. The Initial Assessment Information Form (Appendix F) was used to collect demographic variables from all participants in the study who completed the initial assessment appointment. The information collected on this form includes age, race/ethnicity, current sexual activity, sexual orientation, education, religion, and marital status. These demographics were collected to determine generalizability of the results of this study. The Consumer Satisfaction Survey (Appendix G) is a 15 item, Likert-style survey with answers ranging from 1 (Strongly Disagree) to 5

(Strongly Agree). This survey was given to each participant who completed all ten sessions of treatment to ask their opinions about using a computerized treatment for depression.

Procedure

Adults who were experiencing symptoms of depression were recruited for the present study through the use of posted informational flyers and through classroom recruitment at a large university in Southwest Michigan. Prospective participants called or emailed the Anxiety Disorders Laboratory and left messages requesting to be contacted with more information regarding the current study. A research assistant then contacted prospective participants to describe the research study. Prospective participants who indicated interest in participating in the preset study were given the opportunity to schedule an initial in-person informational meeting which took place in a research laboratory office at Western Michigan University.

After recruitment, potential participants were scheduled for an informational and assessment session where a research assistant greeted them and led them to a private research room. Once in the room, the research assistant provided prospective participants with two copies of the informed consent document (Appendix H) explaining the rationale and course of the study. After reading the consent document, prospective participants were asked to sign both copies of the forms, one of which was retained in the participant's file in the locked laboratory filing cabinet and the other was given to participants to keep for their own records. Those who agreed to continue and consented to participate in the study completed preliminary survey instruments to collect demographic information and screen for depression symptoms. This data was considered

the initial assessment and pre-treatment data for use in later analyses. Participants who scored above 14 on the BDI-II were eligible to participate in the study, and having met initial screening requirements were asked to return one week later for a second more thorough assessment appointment.

At the comprehensive second assessment appointment, participants were greeted by a research assistant completed a BDI-II form. Participants who still maintained a score of 14 or higher on the BDI-II were then asked to complete a SCID-I with the research assistant, who also completed a RHRSD after the interview concluded. Ineligible participants were provided with referral information for local mental health providers.

Participants who were eligible for inclusion in the study on the basis of results from the BDI-II, SCID-I and RHRSD were then randomly assigned to one of two treatment conditions: one group began treatment one week following the second assessment (treatment group); the second group began treatment four weeks after the second assessment (delayed treatment group).

Upon completion of the second assessment and if the participant was evaluated to meet inclusion criteria to participate, the participant was randomly assigned to one of two groups. This random assignment was done using a digital random number generator at the conclusion of the second assessment appointment. If the number was an even number, the participant was assigned to group 1, treatment. Group 1 had their first treatment appointment scheduled 1 week following assessment. If the number was an odd, the participant was assigned to group 2 which asked participants to wait four weeks

for treatment while monitoring their symptoms weekly before starting treatment. Both groups were eligible for treatment.

Delayed treatment group methodology: Those participants who were randomly assigned to group 2 were told that their first treatment session would be scheduled in four weeks after assessment. Researchers asked participants to monitor depression symptoms weekly to assess for any significant change in depression symptom expression. Participants were given the option to either come into the lab to complete a BDI-II, or to speak with a research assistant over the phone, or email their scores to the research team. If the participant showed increased suicidality on item 9 of the BDI-II by indicating a 2 or a 3 on that item, a suicide assessment was conducted according to a pre-established protocol.

Treatment method for both groups: At the beginning of each session, the computerized treatment administrator provided each participant a BDI-II and a SDI to complete. After completing these measures, the research assistant oriented the participant to the computer program start screen and asked if he or she had any questions prior to beginning the session. The research assistant then answered any questions the participant had, and then asked the participant to begin and complete the session on his or her own. The computerized treatment administrator monitored suicidality through the BDI-II and handled elevated suicide risk according to a predetermined protocol. At the end of the session, the research assistant reviewed the session with the participant, reminded the participant to complete his or her homework, and allowed the participant to ask clarifying questions regarding the material presented in the session. The average amount of time the research assistant spent with a participant was less than 10 minutes in

each session. At the end of the tenth treatment session, participants were asked to complete a Consumer Satisfaction Survey to document the participants' experience with this novel treatment delivery. Researchers asked participants to attend follow-up appointments at one, three, and six months post-treatment.

CHAPTER IV

RESULTS

Analysis Plan

This study included a number of hypotheses regarding sexual desire and depressive symptoms over the course of treatment. First, it was hypothesized that BDI-II item 21 which measures sexual desire impairment would be positively correlated with BDI-II total score recorded at intake screening appointments. In order to test this hypothesis, a Pearson Product-Moment Correlation was calculated between each pair of BDI-II total score and item 21 score, to investigate the relationship between sexual desire impairment and overall depression.

Second, it was hypothesized that sexual desire would improve at treatment conclusion. This was measured in three ways. First, it was hypothesized that SDI and BDI- II scores would be negatively correlated for treatment completers when examining paired data points over the course of treatment. In order to test this part of the hypothesis, a Pearson Product Moment Correlation was calculated. Second, by examining BDI-II Item 21 measuring sexual desire impairment to see if it statistically significantly decreased from intake to final treatment session for treatment completers. Lastly, improvement in sexual desire was measured by increased SDI score from participants' first treatment session to their final treatment session. These two aspects of the hypothesis were tested using a one-tailed paired samples *t*-test on pretreatment and postreatment data (treatment conclusion) on BDI-II item 21 and the SDI.

Third, it was hypothesized that participants depression symptoms would improve as a result of completing treatment. Specifically, that a statistically significant decrease in depression as measured by the BDI-II from intake appointment to final treatment session would be seen. Additionally, both treatment groups (treatment and delayed treatment) would show similar decreases in depression by the end of treatment. This hypothesis was tested using a one-tailed *t*-test on change scores on the BDI-II from the treatment group from pretreatment to posttreatment and from the delayed treatment group from pretreatment to the end of the wait period before treatment. Also, a one-tailed paired samples *t*-test was conducted on pretreatment and postreatment data (treatment conclusion) on BDI-II item 21 and the SDI.

Fourth, it was hypothesized that sexual behavior would increase as a result of completing treatment. This was examined in two ways. First, that reported sexual behavior would be positively correlated with sexual desire on the SDI. Second, that reported sexual behavior will increase by the end of treatment. This hypothesis was tested by calculating a Person Product-Moment Correlation between sexual behavior and sexual desire on the SDI. Also, a visual analysis examined trends in sexual behavior for each individual participant.

In addition to conducting statistical analyses, visual analysis of individual participant data tables and graphs was also an aspect of the analysis plan for the current study. Given the low sample size of this study, relying solely on statistical analyses may not have revealed other relevant changes that occurred throughout assessment and treatment on an individual participant level.

Preliminary Analyses

Potential participants indicated interest via email or a phone call to the primary researcher. Some people declined to participate after finding out more about the study, some declined to participate when they were told there was no financial incentive, and a few made appointments but did not show up to their scheduled intake. Of the 44 potential participants who completed at least one assessment appointment after expressing interest in participating in the project, 31 participants did not qualify to enroll in the study. Out of those 31 who did not qualify, eight people did not complete both phases of the assessment required to determine eligibility, 15 participants completed the assessments but did not qualify due to not meeting diagnostic inclusion criteria (low BDI-II score or failure to meet criteria for major depressive disorder or dysthymia), one was disqualified due to a diagnosis of bipolar disorder, four were disqualified because of an active substance abuse disorder, two were not qualified because they were currently active in psychotherapy, one was excluded due to suicidal ideation and was referred to the campus counseling services.

In all, 13 participants qualified to participate and were enrolled in the study. These 13 participants were each randomized into either a treatment group or a delayed treatment group. Four participants were randomly assigned to begin treatment the week following assessment. Nine participants were randomly assigned to delay treatment and monitor symptoms while waiting. Of the four participants assigned to the treatment group, one dropped out before completing Session 5, which is considered a minimum dose of completing BAML-delivered BA therapy. The remaining three participants completed all 10 sessions. Of the nine participants assigned to the delayed treatment

group, two participants dropped out before attending any treatment session, three dropped out before completing Session 5, and the remaining four participants completed at least Session 5, with three of these four participants completing all 10 sessions. Please refer to Appendix K for graphs of groups resulting from randomization and treatment assignment.

Combining the treatment and delayed treatment groups (n = 13), "completers" were those who completed at least five sessions (n = 7) of BAML. The attrition rate of the randomly assigned treatment group was 25% (one out of four dropped out), and the attrition rate of the delayed treatment group was 56% (five out of nine participants dropped out). This overall 46% attrition rate compares with other recently reported BA-relevant treatment studies in the following fashion: Snarski, et al., 2011 – 58% attrition; Kanter et al., 2010—40%; Cullen et al., 2006—32%; Pagoto et al., 2008—28%; Dimidjian et al., 2006—16%; Proudfoot et al., 2004—46% (Beating the Blues© Computer treatment); and Hopko et al., 2011—19%. Given variation in sample sizes and demographics across these investigations, any attempt to directly compare these percentages should be made with caution.

The 46% attrition rate reported in this study is higher than the previous attrition rate from the open trial testing of this treatment software (Spates, et al., 2013) which found a 20% attrition rate. This higher rate is likely due to the addition of a delayed treatment group to which participants had an equally random chance of being assigned. Also, a higher number of participants than expected received the random assignment into the delayed treatment group (nine participants (69.2%) versus four (30.8%) who were assigned to immediate treatment) suggesting sampling error occurred during

randomization observed with this sample and the assignment would have been closer to a 50%-50% split had more people qualified to participate.

The six participants who qualified for the study and were randomized into the two treatment groups who then discontinued participating, five of these participants were randomized to the delayed-treatment group and one participant began treatment following assessment. Two participants dropped out during the waiting period and did not receive any treatment, both citing lack of time to participate further. Of those who started treatment, one dropped out citing lack of interest in continuing after a semester holiday break, one started seeing an individual therapist, one resumed anti-depressant medications, and one was hospitalized for a suicidal attempt. One participant completed seven treatment sessions before discontinuing. This participant started seeing an individual therapist, which is an exclusion criterion for participation.

Demographic data for the participants involved in this study, including the seven treatment completers, is displayed in Table 1 (for the full demographics table, please refer to Appendix K). Of the seven participants who completed the study, six participants (85.7%) were female and 1 participant (14.3%) was male. The mean age of the participants was 26.4 (*SD* = 17.1) years of age and the median age was 20 with range of 18 to 65 years of age. Five participants identified as Caucasian (71.4%) and two participants identified as African American (28.6%). Regarding marital status, six participants (85.7%) identified as single/not married and one participant (14.3%) identified as “other.” Two participants (28.6%) were employed at the time of screening, three participants (42.9%) were unemployed, one (14.3%) received income from disability, and one reported as “other.” Socioeconomic status ranged from five

participants (71.4%) indicating they make less than $5,000 per year, one (14.3%) made $25,000 to 34,999 annually, and one (14.3%) made $50,000 to $74,000 per year. All six participants (100%) indicated they have completed some college, but have not earned a degree, and 6 participants (85.7%) were currently enrolled as students at the time of participation.

Table 1

Demographic variables for full sample, non-qualifiers, qualified/ITT, dropped out, and completers

Variable	Full Sample	Non-Qualifiers	Qualified/ITT	Dropped Out	Completers
N	44	31	13	6	7
Age					
Mean (*SD*)	23.3 (10.3)	21 (4.5)	28.9 (16.8)	31.8 (17.6)	26.4 (17.1)
Median	20	19	20	23.5	20
Range	18-65	18-41	18-65	18-55	18-65
Gender					
Male	14 (31.8%)	12 (38.7%)	2 (15.4%)	1 (20%)	1 (14.3%)
Female	30 (68.2%)	19 (61.3%)	11 (84.6%)	5 (80%)	6 (85.7%)
Race/Ethnicity					
Caucasian	30 (68.2%)	21 (67.74%)	9 (69.2%)	4 (66.7%)	5 (71.4%)
African American	10 (22.7%)	8 (25.80%)	2 (15.4%)	0 (0.0%)	2 (28.6%)
Other	4 (0.9%)	2 (6.45%)	2 (15.4%)	2 (33.3%)	0 (0.0%)

Participants were also asked to report information regarding their experience with computers, comfort using a computer, knowledge of computers, and the estimated average number of hours they use a computer each week. Participants reported an average of 11.2 years (*SD* = 3) using a computer regularly and reported spending 19.2 hours (*SD* = 7.2) using the computer in an average week. Using Likert-style scale ranging from one to ten, with "one" stating "completely uncomfortable" and "ten" indicating "completely comfortable," participants reported an average rating o 9.3 (*SD* = .8) which suggests a high level of comfort with computers. Participants also reported their own perceived knowledge about computers, using a similar one to ten Likert-style scale. On this item, a "one" represented "no knowledge" and a "ten" represented "extensive knowledge," participants reported an average rating of 7.7 (*SD* = 1.8).

Hypothesis One. BDI-2 scores and BDI-II Item 21 relationship.

As previously stated, one purpose of this study was to investigate the relationship between depression scores reported on the BDI-II and participants' reported sexual desire difficulties as indicated by one item of the BDI-II, item 21. Item 21 asks about sexual desire as a "loss of interest in sex." Participants can respond with "0- I have not noticed any recent change in my interest in sex" to a severe rating "3 – I have lost interest in sex completely." Reported difficulty in this area was not a requirement for eligibility for this study.

Out of the 44 participants who presented to the initial assessment appointment to determine eligibility, 42 participants completed a BDI-II inventory. Of these 42 people, 19 (45%) indicated at least a "1" on item 21 of the BDI-II, indicating at least mild

impairment in sexual desire. The means and standard deviations of the BDI-II total score and BDI-II item 21 score from 42 participants are presented in Table 2.

Table 2

Depression and sexual desire distress for initial assessment participants and those who reported sexual desire distress

Group		BDI-II Total		BDI-II Item 21	
	n	*M*	*SD*	*M*	*SD*
Initial Assessment	42	26.2	9.7	.7	.9
Reported Sexual Desire Distress	19	29.8	8.2	1.6	.6
Second Assessment	31	23.7	10.2	.7	.9
Reported Sexual Desire Distress	12	28.2	10.8	1.8	.6

Note. BDI-II: Beck Depression Inventory

Each item 21 score was then correlated with the BDI-II total scores for each participant to examine the relationship between the sexual desire symptom and side effect of major depressive disorder. There was a moderate positive correlation between sexual desire and depression that was statistically significant, $r(40) = .375$, $p < .05$ for the 42 participants who completed the intake assessment (see Figure 1).

