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Testing the Effectiveness of Cognitive-Behavior and Medication Therapy in the Acute Treatment on Unipolar Mood Disorders: Processes and Case Histories

Alyssa H. Kalata

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Alyssa H. Kalata
The present study sought to investigate two areas of interest: (1) the process issues involved in conducting a randomized controlled trial with low-income individuals being seen at community mental health agencies and (2) patterns in case histories of individuals who participated in depression treatment outcome research at community mental health agencies. This study gives a detailed analysis of conducting a randomized controlled trial for unipolar mood disorders in two community mental health agencies in the Southwestern Michigan region. Process issues at the levels of identification and recruitment of participants, attendance and retention of participants, project implementation, and broader systemic issues are identified and discussed. Additionally, patterns in demographic variables, inconsistencies in depression measures, sudden gains, and treatment attendance are also investigated.
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Major Depressive Disorder is a highly prevalent psychological condition, affecting 10% to 25% of women and 5% to 12% of men over the course of their lifetime (American Psychiatric Association, 2000) and 9.5% (18.8 million) American adults each year (NIMH, 2002). Although not as prevalent as Major Depressive Disorder, Dysthymic Disorder also affects a substantial number of individuals, with 6% of individuals affected over the course of their lifetime and 3% of individuals affected at any given point in time (American Psychiatric Association, 2000). These two disorders, in addition to other unipolar mood disorders, have a substantial impact on the affected individuals, the people with whom these individuals interact, and society as a whole. Depression can affect an individual’s academic, occupational, social, and sexual functioning, as well as their sleep, appetite, ability to concentrate, and energy levels (American Psychiatric Association, 2000). Depression also has a negative interpersonal impact. Depressed individuals tend to produce increased levels of negative affect in the individuals with whom they interact and are typically evaluated more negatively by others (Coyne, 1976; Siegel & Alloy, 1990). Depression also negatively impacts social interactions between significant others (Siegel & Alloy, 1990) and is negatively correlated with marital satisfaction (Davila, Karney, Hall, & Bradbury, 2003). Finally, depression is negatively correlated with interpersonal effectiveness and tolerance of coworkers while at work (Motowidlo, Packard, & Manning, 1986). In addition to the
negative personal and interpersonal impacts of unipolar mood disorders, these disorders also have a negative impact on society as a whole. Depression is the leading cause of disability in the United States and Canada for young- to middle-aged adults (The World Health Organization, 2004). Furthermore, the costs associated with depression in the year 2000 were estimated to be eighty-three billion dollars total, with twenty-six billion dollars being spent on treatment and fifty-seven billion dollars associated with economic loss tied to diminished workplace productivity and attendance and lifetime earnings lost due to suicide (NIMH, 2006). The impact of depression extends to everyone, be it through the direct impact of suffering from depression oneself or having a friend or loved one who suffers from the disorder or through the indirect impact of the cost of depression to society as a whole.

Symptoms that are consistent across unipolar mood disorders include depressed mood, weight loss or weight gain, insomnia or hypersomnia, fatigue or loss of energy, feelings of worthlessness, diminished ability to think or concentrate, and indecisiveness (American Psychiatric Association, 2000). The symptoms of a Major Depressive Episode and Dysthymic Disorder are described more specifically in their respective diagnostic criteria (see Appendices A and B), but encompass the symptoms listed above, as well as additional symptoms that are more unique to each disorder.

Although the impact of unipolar mood disorders is substantial, effective treatments exist in the form of psychotherapy and medication-based interventions. Of particular relevance to this study is the literature base that exists in support of two different modalities used to administer cognitive-behavioral therapy in the treatment of depression. Cognitive therapy and behavior therapy have been given the distinction of
being two of the three treatments that currently have extensive enough empirical support
to earn the label of a “well-established” treatment for depression, based on criteria
defined by Division 12 of the American Psychological Association (Chambless, Baker,
Baucom, Beutler, Calhoun, Crits-Cristoph, et al, 1998). Previous meta-analyses (e.g.
Dobson, 1989) provide additional support indicating that cognitive-behavioral therapy
administered by a clinician is effective in the treatment of depression. There is also
preliminary empirical support for the administration of cognitive-behavioral therapy by a
computer (e.g. Selmi, Klein, Greist, Sorrell, & Erdman, 1990; Proudfoot, Goldberg,
Mann, Everitt, Marks, & Gray, 2003). Although effective treatments exist for depression,
up to 90% of depressed patients in primary care settings fail to receive sufficient
treatment for their depression, either through appropriately managed medication regimens
or through empirically supported psychotherapy for depression (Center for the
Advancement of Health, 2000). This alarmingly high number suggests that randomized
controlled trials, while providing important information about the efficacy of
interventions, perhaps do not discuss process-oriented issues in detail. These process-
oriented issues may be what are interfering with empirically supported treatments being
implemented in primary care and mental health settings. In this paper, process issues
pertaining to the implementation of two forms of cognitive-behavioral therapy in a
community mental health setting with a low-income population will be examined in more
detail. These issues include the identification and recruitment of individuals who may
benefit from such treatments, unique features involved in the assessment of individuals
likely to be seen in a community mental health agency, the attendance and retention
rates of individuals who opt for treatment, implementation of these two modalities of
cognitive-behavioral therapy, and systemic issues at an agency level.
Although unipolar mood disorders affect all social strata equally in terms of prevalence, very little research exists on the treatment of unipolar mood disorders in low-income individuals. The literature that does exist consists of primarily randomized controlled trials that focus on outcomes, rather than process issues involved in conducting research with low-income individuals in community mental health settings. Although these studies do not address process issues explicitly, a close examination of the literature suggests that some process themes may exist across studies. This literature review will focus on the themes that emerged across these studies (for details about the studies, please refer to Appendix C).