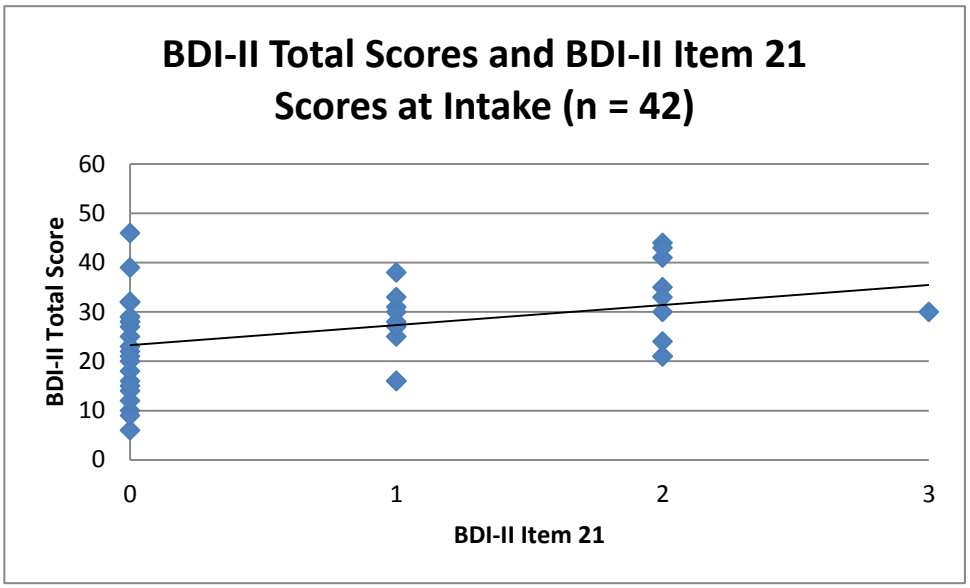


Figure 1. Scatter plot of BDI-II total scores and BDI-II item 21 scores at intake assessment (*n* = 42)

Some of the participants did not return for the second assessment after completing the first initial screening, either due to not qualifying to continue at the first assessment or withdrawing from the study between the first and second assessment appointments. Of the original 42 participants who completed the first assessment, 31 returned to complete a BDI-II during a second assessment appointment. Out of these 31 participants, 12 participants (38.7%) indicated a "1" or greater on item 21 of the BDI-II. The means and standard deviations of the BDI-II total score and BDI-II item 21 score from 31 participants are presented in Table 2. The scores from item 21 of the 31 assessed participants were then correlated with the BDI-II total scores. The correlation was found to have a moderate positive relationship that was significant, $r(29) = .380$, $p < .05$ for this group of 31 assessed participants (see Figure 2). Hypothesis one was supported.

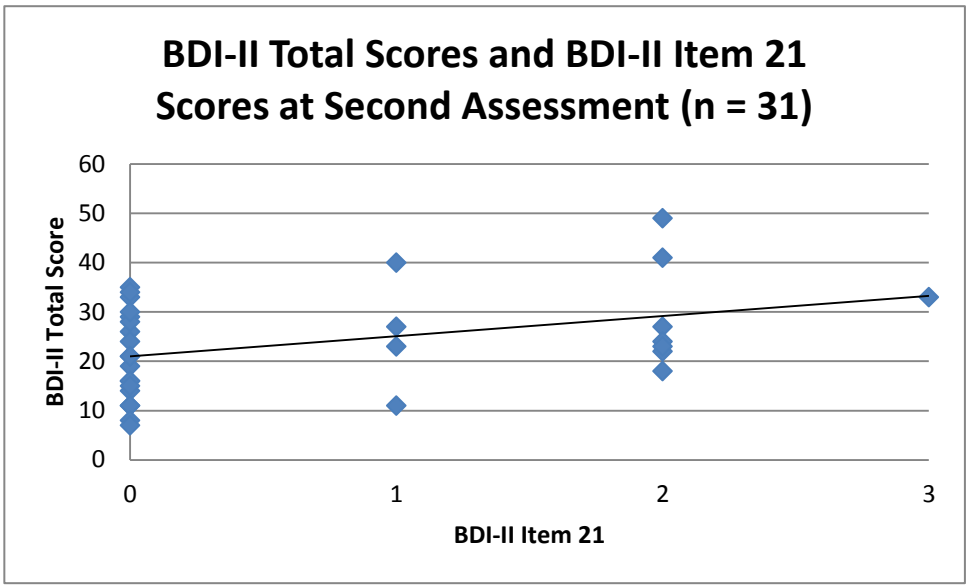


Figure 2. Scatter plot of BDI-II total scores and BDI-II item 21 scores at second assessment (*n* = 31)

Hypothesis Two. Sexual Desire Inventory During Treatment.

To investigate the relationship between depression scores on the BDI-II and sexual desire on the SDI, data from participants who completed treatment (*n* = 7) were used to explore correlation. Each treatment session provided a pair of BDI-II and SDI scores which totaled 67 treatment session pairs. There was a moderate negative correlation between depression and sexual desire that was statistically significant, $r(65) = -.341$ $p < .05$. As scores increased on the BDI-II, signifying more depression, scores on the SDI decreased, signifying lower sexual desire (see Figure 3). Hypothesis two was supported.

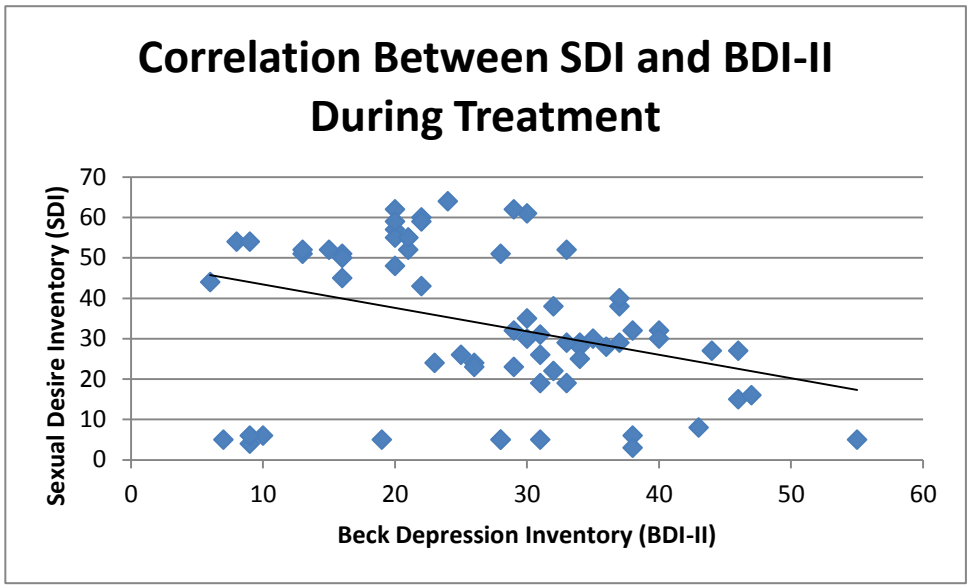


Figure 3. Scatter plot of BDI-II total scores and SDI total scores from each treatment session

In the present study, item 21 from the BDI-II was selected to investigate if change over the course could be detected on this one-item measure of sexual desire impairment. Out of the seven participants who completed treatment, five participants (71%) reported at least mild impairment to sexual desire at the intake assessment before treatment. The change in reported sexual desire on item 21 of the BDI-II from the intake to the final treatment session was not found to be significantly different according to a one-tailed paired samples *t*-test, $t(6) = 1.7$, $p = .07$. These data suggest that there is no significant difference from pretreatment to posttreatment on Item 21 of the BDI-II. However, visual inspection of individual participant scores (Table 3) and graphed data (Figure 4) revealed that two participants saw no change in symptom severity, one participant saw an increase of one point, and the remaining four participants each reported reductions in sexual desire impairment.

Table 3

BDI-II item 21 scores

Participant	Intake Assessment	Second Assessment	Tx 1	Average Tx1-Final	Final Tx	Change from Intake
P1	1	1	1	.9	1	0
P2*	0	0	0	0.57	1	+1
P3	2	2	2	1.6	1	-1
P4	2	1	0	1.1	0	-2
P5	1	0	0	0	0	-1
P6	0	0	0	0.1	0	0
P7	2	2	2	1.1	0	-2
Average (n=7)	1.14	.86	0.71	0.77	0.43	-.71

Note. BDI-II: Beck Depression Inventory; *Participant 2 completed 7 sessions.

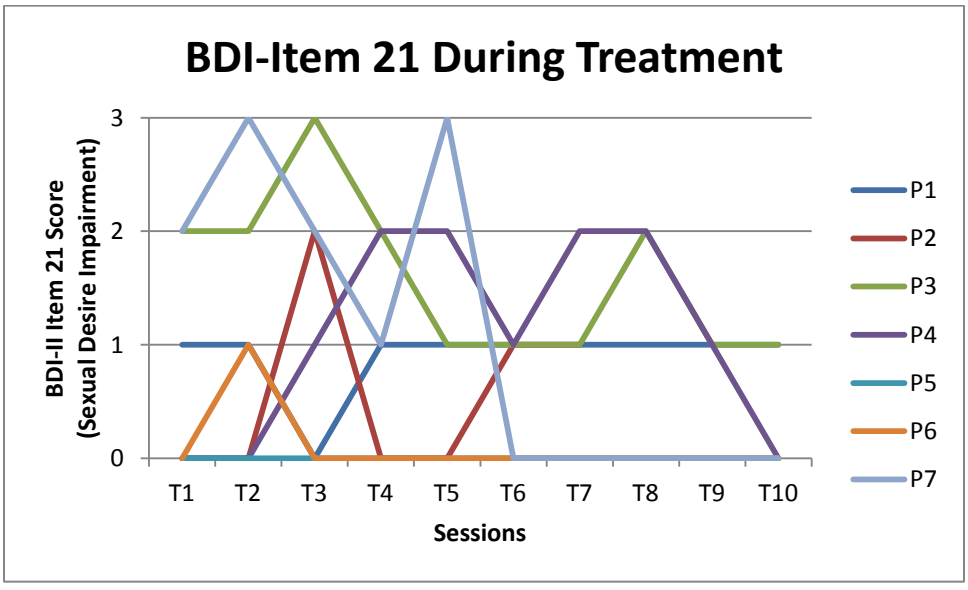


Figure 4. Treatment completers' BDI-II item 21 score during treatment

Overall, the treatment completers (n = 7) reported a average reduction on item 21 of .71, reducing the reported impairment from mild to moderate impairment in sexual desire to below the threshold for mild impairment in sexual desire. Like a reduction in scores on the overall BDI-II measure, a decrease in score on this item is interpreted as an improvement in functioning for this particular symptom of depression. It is possible that the statistical analysis of the aggregated data does not accurately represent the effect of treatment on Item 21 of the BDI-II because of the low sample size of this study.

The present study expanded previous research literature by adding the Sexual Desire Inventory (SDI; Spector, et. al, 1996) to participants undergoing treatment for depression. The SDI was used to measure the cognitive interest in sexual activity, as measured by the amount and strength of thought directed toward initiating or responding to a sexual situation.

The Reliable Change Index (RCI; Jacobson et al., 1984) was calculated to determine the clinical significance of changes in SDI from pretreatment to posttreatment (Jacobson, Follette, & Revenstorf, 1984). Internal consistency was calculated on the SDI using data from the beginning of the first treatment session for the treatment completers (n = 7) Cronbach's alpha (α = .93) which suggests high internal consistency of the items on the SDI completed by these participants. This overall internal consistency compares with the published internal consistency values that were found to be high for the two SDI scales, the dyadic scale (α = .86) and the solitary scale (α= .96; Spector, Carey, & Steinberg, 1996). Using this calculated internal consistency value and the SDI standard deviation from the first session (SD = 22.2), RCI was calculated as 16.65. Increases on

the SDI from the first session to the final treatment session of 16.65 points or more was considered reliable change and would be considered clinically significant improvement to sexual desire for this sample. Five of the seven participants reported reductions in sexual desire, which was contrary to what was hypothesized. Two of the participants did report an improvement in sexual desire, but neither were reliable change (Table 4). One participant (P2) reported a reliable change decrease in sexual desire from session 1 to session 7 before withdrawing from the study.

Table 4

Raw Scores and percent change in scores for treatment completers on SDI

Participant	Pretreatment[a]	Posttreatment	Improvement	% Improvement	Reliable Change
P1	64	59	-5	-8	No
P2[b]	61	31	-30	-49	Yes
P3	15	28	13	87	No
P4	38	43	5	13	No
P5	51	48	-3	-6	No
P6	28	24	-4	-14	No
P7	8	5	-3	-38	No

Note. SDI: Sexual Desire Inventory; [a] SDI was not administered at intake, but was administered before the first treatment session; [b] P2 completed seven treatment sessions.

Overall, the participants (n = 7) reported a SDI score of 37.9 when they presented for the first treatment session. The average score reported at the tenth treatment session

was 34.5, reflecting a reduction in sexual desire by 3.4 points (Table 5; Figure 5). There was not significant effect for sexual desire from the beginning to the end of treatment according to a one-tailed paired samples *t*-test, $t(6) = .772$, $p = .24$. This finding does not support Hypothesis two.

Table 5

Mean scores and SDs for treatment completers on outcome measures

Measure	Pretreatment[a] (*n* = 7)		Posttreatment (*n* = 7)		Effect Size (Cohen's *d*)
	M	*SD*	*M*	*SD*	
SDI	37.9	22.0	34.5	19.4	.16

Note. SDI: Sexual Desire Inventory; [a] SDI was not administered at intake, but was administered before the first treatment session.

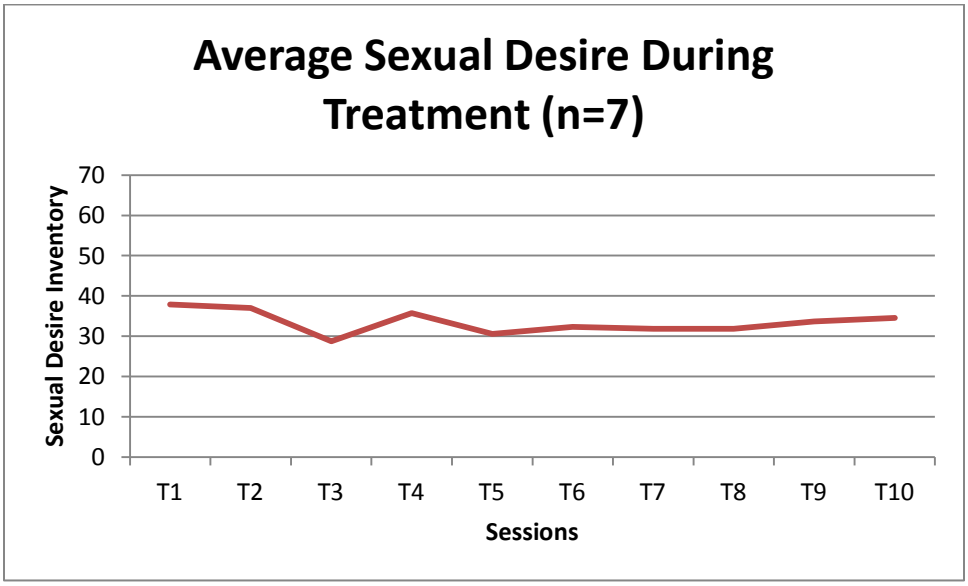


Figure 5. Graph of group average SDI score at each session during treatment

Hypothesis Three. Treatment efficacy across two treatment conditions.

A secondary purpose of this study was to expand previous research that investigated the efficacy of a computerized treatment program for depression, called Building a Meaningful Life through Behavioral Activation (BAML). This treatment has previously documented effectiveness (Spates, et al., 2013) in reducing symptoms of depression as measured by the Beck Depression Inventory-II (BDI-II) in an open trial. The current study sought to expand the previous research by adding a delayed treatment condition after assessment to which participants had an equal chance of being randomly assigned instead of the treatment directly following assessment. The intention of adding this condition was to demonstrate that the treatment itself is related to chance in depression score, rather than the passage of time.

It was hypothesized that, overall, the participants who receive at least 5 treatment sessions of BAML (considered 'completers') would see a clinically significant reduction in depression symptoms as measured by the BDI-II. The group of participants who were considered treatment completers (n = 7) reported an average reduction in depression score of 12.3 points, by the final treatment session (see Table 6 for means and standard deviations). There was a significant effect from intake BDI-II score to the final treatment BDI-II score according to a one-tailed paired samples t-test, $t(6) = 2.47$, $p = .024$, with final treatment scores being statistically significantly lower than intake BDI-II scores. Cohen's effect size value (d = 1.30) suggested a high practical significance. Hypothesis three was supported.

Table 6

Mean scores and SDs for treatment completers on outcome measures for depression

Measure	Pretreatment (n = 7)		Posttreatment (n = 7)		Effect Size (Cohen's d)
	M	*SD*	*M*	*SD*	
BDI-II	34.7	10.1	22.4	8.7	1.30
Hamilton-R	20.7	4.4	-	-	

Note. BDI-II: Beck Depression Inventory-II

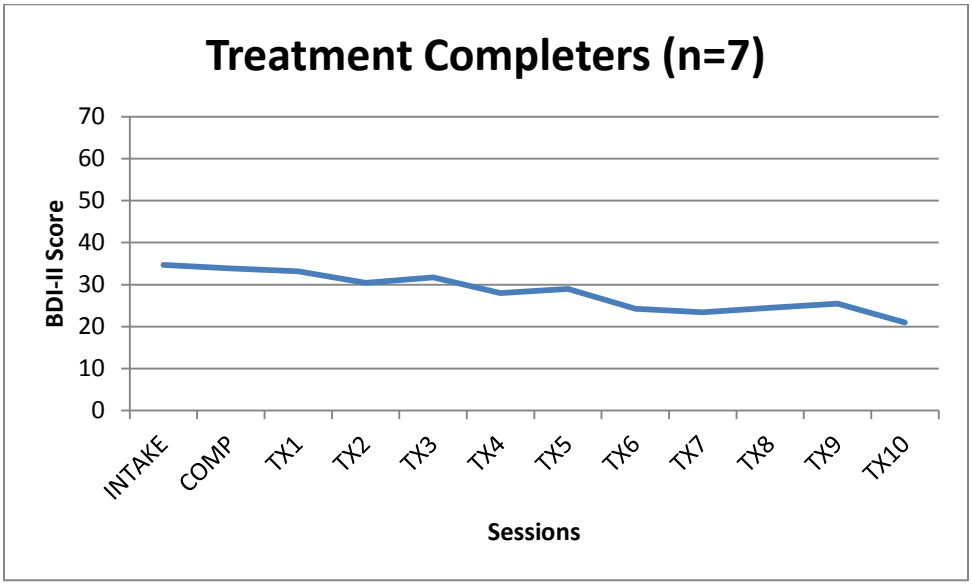


Figure 6. Graph of group average BDI-II score at each session

Raw scores on the BDI-II and the SDI were converted to standard scores for direct comparison of each participant's scores on each measure over the course of treatment. Linear regression was modeled through each participant's BDI-II and SDI scores to reflect the strength of the fit for each self report instrument. An *r* value of +1 indicates the strongest positive linear fit and an r value of -1 indicates the strongest negative linear fit (please reference Appendix L for standardized individual participant graphs). Linear fit for the BDI-II was r = -.92 and for the SDI r = -.30. The graphs

compare data from treatment completers (n = 7) before and after their scores were averaged together at each time point and the average scores were standardized and graphed (See Figure 7 and 8).

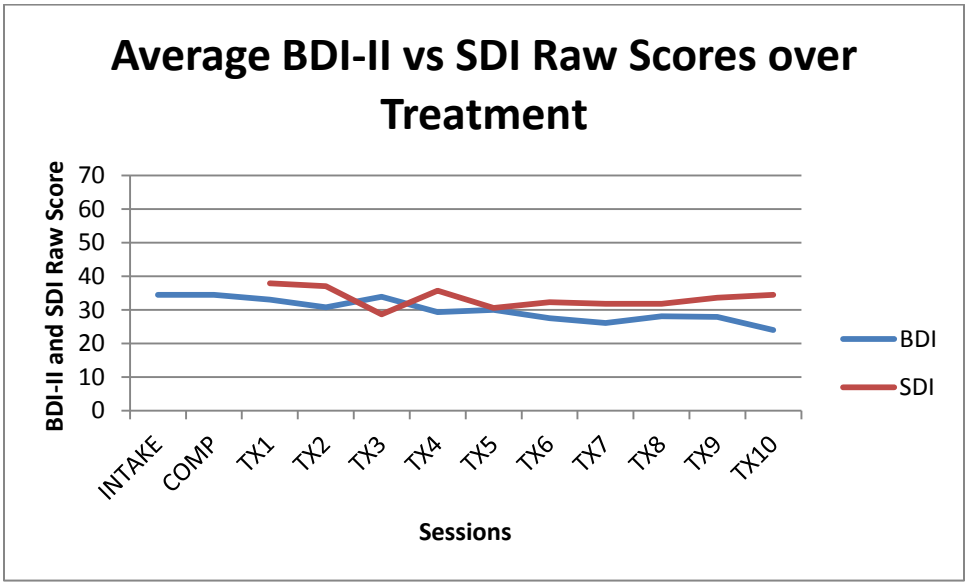


Figure 7. Graph comparing group average BDI-II and SDI scores at each session

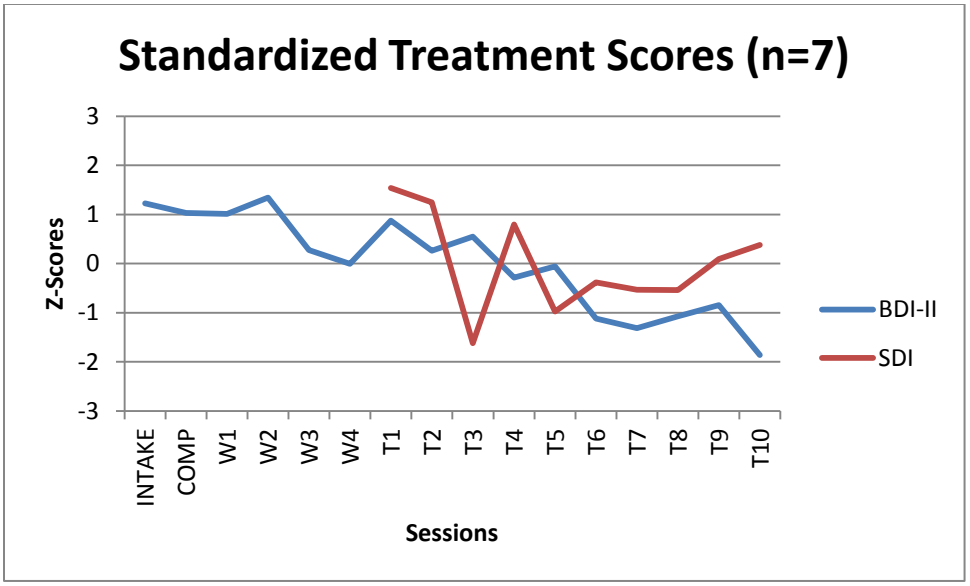


Figure 8. Graph of average standardized scores of each treatment completer at each session

In order to determine the clinical significance of changes in BDI-II from pretreatment to posttreatment, Reliable Change Index (RCI; Jacobson et al., 1984) was calculated. Intake assessment appointment scores from treatment completers (n = 7) on the BDI-II were used to calculate the coefficient of internal consistency, Cronbach's alpha (α = .879). This is comparable to the original published internal consistency for outpatients (α = .92) and for college students (α = .92; Beck, 1996). Using this calculated internal consistency and the BDI-II standard deviation from intake (SD = 10.3), RCI was calculated as 9.92. That means that decreases on the BDI-II score from pretreatment to posttreatment of 9.92 points or greater is considered reliable change, and would be considered clinically significant improvement in depression symptoms for this sample.

Six out of the seven participants reported reductions in depression symptoms with only one participant reporting an increase in symptoms by the conclusion of treatment. Four of the seven participants reported clinically significant (reliable change) reductions of 9.92 points or more on the BDI-II, as shown in Table 7.

It was also hypothesized that both randomly assigned treatment groups (immediately following assessment and the delayed treatment group) would report similar reductions in BDI-II score, demonstrating no treatment difference in waiting for treatment or beginning treatment following assessment. Three participants were randomly assigned to the treatment immediately following assessment condition. All three participants reported reductions in depression symptoms from the intake assessment appointment to their final treatment session. Two out of the three participants saw clinically significant reductions on BDI-II score.

Table 7

Raw scores and percent change in scores for treatment completers on BDI-II

Participant	Pretreatment	Posttreatment	Reduction	% Reduction	Reliable Change
P1	28	20	8	29	No
P2[a]	32	31	1	3	No
P3	44	34	10	23	Yes
P4	41	22	19	46	Yes
P5	16	20	-4	-25	No
P6	39	23	16	41	Yes
P7	43	7	36	84	Yes

Note. BDI-II: Beck Depression Inventory; SDI: Sexual Desire Inventory. [a] P2 completed seven treatment sessions.

Overall, the average reduction of the treatment group was 18 points, reducing from 38.3 down to 20.3 at the end of treatment. Four participants were randomly assigned to delay treatment group. Three out of four of these participants reported reductions in depression symptoms, two of which were clinically significant reductions more than 10 points. One participant reported an increase in symptoms by the end of conclusion. Overall, the average reduction of the delayed treatment group was 8 points, reducing from 32 to 24 at the end of treatment, as displayed in Table 8.

Table 8

BDI-II Treatment scores from both treatment groups

Participant	Intake Assessment	Qualifying Assessment	Final Treatment	Reduction from Intake
P1	28	23	20	8
P7	43	41	7	36
P3	44	49	34	10
Treatment Group Average	38.3	37.7	20.3	18
P5	16	16	20	-4
P4	41	40	22	19
P6	39	35	23	16
P2	32	33	31*	1
Delayed Treatment Group Average	32	31	24	8
Overall Average (n = 7)	34.7 (10.1)	33.9 (11.2)	22.4 (8.7)	12.3 (13.1)

Note: Participant 2 completed 7 sessions

The direct to treatment group had a higher intake BDI-II score than the delayed treatment group average, and also saw a greater reduction in BDI-II scores at the end of treatment. However, no statistically significant difference was detected between the treatment group and the delayed treatment group at intake according to a two-tailed independent samples *t*-test, $t(5) = .79$, $p = 0.46$. Also, no statistically significant

difference was detected between the treatment group and the delayed treatment group at the conclusion of treatment according to a two-tailed independent samples *t*-test, $t(5) = -.51$, $p = .63$. Hypothesis three was supported in the respect that the two groups appear to be similar at intake and at treatment conclusion. However, contrary to what was expected, when the pretreatment and postreatment BDI-II change scores from the treatment group are compared to the pretreatment to post-waiting scores of the delayed treatment group, no significant difference was found according to a one-tailed independent samples *t*-test, $t(5) = 1.99$, $p = .052$, although the value was very close to the established significance value of less than .05. The small sample size ($n = 7$) of this randomized controlled trial may have influenced the ability to detect differences between the two treatment groups at intake and at treatment conclusion. As it stands, the statistical insignificance of the difference between the delayed treatment group and the treatment group suggest the treatment was no better at improving depression than waiting four weeks after assessment. However, the clinical significance of the reliable change scores observed is not to be overlooked, and should be considered with the aforementioned concern about low power to detect the difference between the delay and treatment group.

Hypothesis Four. Sexual behavior, sexual desire, and depression.

Participants responded to a Likert-scale to indicate solo and partnered sexual activity frequency from week to week during treatment, with responses ranging from “0 times” in the last week to “2 or more times” in the last week. Positive correlation between sexual desire and sexual behavior has been previously documented (Spector, et al., 1996). To investigate the relationship between sexual desire on the SDI and reported sexual behavior, data from participants who completed treatment ($n = 7$) were used to explore

correlation. Each treatment session provided a pair of scores which totaled 67 treatment session pairs of SDI and sexual behavior scores. In the present study, a correlation between sexual desire and sexual behavior showed a weak positive relationship that was not significant, $r(65) = .241$, $p > .05$ (see Figure 9). Hypothesis four was not supported in this respect.

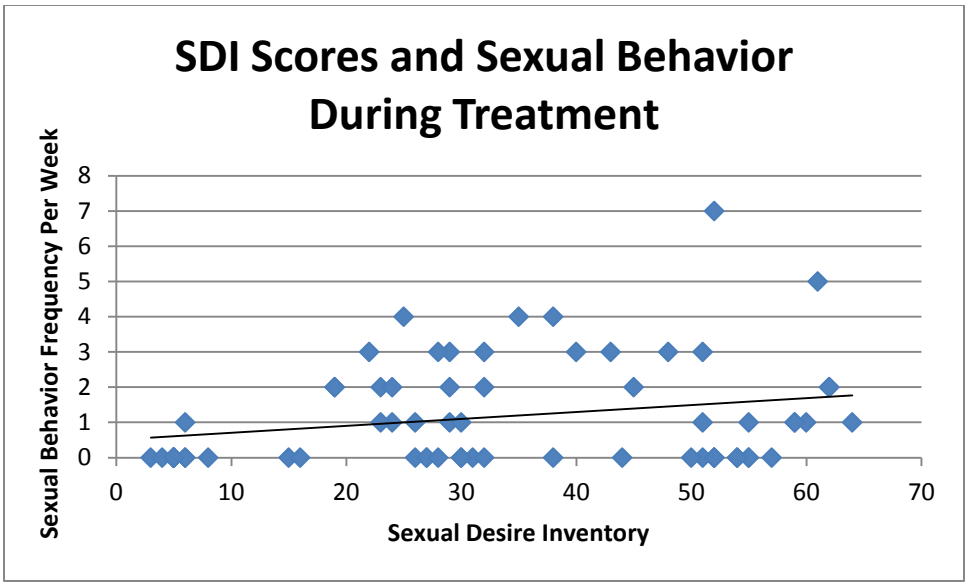


Figure 9. Correlation of SDI and reported sexual behavior frequency over the course of treatment

In the present study, because of the low treatment sample and because of the low rates of sexual behavior reported, individual visual analysis was conducted. Visual inspection on each treatment participant could aid in the investigation of a relationship between depression symptoms reported on the BDI-II, sexual desire reported on the SDI, and sexual behavior. Only one participant reported more sexual behavior in the second half of treatment. The others maintained their level of behavior. Hypothesis four is not supported by examining individual participant progress through treatment.

Participant 1, who was randomly assigned to the immediate treatment group, reported a reduction in depression score from 28 to 20 at the last treatment session (see

Figure 10). Contrary to what was hypothesized, this participant reported a reduction of 5 points on the SDI from the first to the last treatment session, despite the improvement in depression score. When examining sexual behavior, Participant 1 reported more sexual behavior during the second half of treatment than during the first five sessions.