**Length of the Studies.** A review of the literature suggests that conducting psychotherapy outcome studies with low-income individuals in community mental health settings takes a great deal of time in order to obtain a reasonable sample size. Miranda, Chung, Green, Krupnick, Siddique, Revicki, & Belin (2003) conducted screenings for a randomized controlled trial examining the treatment of depression in low-income women over the course of four years and eight months in order to obtain 267 individuals to randomize in to a treatment condition. Merrill, Tolbert, and Wade (2003) had a similar rate of acquisition, requiring approximately three years to obtain 192 individuals to participate in cognitive therapy. Perez Foster (2007) required three and one-half years to obtain 91 participants to randomize in to one of two therapy conditions and Swartz, Shear, Frank, Cherry, Scholle, and Kupfer (2002) required one year and one month to
obtain 12 individuals to participate in a supportive therapy group with cognitive-behavioral elements. Other studies (e.g. Quijano, Stanley, Peterson, Casado, Steinberg, Cully, & Wilson, 2007; Reay, Stuart, & Owen, 2003) did not indicate the time period over which the studies were conducted. In comparison to the rate of participant acquisition when working with low-income individuals receiving services at community mental health agencies, Dimidjian and colleagues (2006) were able to randomize 241 individuals into treatment conditions over the span of only three years. Using the Dimidjian and colleagues (2006) study as a benchmark, this suggests that well-conducted randomized controlled trials run with participants selected from the general population may take less time to obtain adequate or desired sample sizes than studies recruiting directly from agencies. The locations in which the studies were conducted may also have played a role in the amount of time it took to recruit participants. While the Miranda, et al (2003) and Perez Foster (2007) studies were conducted in areas with population sizes comparable to or larger than the area in which the Dimidjian, et al (2006) study was conducted, the Merrill, et al (2003) and Swartz, et al (2002) studies were conducted in a small city and a rural area, respectively. Thus, it is possible that the small population sizes in these areas played a role in increasing the time in which it took to recruit participants.

**Ratio of Individuals Screened to Individuals Assigned to Treatment.** The studies examined suggest that, in general, a very large number of individuals must be screened in order to obtain even modest sample sizes. Miranda and colleagues (2003) screened 16,286 individuals for potential participation in their study. Of these individuals, only 1,011 met initial eligibility requirements, 427 of these individuals completed a structured
diagnostic telephone interview, and only 267 of these individuals completed an in-person clinical interview and were randomized into a treatment condition, representing 62.5% of those individuals who completed the structured diagnostic telephone interview, but only 1.6% of the individuals who were initially screened. Merrill and colleagues (2003) screened 322 clients seeking treatment at a community mental health clinic, 98 of which were excluded because they did not have a primary diagnosis of major depressive disorder and 32 of which were excluded from analysis because of incomplete data, leaving 192 people who participated in the study, or 59.6% of the individuals screened. Perez Foster had an abnormally high rate of inclusion, with only three of the 94 individuals screened excluded from the study, representing a 96.8% inclusion rate. Swartz and colleagues (2002) screened 183 women for eligibility, of which 73 were perceived to be eligible and offered an assessment for inclusion into the study. Of these individuals, 34 declined participation, two were unable to participate, and thirteen could not be contacted. The remaining 24 individuals agreed to an assessment, of which seven failed to attend. Seventeen individuals provided informed consent prior to the assessment and five of these individuals were excluded after being assessed. The remaining twelve women were assigned to treatment, representing 70.6% of those individuals who completed the final assessment, but only 6.6% of the individuals initially screened for potential participation. Quijano and colleagues (2007) screened 348 individuals for depression, of which 172 initially qualified. Of these 172 individuals, 94 individuals were determined eligible based on a more detailed assessment, representing 54% of those individuals who completed a the more comprehensive assessment, but only 27% of the individuals initially screened. Reay and colleagues (2003) did not report the number of
individuals screened to obtain their sample size. In comparison to the Dimidjian, et al (2006) benchmarking study, the rates of individuals who are eligible after a the final assessment phase seem to be roughly comparable between studies conducted with low-income individuals being seen at community mental health agencies and randomized controlled trials conducted with the general population. Dimidjian and colleagues (2006) reported that 241 (62.1%) of the 388 individuals who completed an intake assessment qualified for participation in their study. However, it is difficult to compare this study to the other studies mentioned, as many of these studies involved multi-tiered screening and assessment processes and the Dimidjian, et al (2006) study had a larger number of exclusionary criteria and diagnoses than many of the aforementioned studies.