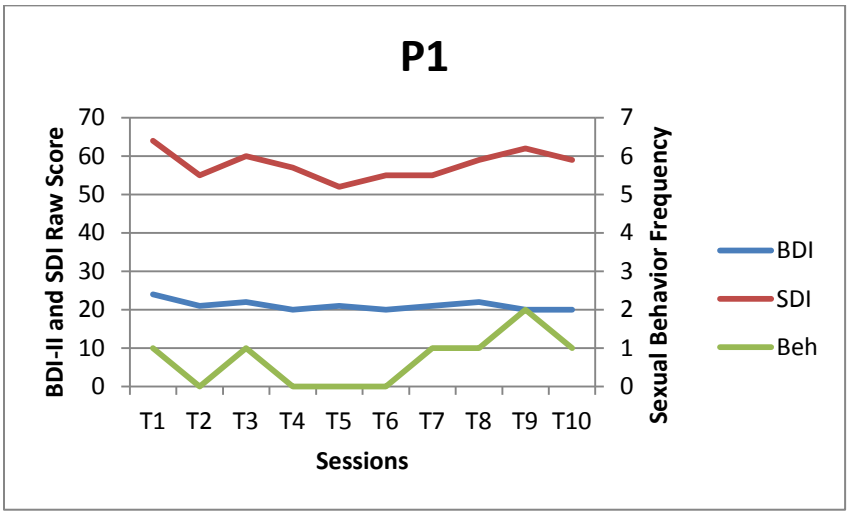


Figure 10. Participant 1 BDI-II, SDI, and sexual behavior over treatment sessions

Participant 2 was assigned to the delayed treatment group. This participant was considered a treatment completer because seven treatment sessions were completed before the participant requested to stop treatment, citing involvement in treatment with an individual therapist. Participant 2 reported a chance in depression score of only 1 point, from a 32 to a 31 during session 7 (Figure 11). This participant reported the largest drop in sexual desire, from a 61 to a 31 on the SDI, and additionally, reported sexual behavior frequency that declined to zero at the final session.

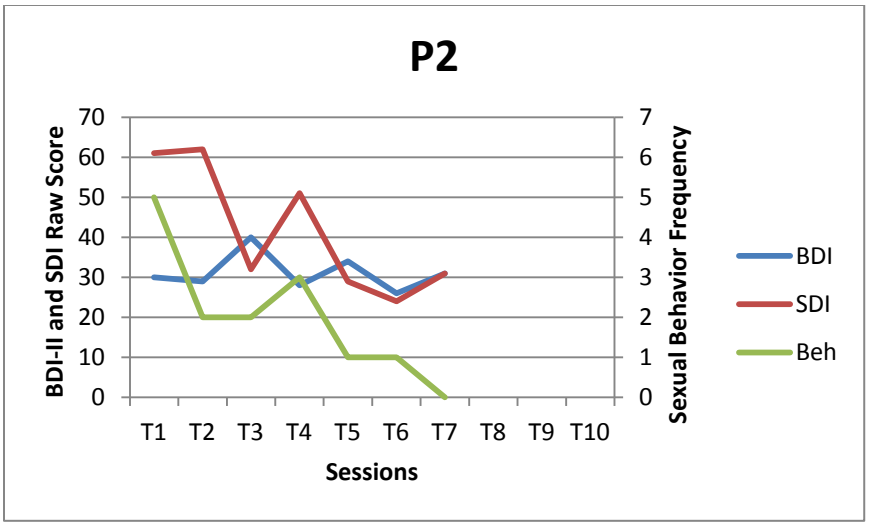


Figure 11. Participant 2 BDI-II, SDI, and sexual behavior over treatment sessions

Participant 3, the third participant in the treatment group, reported a reduction in BDI-II score of 10 points, from 44 at intake to 34 at the final treatment session (Figure 12). This participant reported the highest change in sexual desire on the SDI, from a 15 to a 28 at the final session. Despite this improvement in depression and sexual desire, there was no reported sexual activity during any of the weeks of treatment.

Participant 4 reported an improvement in depression from a 41 at intake to 22 at the end of treatment (Figure 13). Consistent with the hypothesis, this participant also reported an increase in sexual desire by the end of treatment. Participant 4 reported the most cumulative sexual behavior of any of the participants, and the cumulative behavior frequency was the same during each half of treatment.

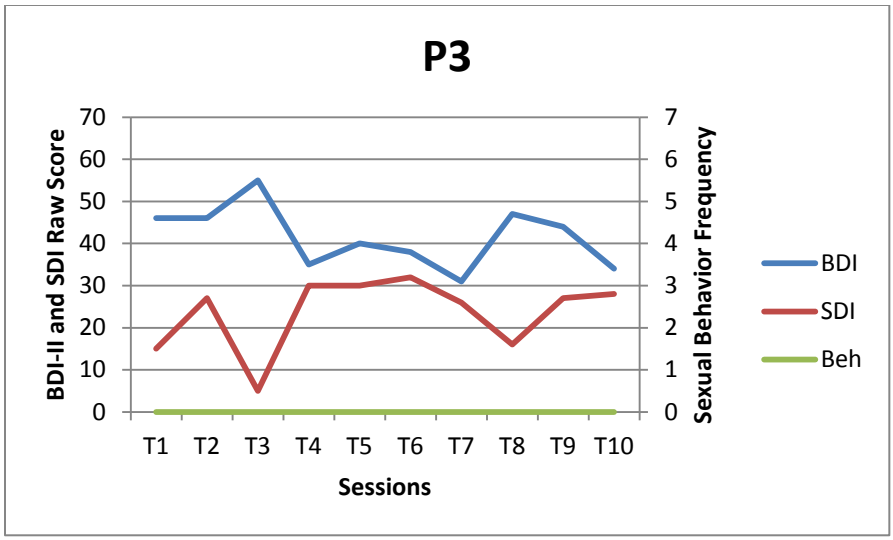


Figure 12. Participant 3 BDI-II, SDI, and sexual behavior over treatment sessions

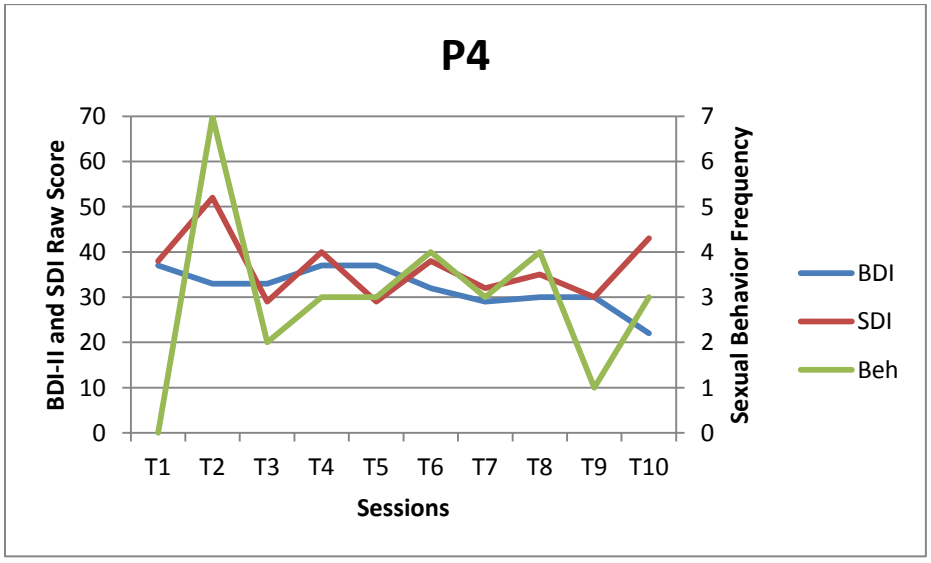


Figure 13. Participant 4 BDI-II, SDI, and sexual behavior over treatment sessions

Participant 5, the first of four who were randomly assigned to wait before beginning treatment, reported an increase in depression symptoms from intake to the final treatment session. This participant reported a decrease in sexual desire as well (Figure 14). The cumulative sexual behavior that was reported was the same during the first half and the second half of treatment. The sudden increase in reported sexual behavior during

the last session was counter to what was hypothesized because of the reported increase in depression and reduction in sexual desire.

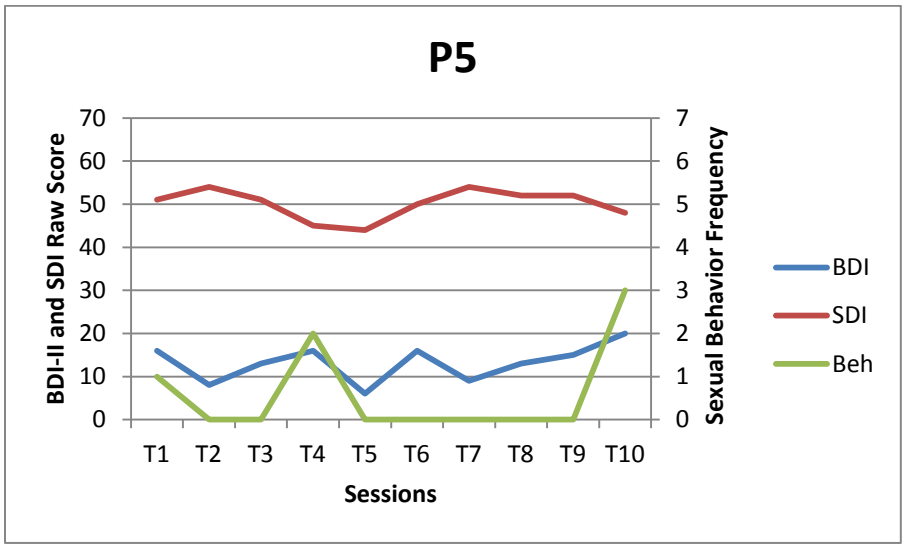


Figure 14. Participant 5 BDI-II, SDI, and sexual behavior over treatment sessions

Participant 6 was also part of the delayed treatment group. This participant reported a clinically significant reduction in depression of 16 points, from a 39 at intake to a 23 at the treatment's conclusion (Figure 15). Contrary to what was hypothesized, this participant reported a decrease in sexual desire at the end of treatment, from a 28 to a 24 on the SDI. In addition, this participant reported more sexual behavior during the first five sessions of treatment when compared to the second half of treatment.

Participant 7 was randomly assigned to the immediate treatment group. This participant reported the most significant reduction in depression symptoms measured by the BDI-II, from a 43 at intake to a 7 at the final treatment (see Figure 16). This participant also reported the lowest sexual desire score during the first session, and it

further lowered from an 8 to a 5 at the end of treatment. There was also no reported sexual behavior, neither solo nor partnered, during any of the weeks of treatment.

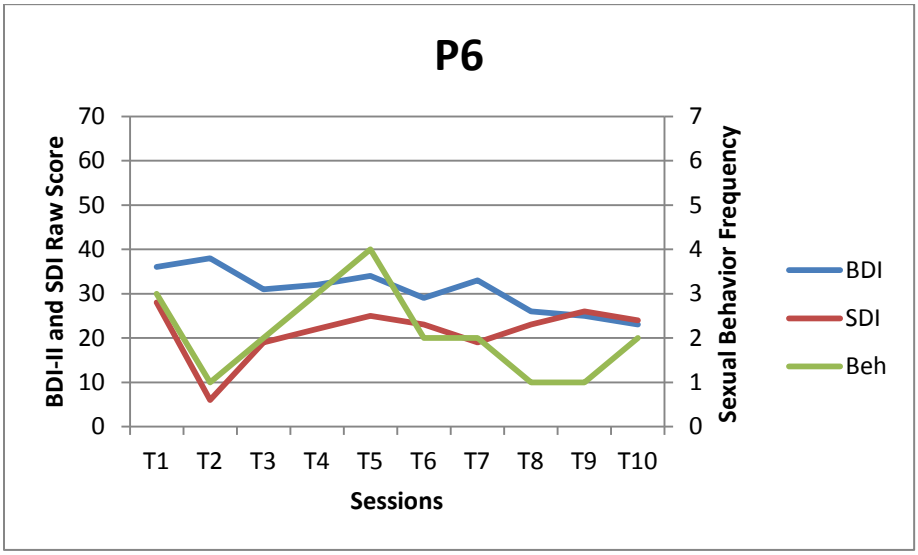


Figure 15. Participant 6 BDI-II, SDI, and sexual behavior over treatment sessions

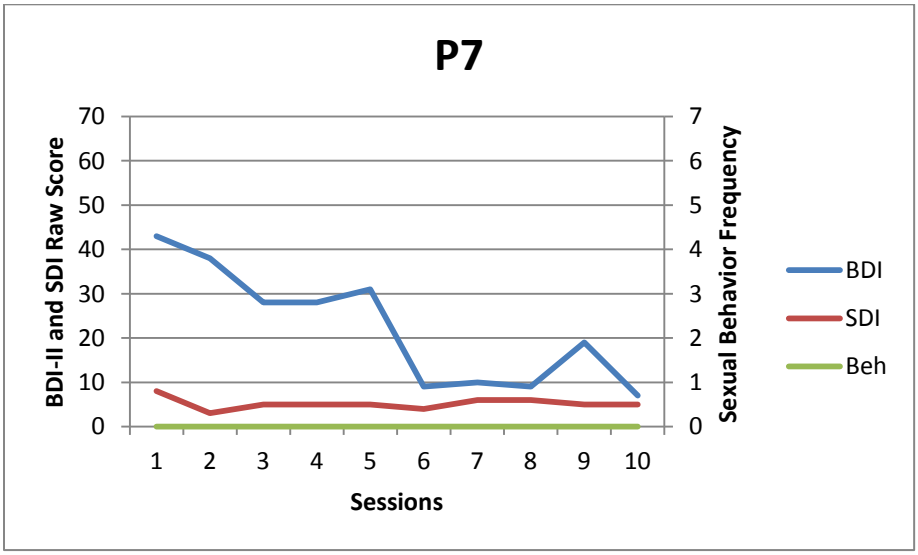


Figure 16. Participant 7 BDI-II, SDI, and sexual behavior over treatment sessions

Additional Analyses. Participant Satisfaction Rating and Standardized Scores

Participants who completed all 10 sessions of BAML treatment were asked to complete a 15-item Customer Satisfaction Survey (Appendix G) to evaluate their experience using this novel computer-delivered treatment. Six participants completed all

sessions of treatment and reported their satisfaction at the end of the last treatment session. Scores on this measure were totaled and averaged to produce a summed score for each participant. Each item was a Likert-Style with responses that ranged from "1 - Strongly Disagree" to "5 - Strongly Agree". Scores on this survey ranged from 2.93 to 4.27 out of a possible five points, which was interpreted as the most satisfied. The average of the satisfaction sores was 3.71, suggesting a relatively high level of satisfaction with the *Building a Meaningful Life Through Behavioral Activation* treatment program.

Finally, the relationship between improvement from treatment and participant satisfaction was investigated using a Pearson Product Moment Correlation. Improvement from treatment, measured in raw change on the BDI-II from intake to session ten, was compared to each participant's average satisfaction rating. A very strong, but not statistically significant relationship was calculated $r(4) = .72$, $p > .05$ (Figure 17). Due to the low number of participants in this sample ($n = 6$) there was not enough power to establish statistical significance. Of note, however, is the participant with the lowest improvement in BDI-II score, a 4 point increase in fact, had the lowest satisfaction rating. Additionally, the participant with the most improvement in BDI-II raw score also reported the highest participant satisfaction.