*Outreach and Supplementary Services.* Many of the studies examined utilized a number of outreach and supplementary services to encourage participation. Three of the studies conducted therapy services outside of a community mental health agency, although the services were still provided to community mental health agency consumers. These settings included a residential shelter for homeless women (Perez Foster, 2007), an outpatient psychiatry clinic (Perez Foster, 2007), a supermarket (Swartz, et al, 2002), in the home of participants (Quijano, et al, 2007), and over the telephone (Quijano, et al, 2007). Women seen at the supermarket stated that they found the “one-stop shopping” convenient and it is likely that those individuals seen in their places of residence likely found therapy in this setting to be a more convenient arrangement according to a survey conducted by the researchers after treatment was completed. Two studies (Miranda, et al, 2003; Swartz, et al, 2002) either provided childcare services at no charge or provided participants with monetary compensation for childcare. One study (Miranda, et al, 2003)
provided a number of different forms of transportation to appointments and another study (Swartz, et al, 2002) cited easy access to parking and bus services at the supermarket as being a distinct advantage to conducting therapy services at such a location. Finally, Miranda and colleagues (2003) used extensive phone contact as a means of encouraging and obtaining participation. Participants were contacted a mean of 4.1 times for their initial phone interview, 7.8 times for a subsequent clinical interview, 8.8 times to schedule their initial medication appointment, and 10.2 times to schedule their initial psychotherapy visit. The Merrill, et al (2003) and Reay, et al (2003) studies did not allude to any outreach procedures or special services utilized to increase the likelihood of participation in their respective studies. As with the Merrill, et al (2003) and Reay, et al (2003) studies, the Dimidjian, et al (2006) benchmarking study did not describe any additional outreach procedures or special services offered to participants to increase the likelihood of participation in their study.

Attrition Rates. As one might expect, attrition rates were high in all of the studies examined. Of those individuals assigned to the therapy condition in the Miranda, et al (2003) study, only 53% completed four or more sessions of therapy and only 36% received six or more sessions of therapy of the eight possible sessions, 75% received nine or more weeks of guideline-based medication services and 45% received 24 or more weeks of guideline-based medication services, and 17% attended one appointment of community care and only 9% attended four or more appointments of community care. In the Merrill, et al (2003) study, 68% of participants terminated therapy prematurely, a number that is fairly comparable to the Miranda, et al (2003) study. The Swartz, et al (2002) study reported slightly lower attrition rates, with 50% of the participants who
initially agreed to participate in treatment completing all sixteen weeks. The Quijano, et al (2007) reported differential rates of attrition for each of the services offered in the study. These services were offered to all participants. 86.2% of participants participated in the education intervention, 56.4% participated in receiving referrals to medical doctors or mental health specialists, and 44.7% participated in the behavioral activation intervention. The Reay, et al (2003) study reported substantially lower attrition rates, with 81% of individuals completing 12 to 16 weeks of interpersonal psychotherapy. Interestingly, Perez Foster (2007) did not report attrition rates. The Dimidjian, et al (2006) study had substantially lower attrition rates in the therapy and placebo conditions than the aforementioned studies, with 86.7% of participants completing the cognitive therapy condition, 83.7% completing the behavioral activation condition, and 77.4% of participants completing the placebo condition. Interestingly, the attrition rates were relatively high in the antidepressant treatment condition, with only 56% of participants completing this condition. This comparison suggests that attrition rates are likely to be higher in studies conducted with low-income individuals seen at community mental health agencies in comparison to those studies conducted recruitment from with the general population and seen in academic clinical research centers.
Although a substantial number of randomized controlled trials of psychological and medication interventions for depression exist and have provided support for a number of different interventions, these studies have generally not included low-income individuals receiving services at community mental health agencies. The lack of studies in this area is cause for concern in terms of the degree to which results obtained from randomized controlled trials not conducted with this population can be generalized to this population in a community mental health setting. Although research conducted with this population and in this setting has increased in recent years, many researchers continue to neglect these individuals in their work. It could be hypothesized that avoidance of working with low-income individuals or in community mental health settings is in part because unique process issues arise working with this population in this type of setting.

Given the paucity of literature available addressing conducting depression treatment outcome research with low-income individuals receiving services at community mental health agencies, questions remain about the process issues and unique features that emerge when conducting research with such populations. As such, the present investigation addressed two primary goals: (1) to examine the experience of conducting depression outcome research with low-income individuals being seen at community mental health agencies with the intent to identify issues that may be of interest to future researchers and (2) to examine case histories of individuals who participated in depression treatment outcome research at community mental health
agencies to identify interesting features of working with these individuals that should be investigated in future research.
CHAPTER IV

METHOD

Recruitment

Inclusion criteria for the study were initially a Beck Depression Inventory – II score of 18 or higher at both pretreatment assessment appointments and a diagnosis of Major Depressive Disorder based on the Structured Clinical Interview for DSM-IV Diagnoses. These criteria were later modified based on the inconsistencies between the three primary measures of depression used in this study. The modified inclusion criteria were a current diagnosis of Major Depressive Disorder, Dysthymic Disorder, or any other unipolar mood disorder based on the Structured Clinical Interview for DSM-IV Diagnoses or a Beck Depression Inventory – II score of 18 or higher at the second assessment appointment. Thus, the inclusion criteria utilized later in the study required that participants only meet the criteria for a unipolar mood disorder on one of these two measures of depression, allowing a greater number of individuals who might benefit from services to be included in the study. The exclusion criteria for the study were current bipolar or psychotic disorders, current alcohol or active substance abuse, the presence of mental retardation or dementias, and current therapy services targeting symptoms of depression.

Participants were recruited from two community mental health systems in Southwestern Michigan. Fifty-two individuals made an initial assessment appointment and twenty-three individuals were randomized in to a treatment condition. The twenty-
nine individuals who were not randomized did not get assigned to a treatment condition for the following reasons: repeated no-shows or drop-out during the assessment phase (7), no current diagnosis of a unipolar mood disorder according to the Structured Clinical Interview for DSM-IV Diagnoses (5), not interested in participating in the study (6), Beck Depression Inventory – II score of less than 18 (5), current diagnosis of psychotic disorder (2), no authorization for services at the community mental health agency (2), current diagnosis of alcohol abuse (1), and currently receiving therapy targeting symptoms of depression (1).

Materials

Beck Depression Inventory – II. Self-reported symptoms of depression were measured using the Beck Depression Inventory – II (BDI-II; Beck, Steer, & Brown, 1996). The Beck Depression Inventory - II is a 21-item, self-report measure that assesses symptoms of depression that correspond to the diagnostic criteria for Major Depressive Disorder in the DSM-IV. Each item is rated on a zero to three scale, with higher numbers representing increasing levels of severity of symptoms.

The Beck Depression Inventory – II has been used extensively in depression treatment outcome studies and demonstrates acceptable reliability and validity. Internal consistency estimates of reliability for the Beck Depression Inventory - II have been found to be .92 in a sample of 500 outpatients and .93 in a sample of 120 college students (Beck, Steer, & Brown, 1996) and test-retest reliability was found to be .93 over the
period of one week in a sample of 26 given the measure at the times of their first and second therapy sessions (Beck, et al, 1996).

The Beck Depression Inventory - II demonstrated a moderate correlation ($r = .71$) with the Revised Hamilton Rating Scale for Depression in a sample of outpatients (Beck, et al, 1996) suggesting some degree of concurrent validity with this measure. The correlation between the Beck Depression Inventory – II and the Revised Hamilton Anxiety Rating scale is relatively low ($r = .47$), although the Beck Depression Inventory – II is correlated somewhat with the Beck Anxiety Inventory ($r = .60$) (Beck, et al, 1996). Given the relationship between anxiety and depression that is commonly observed, this correlation is not entirely unexpected and still suggests that the Beck Depression Inventory – II has adequate psychometric properties in terms of discriminant validity.

Revised Hamilton Rating Scale for Depression. Clinician-reported assessments of severity of depression symptoms were measured using the Revised Hamilton Rating Scale for Depression (RHRSD; Warren, 1994). This measure is used to confirm diagnoses of Major Depressive Disorder and provide information about the severity of symptoms and their impact on everyday functioning.

The Revised Hamilton Rating Scale for Depression demonstrates adequate reliability and validity. The estimate of internal consistency was found to be .79 in the verification sample, although other studies have found internal consistency estimates of .45 to .95 (Warren, 1994).

Studies examining the concurrent validity of the Revised Hamilton Rating Scale for Depression with an assortment of other measures for depression have yielded a correlation of .67, suggesting that the Revised Hamilton Rating Scale for Depression has
adequate concurrent validity (Warren, 1994). As mentioned previously, the Revised Hamilton Rating Scale for Depression demonstrated a correlation of .71 with the Beck Depression Inventory – II in one sample of outpatients.

*Structured Clinical Interview for DSM-IV Disorders.* The Structured Clinical Interview for DSM-IV Disorders (SCID; First, Gibbon, Spitzer, & Williams, 1996) is a semi-structured interview that is used to assess for the presence of Mood Episodes, Psychotic Symptoms, Psychotic Disorders, Mood Disorders, Substance Use Disorders, and Anxiety and Other Disorders through orally administered questions based on the DSM-IV criteria for the aforementioned disorders and symptoms.