To further compare results from this study with previous research using the same computerized treatment program (BAML; Spates, et al., 2013), the treatment completers ($n = 7$) were divided in half using a median split on age. The four oldest participants ($M =$ 32 years) were grouped together in the top group and the youngest three participants ($M =$ 19 years) were in the bottom group. Scores on the BDI-II were averaged for each of these

two groups for each recorded session during assessment and treatment (see Table 9 and Figure 18). Post treatment analysis included participant 2's seventh and final session score as the post treatment score. This is reflected in Table 9 but not in Figure 18.

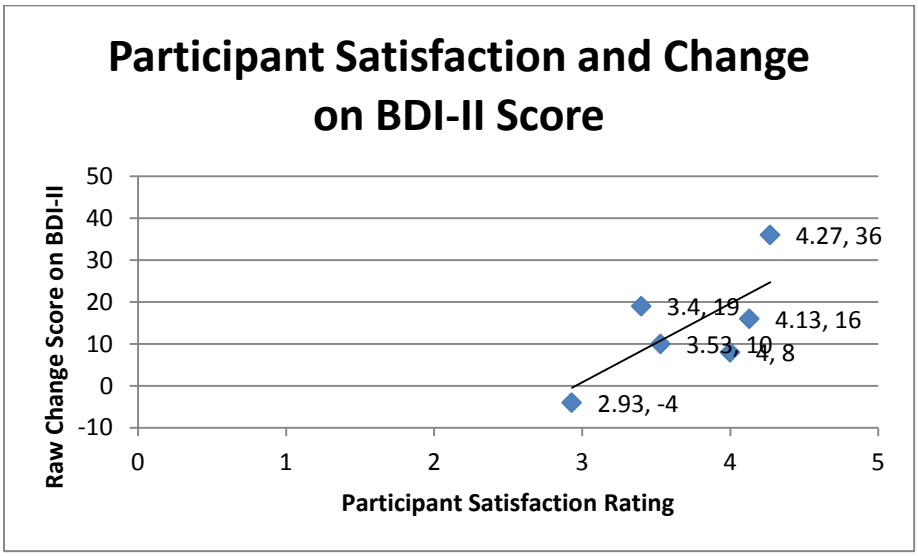


Figure 17. Scatter plot of raw change scores on the BDI-II and participant satisfaction rating

Table 9

Mean scores and SDs for treatment completers divided by age by median split

Median Split	Pretreatment BDI-II		Posttreatment BDI-II	
	M	*SD*	*M*	*SD*
Top (*n* = 4)	29.8	11.1	19.5	9.8
Bottom (*n* = 3)	41.3	2.5	26.3	6.7

Note. BDI-II: Beck Depression Inventory.

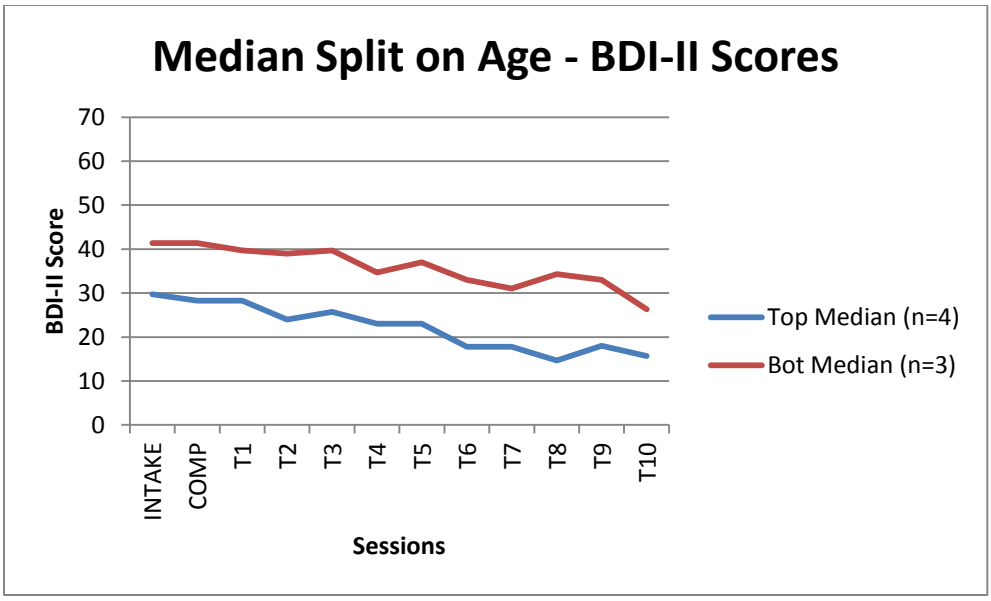


Figure 18. Graph of average BDI-II score over the course of treatment for participants divided into two age groups

Pretreatment and posttreatment scores did not differ significantly for the older (top median) half of the sample according to a one-tailed paired two sample *t*-test, $t(3) = 1.15$, $p = 0.17$. Pretreatment and posttreatment scores did differ significantly for the younger (bottom median) half of the sample according to a one-tailed paired two sample *t*-test, $t(2) = 5.67$, $p = 0.01$. The BDI-II scores of the younger half of the sample ($n = 3$) decreased a significant amount from pretreatment to posttreatment, representing an improvement in depression symptoms over the course of treatment. The means and standard deviations for these data are presented in Table 9. Previous research found the older participants responded better to the treatment than the younger participants by improving more rapidly and having lower BDI-II scores at treatment conclusion (Spates, et al., 2013). In the present study, the younger participants in the bottom median split had higher BDI-II scores than the older participants in the top median split group. The older top median had lower posttreatment scores than the younger bottom median group.

CHAPTER V

DISCUSSION

The purposes of the present study were to build on previous literature in three primary ways. This investigation aimed to add to and clarify whether improvement in depression is also associated with or causes any positive change in sexual desire. The present study was designed to provide preliminary data about the efficacy of this treatment program on sexual desire to see if this side effect would be changed along with other depression symptoms. The present study also sought to provide initial data from a controlled investigation about the efficacy of this treatment program to expand on previous open-trial research using this software treatment delivery.

It was hypothesized that BDI-II item 21, which measures sexual desire impairment, would be positively correlated with BDI-II total score recorded at intake screening appointments, which establishes a connection between sexual desire and depression in the current sample. It was also hypothesized that sexual desire would improve at treatment conclusion, and this could be measured in multiple ways. Third, it was hypothesized that participants depression symptoms would improve as a result of completing treatment which would build on the previous open-trial that used this treatment program . Lastly, it was hypothesized that sexual behavior would increase as a result of completing treatment.

Outcomes of the Present Study

The first goal of the present study was to establish the relationship between sexual desire impairment and depression. The participants that presented for the assessment

appointments provided the largest sample pool of available data to investigate this relationship. Results found that there was a moderate relationship between increased sexual desire impairment and increased overall depression, which supports the first hypothesis. Now that there is an established relationship between sexual desire and depression in the current study, the other analyses of sexual desire could provide further understanding of the impact of treatment on this depression side effect.

The second hypothesis used three different ways to measure sexual desire during treatment. First, when data pairs of the sexual desire score and the depression were correlated together from all of the treatment session data, a moderate negative correlation was found between sexual desire and depression. As depression scores on the BDI-II increased (worsening depression), scores on the SDI decreased, suggesting lower sexual desire with increased depression. If impaired sexual desire is a side effect or symptom of major depressive disorder, and if there is a negative correlation between depression scores and sexual desire scores, then sexual desire should increase (higher SDI scores; improvement from impairment) as reported depression decreases (lower BDI-II scores). In this respect, the hypothesis was partially supported.

One of the purposes of running this study was to examine the effectiveness of using one question from the BDI-II, Item 21, as a treatment outcome measure for sexual desire. Four of the participants reported decreased sexual desire distress, as noted by lower BDI-II Item 21 score; however, statistically there was no significant difference from pretreatment to posttreatment. These results were trending toward significance and may have been significant with more participants or with participants who reported more sexual desire distress at intake. Overall, results show that it is not directly helpful to use

Item 21 on its own as a measure of sexual desire impairment with people dealing with depression.

It was hypothesized that participants who completed the BAML treatment for depression would see a decrease in reported depression scores, and would also see an increase in sexual desire scores measured by the SDI. This was investigated to explore if the treatment software would also improve sexual desire despite the fact that the treatment does not discuss sexual desire at any point during the course of treatment. If it did improve sexual desire and improve depression, the sexual desire improvement could be an additional benefit to the treatment package to help people who are experiencing difficulty in both of these areas, especially in people who are either reluctant to talk with their treatment provider about sexual difficulties, or people who are unaware of sexual problems that may be related to their depression. The results from the study did not support this hypothesis, however. This indicates that the behavioral activation treatment is not enough to improve sexual desire on its own. These findings could be the result of participants who did not have a clinical "problem" with low sexual desire, and as a result they did not see much change during the course of treatment. Participants were not selected based on their sexual desire scores, and were not excluded for having low or high sexual desire. Had this study been designed to recruit participants who wanted treatment for low sexual desire, participants would have had to meet a threshold on the SDI that would have indicated a low sexual desire that needed treatment.

A secondary purpose of this study was to add additional control to the treatment process to expand on a previous study that used an open-trial method to test the efficacy of the BAML software. While this study was designed as a small-scale randomized

control trial, randomly assigning qualified participants into a direct-to-treatment condition or a four-week-delay treatment condition, the low participant qualification rate coupled with the high attrition resulted in too few participants to adequately label this study a randomized control trial. Analyses were still conducted to explore some of the questions posed by setting up an RCT, but this study is best interpreted as a case series analysis. That said, results did indicate that treatment completers as a group overall showed clinical and statistical reduction in depression scores after completing the treatment program. Specifically, four of the seven participants showed reliable change improvement in depression by the time they finished the treatment program. This finding is consistent with the previous results on behavioral activation and for the BAML program. Additionally, the direct-to-treatment group and the delayed treatment group were similar at the time of intake and at the end of treatment. This suggests that, even with few participants, the randomization into the two groups was effective, or, alternatively, there were not enough participants to detect differences between the two conditions. With both groups showing similarity in their BDI-II scores before and after treatment, and with the treatment completers showing an overall average improvement in depression, it suggests that the treatment program itself is related to the improvement in depression rather than simply a passage of time.

Another aspect to this study was the exploration of the relationship between sexual desire and sexual behavior during the depression treatment. Previous research has documented a correlation between sexual desire and sexual behavior, but results from this study did not confirm that finding. There was an apparent floor effect to the sexual behavior frequency data. Participants were able to report any sexual behavior that

occurred beyond kissing and petting with a partner. They weren't asked to only report frequency of intercourse. In designing this question, it was assumed that there would be more varied behavior reported more frequently. The un-partnered sexual activity question was included to attempt to capture solo sexual behavior so that a participant who did not have opportunity to behave with a partner could still report solo sexual activity if it occurred. However, this also occurred far less often than what was expected. As a result of the few treatment participants and the low rates of sexual behavior, it was difficult to determine any effect of sexual desire and depression on sexual behavior.

Limitations of the Present Study

There are a number of limitations of the preset study that are worth exploring. First, the small sample size of seven participants in the present study limits the extent to which conclusions can be drawn from the data presented earlier. Additionally, only six participants completed all 10 treatment sessions. Participant 2 was included as a treatment completer because the minimum threshold for treatment, Session 5, was surpassed, however the fact that this participant dropped out early and was noted to have drastic reductions in sexual desire and sexual behavior the session before termination calls into question the similarity of this participant with the other six participants that did complete the treatment program. Also of note, six of the seven treatment completers were students at Western Michigan University. While depressed college students are an important demographic to target, it also limits the generalizability of the findings of the current study due to factors such as younger age. Also, six out of seven participants were

female, and although depression is more common in women than men, it likely limited the types of responses recorded on the different measures.

Participant attrition from qualification through the beginning treatment sessions was high, with six of the 13 original qualifying participants dropping out of the study. It appeared that the waiting condition influenced whether a participant continued with the study or terminated early. Participant 2 specifically told the researcher that if the waiting condition was any longer than four weeks, he or she would have discontinued participation and sought services elsewhere. This was the same participant that ended up dropping out of the study after the seventh session. Researchers should consider the time frame necessary for a waiting condition, if implemented at all, in future studies.

Self-report questionnaires inherently have limitations because they rely on participants' accurate recollection and reporting. Participants were asked to recall over a one week period about mood, sexual desire, and sexual behavior. If future studies are interested in accurate quantification of low frequency sexual behavior, a different recording method should be considered like using a journal that the participant can use to record at the end of each day and turn in at the next treatment. A concern that occurs with sexual measures is the possibility of underreporting sexual behavior or desire. This underreporting could also lead to inaccurate recollections of behavior, and could have contributed to the overall low rates of behavior seen in this sample.

Future Investigation and Conclusion

Given the stated limitations mentioned previously, a natural future project design would include a larger sample size. While recruitment efforts and lowered eligibility

requirements in the current study did improve enrollment, future studies should consider a direct referral system from health care providers or community mental health to increase the likelihood of participants fitting the recruitment for a depression study. Also, future studies could consider ways of increasing participant retention. One possible way of attracting and retaining participants could be to offer a financial incentive to participate, however this has its own ethical and research implications that need to be carefully considered.

An alternative way of designing the current study could have used low sexual desire as the primary variable of interest and recruitment. By including participants specifically reporting low sexual desire, researchers could have better results measuring change in sexual desire after a treatment has occurred. Different research tools could be considered for future projects to measure sexual variables. Using a different measure of sexual desire, sexual functioning, or sexual dysfunction (Rizvi, Yeung, & Kennedy, 2011) may reveal insights not captured by the measures in the current study.

The BAML treatment program was not designed to treat low sexual desire. Therefore, it is not entirely surprising that treatment participants did not show an improvement in an area that the treatment was not designed for. Future treatment packages could include a module that addresses sexual desire or even romantic relationships, similar to the way the treatment program includes modules to address communication skills and anger management skills.

In conclusion, the results of this study provide some support for the connection between sexual desire and depression, but results did not indicate that sexual desire improved as a result of completing a depression treatment program. Results did show that

the BAML treatment program was effective for those participants who completed at least five sessions of treatment. Future research in this area should allow for alternative methods to assess for and treat low sexual desire in participants who are interested in improving their sexual desire.

Appendix A

Beck Depression Inventory-II

Appendix B

Revised Hamilton Rating Scale for Depression

Appendix C

Structured Clinical Interview for DSM-IV Disorders

Structured Clinical Interview for DSM-IV Disorders is copywrited by First, Michael B., Spitzer, Robert L, Gibbon Miriam, and Williams, Janet B.W.: Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition. (SCID-I/P) New York: Biometrics Research, New York State Psychiatric Institute, November 2002.

Appendix D

Sexual Desire Inventory

This inventory was originally published in "The Sexual Desire Inventory: Development, Factor, Structure, and Evidence of Reliability," by I. P. Spector, M. P. Carey, and L. Steinberg. 1996, Journal of Sex & Marital Therapy, 22, 175-190. Correspondence can be directed to the lead author: Ilana P. Spector, Community Psychiatric Center, Douglas Hospital, 6875 LaSalle Blvd, Verdun, Quebec, Canada H4H IR3.

Appendix E

Sexual Behavior Inventory

Directions: Please answer each question to the best of your ability for a period of the last week.