Studies investigating the interrater reliability of the Structured Clinical Interview for DSM-IV Disorders have found that interrater reliability is generally high. An earlier study conducted using the Structured Clinical Interview for DSM-III-R Disorders involved three raters examining fifty-four audiotaped interviews (Skre, Onstad, Torgersen, & Kringlen, 1991). The interrater reliability scores for major depressive disorder and dysthymia were .93 and .88, respectively, indicating high interrater reliability for these two diagnoses (Skre, et al, 1991). A second study examined the impact of a Training and Quality Assurance Program for SCID interviewers (Ventura, Liberman, Green, Shaner, & Mintz, 1998). Immediately after the training, the thirty individuals who had completed the training demonstrated an agreement rating of .85 and at a later Quality Assurance check demonstrated an agreement rating of .76, suggesting that agreement decreases slightly over time with individuals utilizing the Structured Clinical Interview for DSM-IV Disorders, but continues to remain relatively high (Ventura, et al, 1998)
Brief Anxiety and Depression Ratings. The Brief Anxiety and Depression Ratings used in this study asked participants to respond to the following two questions: “How anxious or stressed have you felt in the past week?” and “How depressed have you felt in the past week?” Participants were asked to rate their responses on a zero to eight scale, with zero representing “not at all anxious/depressed” and eight representing “extremely anxious/depressed”. No data regarding the psychometric properties of this measure exists.

Medication Status Form. At each appointment, participants were asked to indicate if they were currently taking medications for depression and indicate what medications they were currently taking.

Additional Services Form. At all follow-up appointments, participants were asked to indicate what treatments for depression (if any) they had sought since their last appointment related to the study.

Session Evaluation Forms. Two session evaluation forms were used in this study to assess a variety of aspects of each session. Session Evaluation Form #1 asked participants to rate the usefulness, relevance, and easy of following each session on a scale of zero to eight, with zero representing “not at all” and eight representing “very”. Participants were also asked to select which aspect of each session they found to be most useful (e.g. “recognizing that pleasurable events improve your mood,” “understanding that thoughts influence feelings”). Session Evaluation Form #2 asked participants to rate the responsiveness of therapy, the degree to which therapy was tailored to the participants as individuals, the appropriateness of the pace of therapy, the degree to which they felt as
though they had choice and input into therapy, the clarity of the rationale and goals of therapy, and the relevance of homework to their problems following each session on a scale of zero to eight, with zero representing “not at all” and eight representing “very”. No data regarding the psychometric properties of these measures exists.

*Consumer Satisfaction Survey.* The Consumer Satisfaction Survey is a twenty-three item, self-report measure that was completed by participants at the one-week follow-up appointment. This survey asked participants to provide feedback about the quality and acceptability of the services they received through their participation in the study, on a one to five scale, with one representing “strongly disagree” and five representing “strongly agree”. The measure also used a zero score to represent a response of “does not apply”. Responses of “does not apply” were not factored in to the overall rating of treatment satisfaction. No data regarding the psychometric properties of this measure exists.

**Procedure**

Participants were recruited through two different methods. The first method involved phone calls placed by either a nurse or project coordinator to individuals who had been identified by their respective agencies as having met criteria for a unipolar or bipolar mood disorder at a recent visit to the agency. The second method involved word-of-mouth information passed on to potential participants by case managers and intake staff at each agency. Individuals expressing interest in participating in the study were scheduled for an initial assessment appointment, at which time initial consent to
participate in the study was obtained (see Appendix D) and a Medication Status Form and Beck Depression Inventory – II were completed. Those individuals who met criteria for participation and indicated a continued interest in participating were scheduled for a second assessment appointment one week later. At the second assessment appointment, individuals were assessed more extensively and determinations were made about whether they continued to meet criteria for participation. At the second assessment appointment, potential participants completed a Medication Status Form and a Beck Depression Inventory – II. An independent assessor then completed a Structured Clinical Interview for DSM-IV Diagnoses and a Revised Hamilton Rating Scale for Depression with the potential participant. Those individuals meeting criteria for participation were then randomized in to a treatment condition and asked to give continued consent to participate in the study (see Appendix D). The four conditions in to which participants could be randomized are as follows: Face-to-Face Cognitive-Behavioral Therapy, Interactive Multimedia Assisted Cognitive-Behavioral Therapy, Michigan Implementation of Medication Algorithms, and Treatment-as-Usual. For purposes of this study, only the cognitive-behavioral therapy conditions will be discussed further. Those participants assigned to the Face-to-Face Cognitive-Behavioral Therapy condition received eight weeks of cognitive-behavioral therapy provided by a doctoral level student therapist. Those participants assigned to the Interactive Multimedia Assisted Cognitive-Behavioral Therapy condition received eight weeks of cognitive-behavioral therapy administered by a computer program with the aid of a nurse or research assistant. The computer program used in the Interactive Multimedia Assisted Cognitive-Behavioral Therapy condition was called Beating the Blues (Ultrasis; www.ultrasis.com). This program is designed to
address symptoms of both depression and anxiety. The cognitive components of the program address automatic thoughts, thinking errors and distraction, challenging unhelpful thinking, core beliefs, and attributional style. The behavioral components of the program include activity scheduling, problem-solving, graded exposure, task breakdown, and sleep management. The final session of the treatment protocol focuses on action planning and the conclusion of therapy. The content of the Face-to-Face Cognitive-Behavioral Therapy sessions was identical to that covered in Beating the Blues. Upon completion of the eight-week acute treatment phase, those participants who still met criteria for depression were offered their choice of participating in any of the other conditions offered by the study. All participants were then asked to attend follow-up appointments at one week, one month, three months, and six months post-treatment. At the one-week follow-up appointment, participants completed a Medication Status Form, an Additional Services Form, a Beck Depression Inventory – II, and a Consumer Satisfaction Survey. An independent assessor also completed a Structured Clinical Interview for DSM-IV Diagnoses and a Revised Hamilton Rating Scale for Depression with the participant. At the one-month, three-month, and six-month follow-up appointments, participants completed a Medication Status Form, an Additional Services Form, and a Beck Depression Inventory – II. As with the one-week follow-up appointment, an independent assessor also completed a Structured Clinical Interview for DSM-IV Diagnoses and a Revised Hamilton Rating Scale for Depression with the participant at each of these follow-up appointments.
Analysis