1	2	3	4	5	6	7	8	9
Zero Times	Once	Twice	Three times	Four times	Five times	Six times	Once per day	Twice or more times per day

Please use the following scale:

1. How many times did you masturbate: _____
2. How many times did you engage in partnered sexual activity
3. (beyond kissing and petting) _____

Appendix F

Initial Assessment Information Form

Initial Assessment Information Form for Participant Number _____

Date of Birth: _____ Age: _____

Race/Ethnicity:

1 = Caucasian/White 2 = African-American 3 = Hispanic/Latino

4 = Asian-American 5 = Native American 6 = Arab-American

7 = Alaskan American 8 = Multiracial _____

9 = International / Non-US Resident _____

10 = Other _____

Sex:

1 = Male 2 = Female

Marital Status:

1 = Single 2 = Married 3 = Domestic Partnership

4 = Engaged 5 = Separated 6 = Divorced or Annulled

7 = Widowed 8 = Other _____

Occupational Status:

1 = Currently Employed 2 = Unemployed 3 = On Disability

4 = Stay at Home Parent 5 = Retired 6 = Other _____

Household Income:

1 = Under $5,000 2 = $5,000 - $9,999 3 = $10,000 - $14,999

4 = $15,000 - $24,999 5 = $25,000 - $34,999 6 = $35,000 - $49,999

7 = $50,000 - $74,999 8 = $75,000 - $99,999 9 = $100,000 and over

Education Level:

1 = Less than 7th Grade	2 = 7th – 12th Grade (Did Not Graduate)	3 = Graduated High School
4 = GED	5 = Some College	6 = Graduated 2-Year College or Technical School
7 = Graduated 4-Year College	8 = Some Graduate School	9 = Graduate Degree (e.g. Ph.D., M.A., M.D.)

PREVIOUS Treatment(s) for Depression (Circle All That Apply):

1 = None	2 = Medications	3 = Individual Therapy
4 = Group Therapy	5 = Support Group	6 = Case Management
7 = Pastoral Care	8 = Hospital (Inpatient or Partial Hospitalization)	

9 = Other _____

CURRENT Treatment(s) for Depression (Circle All That Apply):

1 = None	2 = Medications	3 = Individual Therapy
4 = Group Therapy	5 = Support Group	6 = Case Management
7 = Pastoral Care	8 = Hospital (Inpatient or Partial Hospitalization)	

9 = Other _____

Are you currently taking any medication prescribed for symptoms of depression?
For instance Citalopram (Celexa). Escitalopram (Lexapro), Fluoxetine (Prozac), Fluvoxamine (Luvox), Paroxetine (Paxil), Sertraline (Zoloft), Duloxetine (Cymbalta), Venlafaxine (Effexor), Buproprion (Wellbutrin).

1 = Yes 2 = No

If Yes, Number of Weeks You Have Been Taking Antidepressant Medications:
_____ weeks

How Many Years of Experience Do You Have With Computers? _____ year(s)

How Comfortable Are You With a Computer?

1 2 3 4 5 6 7 8 9 10

Completely Uncomfortable Completely Comfortable

How Much Knowledge Do You Have About Computers?

1 2 3 4 5 6 7 8 9 10

No Knowledge Extensive Knowledge

On Average, How Many Hours Do You Use a Computer Each Week? _____ hour(s)

Appendix G

Consumer Satisfaction Survey

Consumer Satisfaction Survey for Participant Number _____

INSTRUCTIONS: This survey asks for your opinions about the computerized treatment for depression you have completed. Your feedback will be used to help improve this program for future use by other individuals experiencing symptoms of depression. There are no right or wrong answers to questions on this survey. Please answer each question by circling the number of the choice that matches your opinion at the present time.

1. As a result of completing the computerized treatment for depression, I deal more effectively with daily problems.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

2. The techniques I have learned from completing the computerized treatment for depression are likely to help me in the future.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

3. As a result of completing the computerized treatment for depression, I am better able to deal with a crisis.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

4. If necessary in the future, I would use a computerized treatment program for a psychological problem.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

5. I would recommend the computerized treatment for depression I completed to a friend or family member.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

6. As a result of completing the computerized treatment for depression, my day-to-day functioning has improved.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

7. As a result of completing the computerized treatment for depression, my leisure time is better spent.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

8. As a result of completing the computerized treatment for depression, I do better in social situations.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

9. The computerized treatment for depression provided me with services that were as good or better than the therapy services I would expect from a human therapist.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

10. The computerized treatment for depression was easy to use.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

11. The computerized treatment for depression was easy to understand.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

12. The patients whose stories were presented in the computerized treatment for depression had similar problems to my own.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

13. The computerized treatment for depression fit my individual needs.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

14. I liked the therapist(s) I selected in the computerized treatment for depression.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

15. Overall, I am satisfied with the computerized treatment for depression.

5	4	3	2	1	0
Strongly Agree	Agree	In Between	Disagree	Strongly Disagree	Does Not Apply

In the space below, please give us any comments you would like to make about what you like and dislike about the services you receive, and suggestions for how to make things better. (You may use the back of this sheet if necessary)

Appendix H

Informed Consent Document

Western Michigan University
Department of Psychology

Principal Investigator: C. Richard Spates, Ph.D.
Student Investigator: Anthony Bonita, M.A.
Title of study: "Testing the Effectiveness of Computerized Behavioral Activation Therapy in Acute Treatment"

You have been invited to participate in a research project entitled "Testing the Effectiveness of Computerized Behavioral Activation Therapy in Acute Treatment of Depression". This project will serve in part as the dissertation project for Anthony Bonita for the requirements of a Ph.D. in Clinical Psychology. This consent document will explain the purpose of this research project and will go over all of the time commitments, the procedures used in the study, and the risks and benefits of participating in this research project. Please read this consent form carefully and completely and please ask any questions if you need more clarification.

What are we trying to find out in this study?
This research is intended to measure the effectiveness of a computer-delivered behavioral activation treatment as a therapeutic tool to treat individuals suffering with symptoms of depression. This psychological therapy has been shown to be effective with many people when administered by a therapist. We are doing this study because we would like to know how effective this psychological therapy is when administered by a computer.

Who can participate in this study?
If you agree and consent to participate in this study, you will be asked to complete a brief initial assessment during today's appointment, during which you will complete a personal information form and one measure of your symptoms of depression. This brief initial assessment, which includes multiple choice assessment measures of your symptoms, will take approximately 15 minutes to complete. You will then be asked to complete a comprehensive second assessment approximately one week from today, during which you will complete measures of your symptoms of depression and a psychological interview. This comprehensive second assessment appointment will take approximately two hours to complete. Based on the results of this comprehensive second assessment appointment, it will be determined if you qualify to participate in the study.

Individuals who meet criteria for a depressive disorder, as determined by two of the primary assessment measures for the study, will be eligible to participate. A diagnosis of bipolar disorder, psychotic disorder, abuse of certain substances, mental retardation and/or dementia will exclude you from the study. You will also be excluded from the study if you are currently receiving therapy services for your symptoms of depression or if you are taking antidepressant medications and have been taking these medications for less than eight weeks. Regardless of

whether you qualify for participation in the study, you will be provided with a list of local mental health service providers, including some locations that offer reduced-fee services. These may be an alternative to participation in the present study.

Where will this study take place?
Assessment and therapy meetings will be conducted in private laboratory rooms on the second floor of Wood Hall, room 2502, located on the campus of Western Michigan University. This laboratory space has three rooms that have a table, chairs, and doors to ensure privacy and confidentiality.

What is the time commitment for participating in this study?
The time commitment for participating in this study includes participation in assessment meetings, ten treatment appointments, homework in between sessions, and three follow up appointments. The first consent and assessment meeting will take approximately 30 minutes to complete. The second assessment appointment will take up to two hours. Each of the ten treatment sessions take approximately 45-60 minutes each to complete. One month after completing treatment, and at three and six months after treatment has ended, you will be asked to return to complete follow-up treatment appointments which include assessment measures completed in the first two assessments. Each of these follow-up appointments will take approximately two hours to complete. If you complete the entire course of treatment, your involvement will include approximately 15 -19 hours of participation in the lab, plus the additional "homework" time of practicing what you can learn from the treatment sessions.

What will you be asked to do if you choose to participate in this study?
If you choose to participate and meet the eligibility criteria for the study, you will be randomly assigned to one of two treatment conditions.

- In one condition, you will immediately begin a weekly Computerized Behavioral Activation treatment for depression. This treatment will be administered with the aid of the researcher or a research assistant. During treatment, you will interact with a multimedia interactive computer treatment program, which involves ten weekly treatment sessions, lasting approximately forty-five minutes to one-hour each. In this therapy, you will be guided to look at how your behavior impacts your mood and your symptoms of depression, and you will be assisted in altering your behavior such that it has more positive effects in reducing or eliminating your symptoms of depression. At the final treatment session, you will also be asked to complete a 5-minute Client Satisfaction Survey.

- In the second condition, Computerized Behavioral Activation treatment will be delayed for approximately four weeks. Once per week and until the end of the four-week period, you will be tested with a 10-minute psychological questionnaire. In the last week of this

four-week period you will be given a 10-minute psychological interview, and if you continue to qualify for the study, you will be scheduled for treatment. You will be enrolled in treatment immediately thereafter.

Both groups will receive treatment for 10 weeks and will be asked weekly to report activity level, complete a 10-minute multiple choice survey of depression symptoms and a survey of sexual desire. Your involvement in therapy includes "homework" of practicing behaviors and activities in your daily life, which will take time during each week to practice the activities. The amount of time it takes depends on which activities you choose and how much you practice. During each of the ten treatment sessions, you will be asked to report your activity level from the previous week.

There will be three follow up appointments after treatment ends. One month after completing treatment, and at three and six months after treatment has ended, you will be asked to return to complete the same 10-minute multiple choice survey of depression, survey of sexual desire, and be interviewed a last time with the two psychological interviews already given. Each of these follow up appointments will take approximately two hours to complete.

What information is being measured during the study?
During the assessment appointments we will be collecting information about you to determine your demographic characteristics. We will also be measuring your symptoms of depression through surveys that you complete and through an interview with a trained research assistant. During the treatment sessions we will be measuring your symptoms of depression with a survey, your activity level from the last week, and your sexual desire with a survey. During the follow up appointments after treatment we will be measuring your symptoms of depression through surveys and through an interview with the research assistant.

What are the risks of participating in this study and how will these risks be minimized?
As in all research, there may be unforeseen risks to the participant. One potential risk of your participation in this project is that you may experience unpleasant emotions, including anger, frustration, depression, and disappointment, as you recall your problems and experiences and actively work to change certain behaviors in order to reduce your depression. The Anxiety Disorders Lab is prepared to make a referral should emergency care become necessary. You will be responsible for the cost of emergency care should such care become necessary. If an increase in suicidal thinking, intention, or planning is reported or discussed, appropriate emergency measures will be taken; however, no compensation or treatment will be made available except as otherwise specified in this consent form. If necessary, your name and contact information may be disclosed to an outside agency only in the unexpected event when suicidal thinking, intention, and planning suggests additional support is required.

What are the benefits of participating in this study?
The primary potential benefit of participation in this study is the alleviation or elimination of symptoms of depression. This may occur through using different techniques and strategies that you will learn during your weekly sessions of behavioral activation therapy. Furthermore, knowledge gained from this study may lead to the development of more effective, accessible, and affordable treatments for depression, which may in turn help other individuals experiencing symptoms of depression.

Are there any costs associated with participating in this study?
The most significant "cost" of your participation is time involved in treatment, and time practicing the skills that are addressed in treatment as "homework." Additional cost may be involved in transportation and parking to arrive to appointments, which is the responsibility of each participant.

Is there any compensation for participating in this study?
There is no compensation or payment for participating in this study. If you are currently enrolled in a course that provides extra credit for participation in research, we will provide documentation of your time to any professors you request.

Who will have access to the information collected during this study?
The only people who will have access to the information collected in this study will be the primary investigator, student investigator, and trained research assistants. All research information collected from will be kept confidential. This means that your name will not appear on any research questionnaires you complete or on any other research forms that contain personal information you have provided. These forms will be kept in a research folder in a locked file cabinet in the Anxiety Disorders Research Laboratory during your participation in the study. At the end of your participation in the study, your research folder will be stored for at least three years after the completion of this study. It will then be destroyed. The laboratory will keep a separate master list with the names and research code numbers of participants from this study. The master list will be the only link between the data on the recording forms and your identity. The master list will be destroyed once all data has been collected and analyzed.

What if you want to stop participating in this study?
You can choose to stop participating in the study at anytime for any reason. You will not suffer any prejudice or penalty by your decision to stop your participation. You will experience NO consequences either academically or personally if you choose to withdraw from this study.

The investigator can also decide to stop your participation in the study without your consent.

Should you have any questions prior to or during the study, you can contact the primary investigator, Dr. Richard Spates at (269) 387-4329 or Anthony Bonita at (269) 352-9433. You

WESTERN MICHIGAN UNIVERSITY
H. S. I. R. B.
Approved for use for one year from this date:
JUN 15 2013
x
HSIRB Chair

may also contact the Chair, Human Subjects Institutional Review Board at 269-387-8293 or the Vice President for Research at 269-387-8298 if questions arise during the course of the study.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and signature of the board chair in the upper right corner. Do not participate in this study if the stamped date is older than one year.

I have read this informed consent document. The risks and benefits have been explained to me. I agree to take part in this study.

_____
Please Print Your Name

_____ _____
Participant's signature Date

Consent obtained by: _____ _____
Signature of researcher Date

Appendix I

Oral Recruitment Script

Oral Recruitment Script

Hello, my name is (YOUR NAME), and I am a (RESEARCHER/RESEARCH ASSISTANT) in the Anxiety Disorders Lab at Western Michigan University. I'd like to tell you about a project for which we are currently seeking volunteers, the ages of 18 and older, who are experiencing symptoms of depression and who are not currently receiving psychotherapy services for their symptoms of depression.

This research study is intending to investigate the effectiveness a computerized treatment for depression, and to monitor the treatment on side effects of depression, specifically sexual desire. This study is seeking individuals who are experiencing symptoms of depression for participation in the study.

This study is a treatment study. Qualified participants will receive a treatment that focuses on reducing a number of different symptoms of depression. Participants will attend two assessment appointments prior to beginning treatment, one that will be approximately one half-hour in length and the other that will be approximately two hours in length. Participants will then attend ten, weekly, hour-long sessions of treatment. Participants will fill out several self-report measures in addition to receiving treatment, including measures of your mood and measures of sexual desire which can be a side effect of depression for some people. After treatment, participants will attend three follow-up assessments that will be approximately two hours each in duration.

If you are interested in knowing more details pertaining to this study, please call the Anxiety Disorders Lab at 269-262-1633 and leave a message for Anthony Bonita or send an e-mail to anxietybaml@gmail.com. If you have any questions or concerns about this study, you may contact the principle investigator, Dr. Richard Spates, at (269) 387-4329. Interested individuals can also pick up a piece of paper with this contact information from me at this time. Thank you.

The following will be printed on a 3x3 inch paper and will be distributed throughout the room for interested individuals to take:

Investigator: Anthony Bonita, MA
Anxiety Disorders Lab
Phone: 269-262-1633
E-mail: anxietybaml@gmail.com
Study: Testing the Effectiveness of Computerized Behavioral Activation Therapy in Acute Treatment of Depression

Appendix J

Phone Script

Phone Script

(Research Assistant): Hello. My name is _____. May I speak with _____?

YES: (wait for phone to be given to potential participant and/or begin script below)
NO: Do you know a time during which I may be able to reach him/her?

YES: (MAKE NOTE OF TIME). Thank you for your assistance.
NO: Thank you for your time, I will call back later.

(Research Assistant): Hello. My name is _____ and I am a research assistant at Western Michigan University. I am calling because you left a message on our laboratory phone regarding a depression study we are conducting. Are you interested in learning more about the study?

NO: Okay, thank you for your time.

YES: If you decide to participate and qualify for the study, you would receive a computerized behavioral activation treatment for depression called "Building a Meaningful Life Through Behavioral Activation". The treatment involves learning new strategies to alleviate your symptoms of depression and has been previously shown to be effective for many people who are experiencing symptoms of depression.
You will first be invited for an initial appointment to learn more about the study. If you are interested and consent to participating, you will be evaluated for participation during two appointments scheduled one week apart. If you meet criteria for participating and you'd like to continue, you will be eligible for the treatment phase of the study. Treatment would take place over the course of approximately two-and-a-half months and would involve ten weekly sessions of behavioral activation therapy, administered by a computer with the aid of a research assistant. These sessions will be approximately one hour in length. In addition to attending these weekly sessions, it is also expected that you will practice the strategies learned in therapy over the course of your week. During each of the ten treatment sessions, you will be asked to report your activity level for the previous week. Also, you will be asked to complete a survey that asks about depression symptoms and a survey that asks about sexual desire. You would also be asked to attend three follow-up appointments to thoroughly evaluate your symptoms of depression, the last of which would occur six months after the completion of treatment. Do you have any questions about participating in this research project?

YES: (ANSWER ANY QUESTIONS). If you are still interested in learning more about the study, the next step would be to schedule an initial appointment. This appointment may take approximately one half-hour to complete. During this appointment, you will be asked to read an informed consent document and if you agree to participate, sign it, and proceed with two self-report measures. Would you be interested in scheduling an initial appointment?

NO: If you are still interested in learning more about the study, the next step would be to schedule an initial appointment. This appointment may take approximately one half-hour to complete. During this appointment, you will be asked to read an informed consent document and if you agree to participate, sign it, and proceed

with two self-report measures. Would you be interested in scheduling an initial appointment?

NO: Okay. Thank you for your time. Goodbye.

YES: Okay, at this time I would like to set up your initial screening appointment. (SET UP A DATE AND TIME). Would you like to receive a reminder phone call? (IF YES, MAKE REMINDER PHONE CALL ARRANGEMENT). Thank you for your time.

Appendix K

Demographics Table

Table 1 - Continued

Demographic variables for full sample, non-qualifiers, qualified/ITT, dropped out, and completers

Variable	Full Sample	Non-Qualifiers	Qualified/ ITT	Dropped Out	Completers
N	44	31	13	6	7
Age					
Mean (*SD*)	23.3 (10.3)	21 (4.5)	28.9 (16.8)	31.8 (17.6)	26.4 (17.1)
Median	20	19	20	23.5	20
Range	18-65	18-41	18-65	18-55	18-65
Gender					
Male	14 (31.8%)	12 (38.7%)	2 (15.4%)	1 (20%)	1 (14.3%)
Female	30 (68.2%)	19 (61.3%)	11 (84.6%)	5 (80%)	6 (85.7%)
Race/Ethnicity					
Caucasian	30 (68.2%)	21 (67.74%)	9 (69.2%)	4 (66.7%)	5 (71.4%)
African American	10 (22.7%)	8 (25.80%)	2 (15.4%)	0 (0.0%)	2 (28.6%)
Other	4 (0.9%)	2 (6.45%)	2 (15.4%)	2 (33.3%)	0 (0.0%)

Marital Status					
Single	39 (88.6%)	29 (93.5%)	10 (76.9%)	4 (66.7%)	6 (85.7%)
Married	2 (4.5%)	0 (0.0%)	2 (15.4%)	2 (33.3%)	0 (0.00%)
Separated	1 (2.3%)	1 (3.2%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Divorced or Annulled	0 (0.00%)	0 (0.0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Widowed	0 (0.00%)	0 (0.0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other	2 (4.5%)	1 (3.2%)	1 (7.7%)	0 (0.00%)	1 (14.3%)

Occupational Status					
Currently Employed	20 (45.5%)	17 (54.8%)	3 (23.1%)	1 (16.7%)	2 (28.6%)
Unemployed	20 (45.5%)	12 (38.7%)	8 (61.5%)	5 (83.3%)	3 (42.9%)
Disability	1 (2.3%)	0 (0.0%)	1 (7.7%)	0 (0.00%)	1 (14.3%)
Stay At Home	1 (2.3%)	1 (3.2%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Retired	0 (0.00%)	0 (0.0%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other	2 (4.5%)	1 (3.2%)	1 (7.7%)	0 (0.00%)	1 (14.3%)

Socioeconomic Status

Under $5,000	25 (56.8%)	17 (54.8%)	8 (61.5%)	3 (50.00%)	5 (71.4%)
$5,000 - $9,999	4(9.1%)	4 (12.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
$10,000 - $14,999	5 (11.4%)	5 (16.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
$15,000 - $24,999	2 (4.5%)	1 (3.2%)	1 (7.7%)	1 (16.7%)	0 (0.00%)
$25,000 - $34,999	2 (4.5%)	1 (3.2%)	1 (7.7%)	0 (0.0%)	1 (14.3%)
$35,000 - $49,999	3 (6.8%)	3 (9.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
$50,000 - $74,999	2 (4.5%)	0 (0.0%)	2 (15.4%)	1 (16.7%)	1 (14.3%)
$75,000 - $99,999	0 (0.00%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
$100,000 and over	1 (2.3%)	0 (0.0%)	1 (7.7%)	1 (16.7%)	0 (0.0%)

Education					
Less than 7th Grade	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
7th – 12th Grade	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Graduated High School	7 (15.9%)	6 (19.4%)	1 (7.7%)	1 (16.7%)	0 (0.0%)
GED	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Some College	29 (65.9%)	20 (64.5%)	9 (69.2%)	2 (33.3%)	6 (100.00%)
Graduated 2-Year	4 (9.1%)	2 (6.5%)	2 (15.4%)	2 (33.3%)	0 (0.0%)
Graduated 4-Year	1 (2.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Some Graduate School	2 (4.5%)	1 (3.2%)	1 (7.7%)	1 (16.7%)	0 (0.00%)
Graduate Degree	1 (2.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

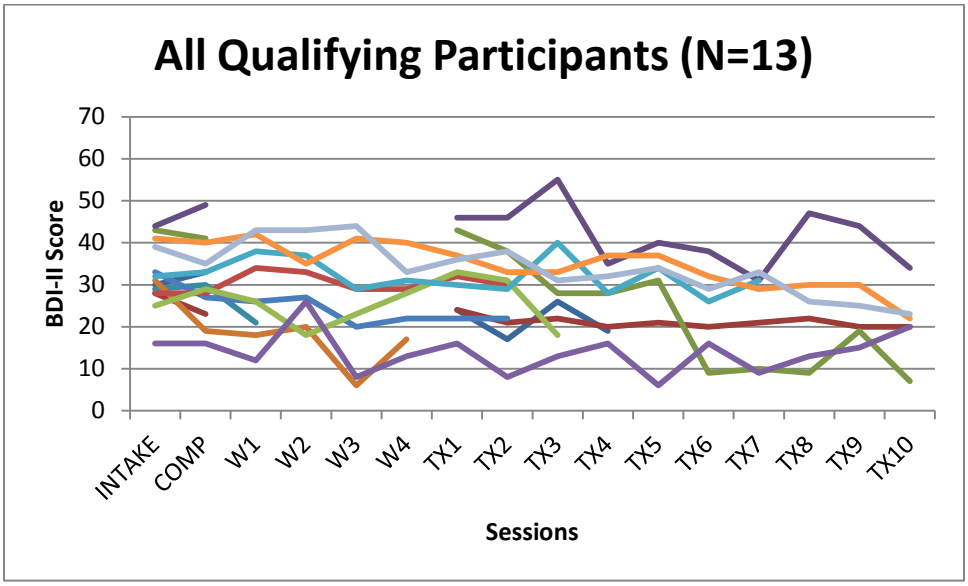
Computer Experience (Mean (*SD*))

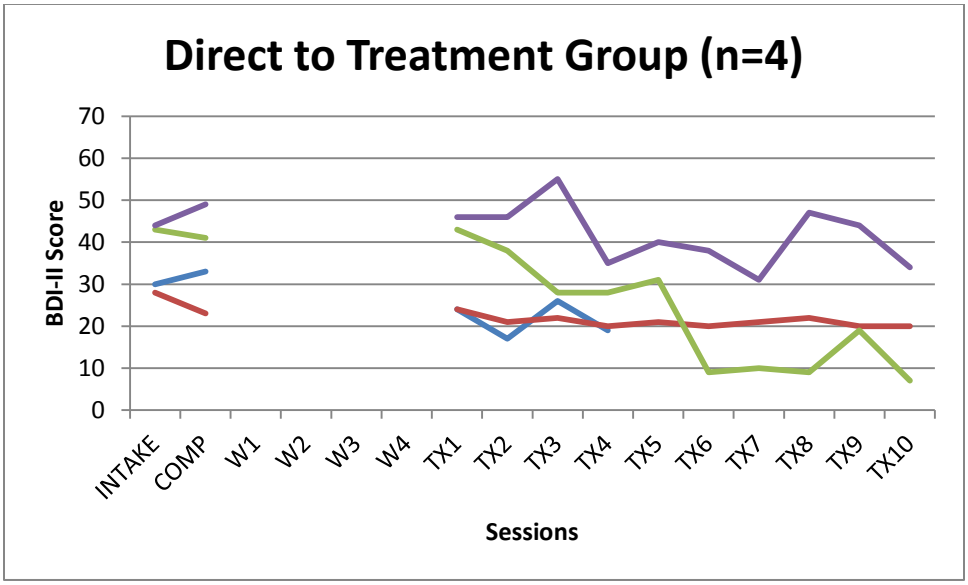
Years Experience	11.5 (4.3)	10.8 (3)	13.5 (6.3)	15.8 (8.2)	11.2 (3)
Degree of Comfort	9.0 (1.1)	8.9 (1.2)	9.1 (1)	8.8 (1.2)	9.3 (.8)
Amount of Knowledge	7.4 (1.5)	7.2 (1.4)	8 (1.5)	8.3 (1.2	7.7 (1.8)
Hours Weekly Computer Use	22.9 (13.9)	23.2 (16)	21.9 (6.4)	24.7 (4.5)	19.2 (7.2)