The present study employed a process and individual case history method of analysis. The process of conducting the study was examined in detail to elucidate potential difficulties future researchers may encounter in conducting research with a similar population or in a similar setting and potential solutions future researchers may consider using to address such difficulties. The process analysis portion of this study was then related to available literature on studies conducted with similar populations in similar settings to determine if the phenomena reported in this study have been observed previously. The case history portion of this study involved the identification of unique features observed in working with specific individuals in this study. These features were then related to the available literature to identify phenomena that future researchers should consider examining.
CHAPTER V
HUMAN SUBJECTS PROTECTION

Significant efforts were made to protect the participants involved in this study from all anticipated risks. Participation in the study was entirely voluntary and declining to participate did not negatively impact the services rendered at each agency in any way. Only a small amount of financial compensation (ten dollars per session) was provided, in order to avoid coercing participation. A two-tiered consent process was used to ensure that participants fully understood the nature of their participation. The first set of consent documents provided an overview of the study, a general description of what was involved in participation in each of the four conditions, the risks and benefits of participation, information about confidentiality, and a list of numbers that participants could call with questions or concerns about the study (Appendix D). The second set of consent documents provided a more detailed description of the condition to which participants were assigned (e.g. face-to-face cognitive-behavioral therapy, interactive multimedia assisted cognitive-behavioral therapy) and again provided a list of numbers that participants could call with questions or concerns about the study (Appendix D). Written consent was obtained at both tiers of the consent process. Risks of participation were minimized through having appropriately trained professionals administer all treatment conditions according to a detailed protocol. The risk of suicide was also carefully monitored on a week-to-week basis through the administration of Beck Depression Inventory – II measures. Individuals scoring a two or three on item nine of the Beck Depression Inventory – II were immediately seen by a psychiatrist to assess for
suicide risk and make appropriate decisions based on this assessment. Significant efforts were also made to protect the identities and confidentiality of participants. Participants were assigned a code number upon entry into the study. While participant names were used on the forms filled out by participants for the study, the information gained from these forms was then transferred to a universal data collection form, which used only the participant’s code number and contained no identifying information. All forms with identifying information were retained in locked file cabinets at each agency and will be destroyed after the data has been transferred and analyzed. Information from the universal data collection form was entered into a computerized data file that is password protected and maintained on a computer in the researcher’s laboratory at Western Michigan University. This data file will be maintained indefinitely. Finally, this study was approved by the Human Subjects Institutional Review Boards at Western Michigan University (see Appendix E for the Human Subjects Institutional Review Board letter) and the State of Michigan.
CHAPTER VI
PROCESS ANALYSIS

Randomized controlled trials often yield a great deal of valuable information about between-group differences on standardized clinical measures, however these studies often fail to address the pragmatics of implementing the various interventions under investigation. The importance of examining the pragmatics of implementation is increased when the setting of the randomized controlled trial is not a laboratory or academic clinical research program, but rather a community mental health agency or primary care setting. These aspects of implementation also become increasingly important when the intervention being investigated is new or untested. This study was conducted in two community mental health agencies with two relatively new interventions and two more established interventions. These included an evidence-based medication algorithm guided intervention (MIMA) and interactive multimedia assisted cognitive-behavioral therapy (IMM-CBT). This latter intervention, one primary focus of the present study, has only been tested in a very small number of studies (Proudfoot, Swain, Widmer, Watkins, Goldberg, Marks, Mann, & Gray, 2003; Proudfoot, Ryden, Everitt, Shapiro, Goldberg, Mann, Tylee, Marks, & Gray, 2004; Van Den Berg, Shapiro, Bickerstaffe, & Cavanagh, 2004). One of these studies (Van Den Berg, et al, 2004) briefly addressed issues pertaining implementation, although it is clear that far more information is needed in this area. This study encountered a number of difficulties in implementing a randomized controlled trial of interventions for unipolar mood disorders in a community mental health setting, including obtaining accurate lists of potential
participants, making telephone contact with potential participants, creating interest in potential participation in the study, determining optimal inclusion criteria for the measures utilized in the study, encouraging regular session attendance, preventing treatment drop-out, minimizing extensive work involved in implementation, coping with high agency employee turnover rates, establishing agency staff availability, and maintaining agency interest in the project. While some of the difficulties encountered are unique to implementation in the context of research versus standard practice, other difficulties encountered could be generalized to implementation under both research and standard practice.

Identification and Recruitment of Participants

Data from what is perhaps the largest depression treatment outcome study conducted with low-income individuals (Miranda, et al, 2003) suggests that identification and recruitment of potential participants is perhaps the most difficult aspect of the research process when working with this population. Consistent with this previous research, identification and recruitment of potential participants has been arguably the most challenging stage of the research process in the present study. At the primary site for this study, a list of over one thousand potential participants was provided. However, after contacting a substantial number of individuals on the list, only twenty-two people attended an initial assessment appointment for the study. Of these twenty-two individuals, only twelve were eventually randomized into a treatment condition. At the secondary site for the study, two-hundred and eighty-seven individuals had been called
via telephone at the most recent count and nine additional individuals had been referred to the study through the agency’s intake procedure. Only thirty of these individuals made an initial assessment appointment for the study, and only ten were eventually randomized in to a treatment condition.

A number of variables may account for the problem encountered in the identification and recruitment stage of this research study. First, the system for identifying potential participants through computerized clinical records was inefficient at both sites. Individuals involved with the study on a day-to-day basis, such as agency employees or research assistants, could not search the computerized clinical records in such a way that could generate lists of consumers diagnosed with qualifying unipolar mood disorders. This task was delegated to employees working at each site who had the necessary skills and permission to access the computerized clinical records in a way that such a list could be generated. Unfortunately, these employees typically had no contact with the study prior to the requests to generate the aforementioned lists. Confusion about the inclusion and exclusion criteria to be used to generate such a list and more pressing agency demands slowed down the process of generating lists at both agencies substantially. It is recommended that researchers who intend on conducting studies using a similar method of recruitment discuss the process for identifying potential participants using clinical records during the first few planning meetings with agency employees and researchers. Researchers should strongly consider identifying the employees who will be responsible for generating these lists and include these employees in subsequent meetings so they will have familiarity with the research protocol, feel as though they have a role in the research, and ideally, develop a sense of obligation to the study. Given the limited
number of Information Technology personnel and pressing workloads, this element may still hamper the research investigation from being given top agency priority. However, the direct contact between researchers and the data interrogator might facilitate a quicker response, rather than if the request is translated through other agency administrative personnel.

Second, despite providing both sites with detailed inclusion and exclusion criteria, the lists that were ultimately generated included consumers who should not have been on the list. At the primary site, consumers who were children, mentally retarded, or who did not have any diagnosis of a unipolar mood disorder were included on the list provided to the research team. A review of each computerized clinical record of individuals included on the list became necessary to make further exclusions prior to making recruitment phone calls. At both sites, consumers who had not received services at the agency for a number of years were also included on the lists. At the secondary site, this difficulty was rectified through the generation of an updated list. At the primary site, the generation of an updated list did not occur. Future researchers should consider a number of possible methods for addressing this problem. It is possible that the lists generated included consumers who should not have been included because of an error on the part of the employees generating the lists. Ideally, involving these employees more extensively in the research project could rectify this problem, as they would be more familiar with the criteria that should be used to generate such lists. It is also possible that the difficulties with these lists simply reflect outdated record keeping systems likely to be encountered at community mental health agencies. Alternatively, research assistants can be utilized to sort through clinical records to identify those individuals who should be contacted and
those individuals who should not be contacted on the basis of exclusionary criteria or last date of contact with the community mental health agency. Training research assistants who have not worked with community mental health data systems would require time, supervision, and a level of access to information systems, which if approved, might assist in but may not fully resolve the seeming delay in acquiring a high fidelity list of potential participants.