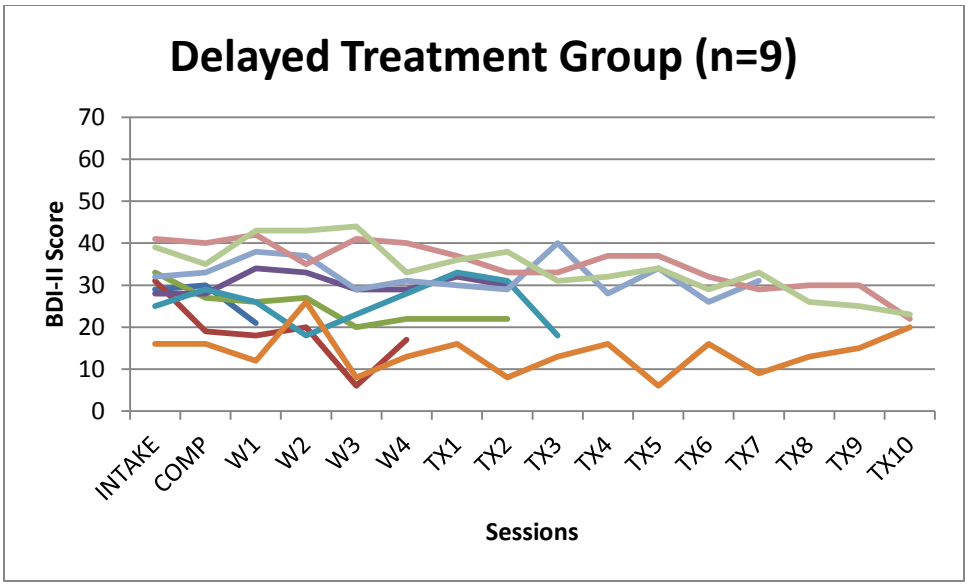
Appendix L

Additional Participant Graphs

Additional Participant Group Graphs



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60
50
40
30
20
10
0
INTAKE
COMP
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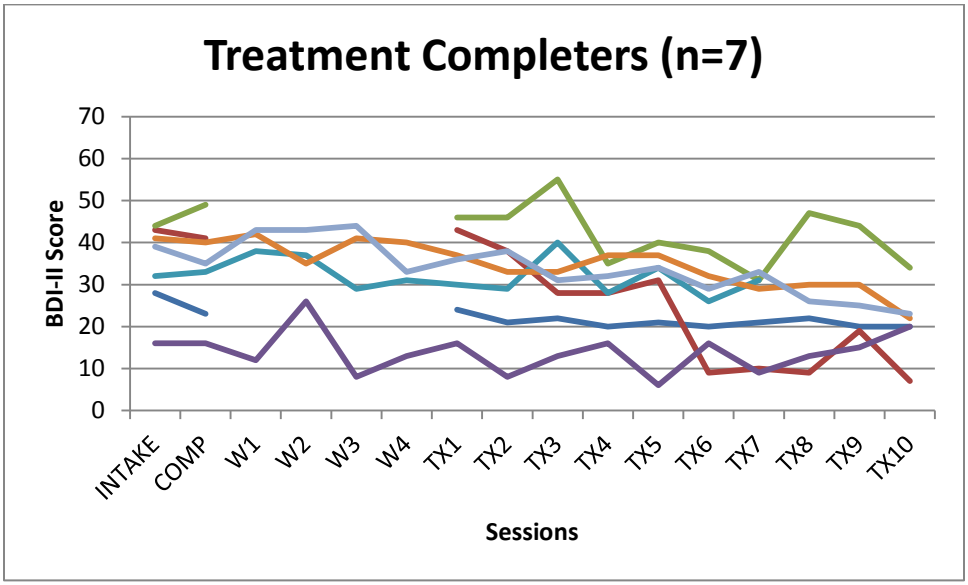
TX2
TX3
TX4
TX5
TX6
TX7
TX8
TX9
TX10
Sessions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60
50
40
30
20
10
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INTAKE
COMP
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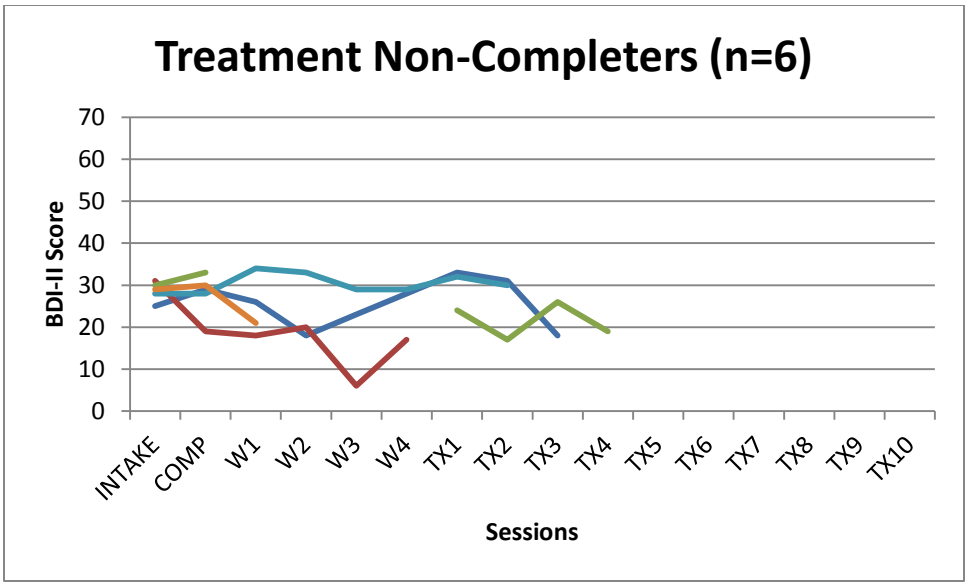
TX2
TX3
TX4
TX5
TX6
TX7
TX8
TX9
TX10
Sessions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40
30
20
10
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INTAKE
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W3
W4
TX1
TX2
TX3
TX4
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TX7
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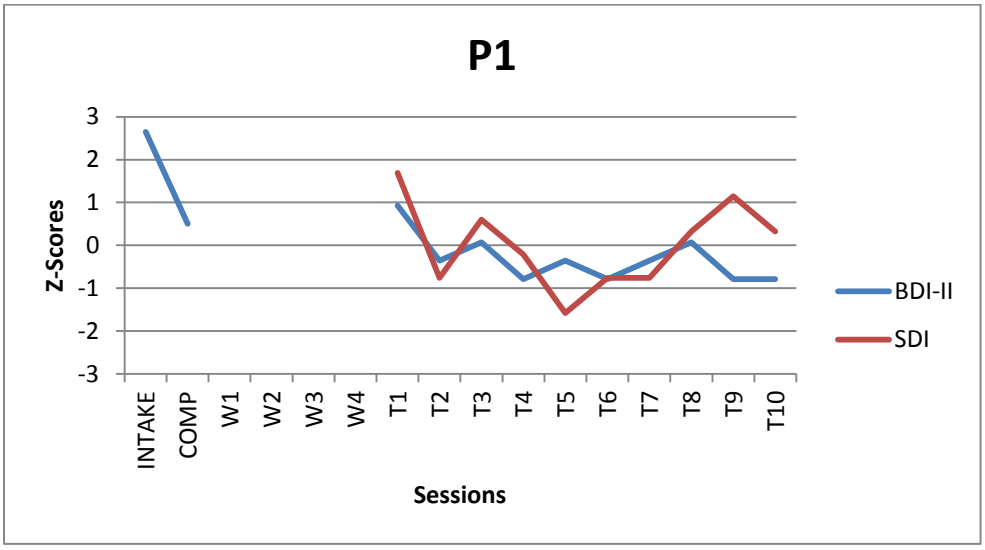
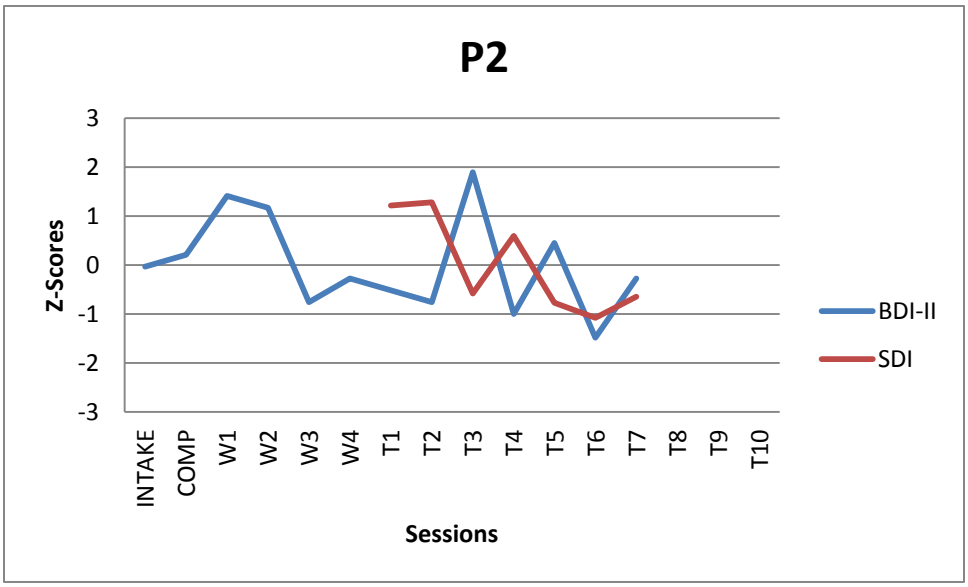
TX9
TX10
Sessions

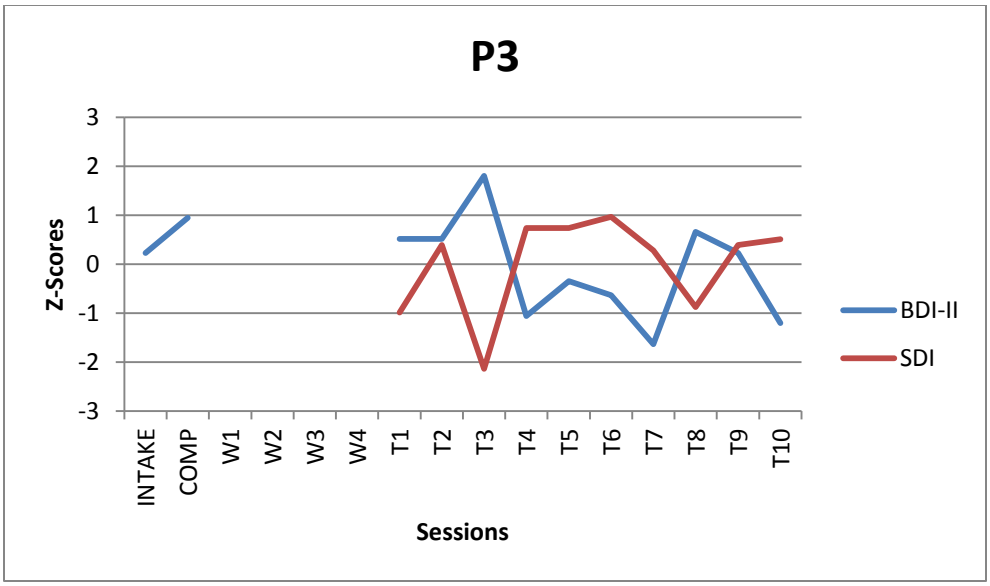
Appendix M

Individual Participant Graphs of Standardized Treatment Scores

Individual Participant Graphs of Standardized Treatment Scores



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Z-Scores
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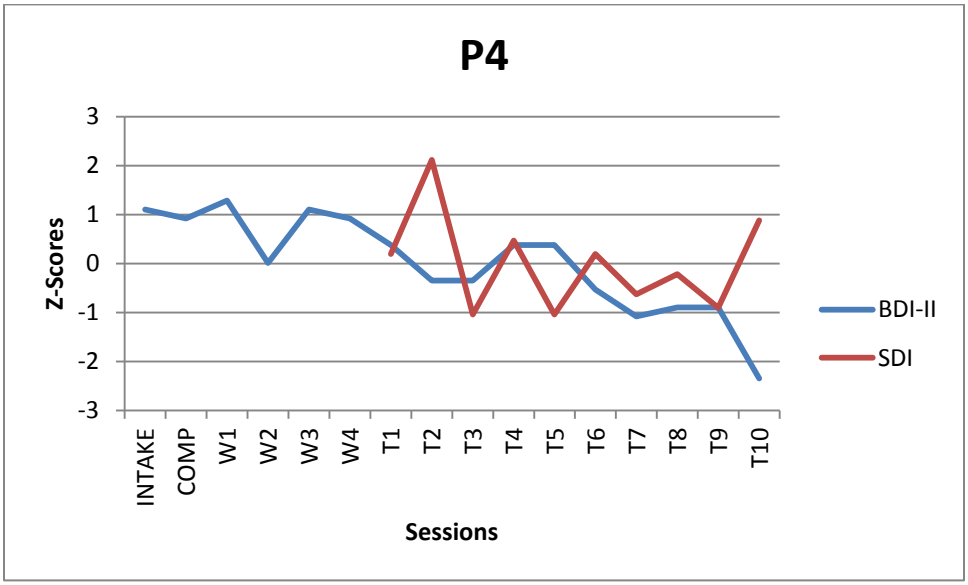
T9
T10
Sessions
BDI-II
SDI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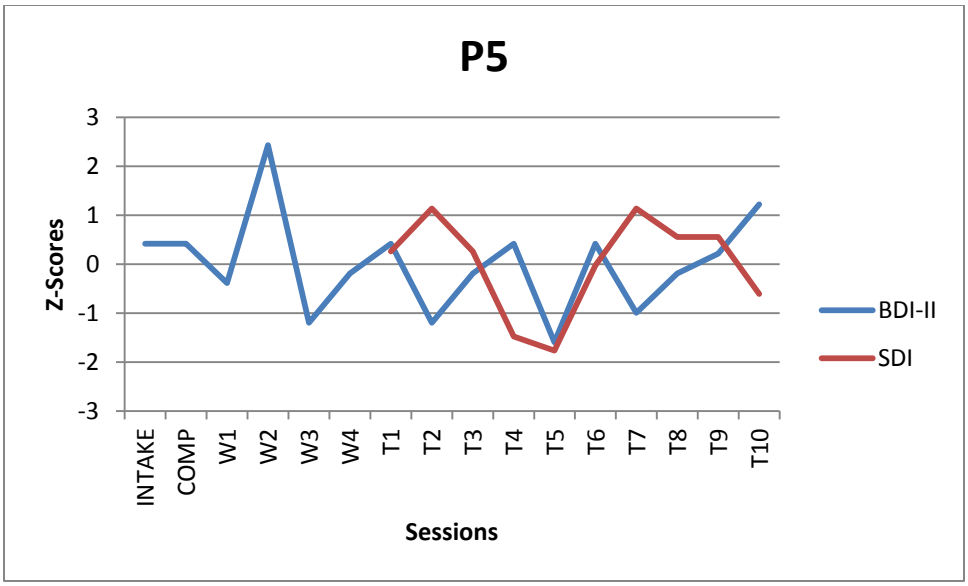
SDI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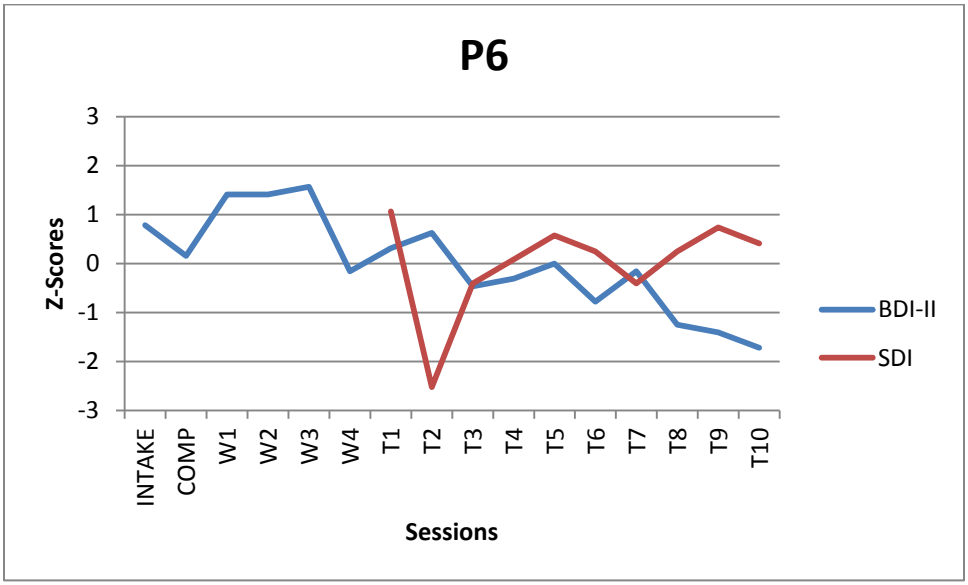
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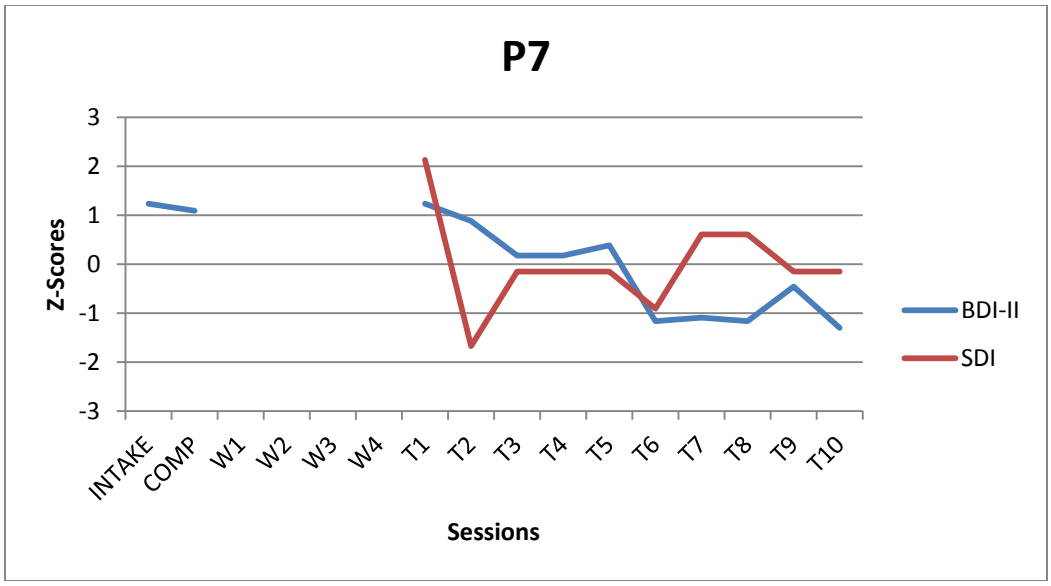
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INTAKE
COMP
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T6
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T8
T9
T10
Sessions
BDI-II
SDI

Appendix N

Approval Letter from the Human Subjects Institutional Review Board

WESTERN MICHIGAN UNIVERSITY

Human Subjects Institutional Review Board

Date: November 7, 2011

To: Richard Spates, Principal Investigator
Anthony Bonita , Student Investigator

From: Victoria Janson, Interim Chair

Re: HSIRB Project Number 11-06-04

This letter will serve as confirmation that your research project titled "Testing the Effectiveness of Computerized Behavioral Activation Therapy in Acute Treatment of Depression" has been **approved** under the **full** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: June 15, 2012

Walwood Hall, Kalamazoo, MI 49008-5456
PHONE: (269) 387-8293 FAX: (269) 387-8276

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