Third, at the primary site in particular, there was concern about the accuracy of existing diagnoses of bipolar disorder that had been given to potential participants, leading to their exclusion from the list of individuals to contact. At this site, the psychiatrist involved with the study noted that in recent years he had given diagnoses of bipolar disorder to consumers far more frequently than he had given diagnoses of unipolar disorder. He expressed concern that the prevalence of bipolar disorder at the agency would prevent the study from obtaining its targeted number of participants. Epidemiological data suggests that lifetime incidence of Major Depressive Disorder is ten to twenty-five percent for women and five to twelve percent for men in the general population (American Psychiatric Association, 2000). In comparison, the lifetime prevalence of Bipolar I Disorder is estimated to be between 0.4 percent and 1.6 percent in the general population (American Psychiatric Association, 2000). However, unlike with Major Depressive Disorder, there is some evidence to indicate that bipolar disorder is more prevalent in low-income populations than the general population. Prevalence rates in studies conducted with low-income populations reported prevalence rates of 4.6% point prevalence (Olfson, Das, Gameroff, Pilowsky, Feder, Gross, Lantigua, Shea, & Weissman, 2005) and 9.8% lifetime prevalence (Das, Olfson, Gameroff, Pilowsky,
Blanco, Feder, Gross, Neria, Lantigua, Shea, & Weisman, 2005) for bipolar disorder. While these rates are higher than the rates reported in the general population for bipolar disorder, it is important to note that these rates are still substantially lower than the prevalence rates for Major Depressive Disorder. The inconsistency of the psychiatrist’s report with epidemiological data called in to question the accuracy and utility of the lists of potential participants provided to the researchers. Researchers in this study were faced with the conundrum of whether to contact individuals diagnosed with a bipolar disorder according to their computerized clinical records. On one hand, there was the risk that numerous individuals would self-exclude on the basis of their diagnosis or indeed meet criteria for a bipolar disorder and be excluded after their second assessment appointment. On the other hand, not contacting these individuals could potentially exclude a large number of individuals who would otherwise qualify for the study. The present study addressed this issue by using a tiered system of contacts, with individuals diagnosed with unipolar mood disorders being contacted first regarding participation, followed by those individuals diagnosed with bipolar mood disorders in the hopes of maximizing the number of individuals who were able to participate in the study. Alternatively, it is recommended that researchers encourage the use of empirically supported assessment measures at the agencies where they conduct their research, in that brief self-report measures can routinely be provided to consumers at the agencies to help identify individuals who may meet criteria for inclusion in to the study. Furthermore, in terms of benefit to the agency, these measures may help psychiatrists and other clinicians to base their diagnostic judgments less on impressions obtained through unstructured clinical interviews and more through empirically supported methods of assessment. On the other
hand, the use of any assessment instruments for diagnosis in community agencies is relatively rare, with diagnoses normally rendered quickly and impressionistically by psychiatrists. Frequent complaints among non-psychological mental health staff concerns the “paperwork” demands of the job, and little distinction is made between the paperwork required by diagnostic and treatment evaluation and other administrative purposes. Mental health staff who are psychologists often have had training that assumes formal assessments for diagnosis and treatment evaluation. But increasingly community agencies have come to rely on social work and other non-psychological disciplines for treating clients. Thus, training staff in empirically supported assessments may be met with resistance on the part of professionals who have not made contact with such measures during their training. One study in particular (Reay, et al, 2003) alluded to the difficulty in getting mental health practitioners to incorporate even infrequent assessments into their clinical practice for purposes of data collection for the study. Other studies seemed to anticipate the difficulty of incorporating assessment into practice and addressed this challenge in one of two ways. Reay and colleagues (2003) offered practitioners the choice of one of three depression measures, such that the practitioners could have an opportunity to select a measure with which they were most comfortable. Quijano and colleagues (2007) selected a limited number of questions (typically two to four) from a variety of assessment measures and had practitioners only administer these items, presumably to minimize the amount of time that practitioners would have to spend administering the full assessment measures. In future studies, if such measures were adopted for purposes of the research, ongoing training and
supervision would have to be built in to the implementation process, assuming that the challenge of initial resistance could be successfully overcome.

Fourth, the recruitment method of contacting potential participants based on a list of all consumers being served at the two sites who had diagnoses of unipolar mood disorders was not a particularly efficient or successful method to use for recruitment. Contact information for consumers was outdated in some circumstances however in the majority of circumstances, consumers did not answer their phones and did not respond to messages regarding the study. Two alternative methods of recruitment are recommended instead of the method primarily used in this study. First, case managers, psychiatrists, nurses, and other individuals at the relevant agencies should be notified and given information about the study and encouraged to pass information about the study on to consumers who may benefit from participation. At the primary research site, this “word of mouth” approach led to an unmeasured, but perceptible increase in consumers interested in the study. Second, community mental health agencies should be provided with brief measures of depression symptoms, such as the Beck Depression Inventory – II, to administer at intake appointments or at routine clinical appointments to help identify consumers who may benefit from participation in the study. To prevent agency staff from becoming annoyed with the addition of paperwork, the approach utilized by Quijano and colleagues (2007) could be taken, in which a very brief screener for depression is created or an existing brief screener for depression (e.g. Beck Depression Inventory – Short Form) is utilized instead of a more extensive and time-intensive screening measures. As mentioned previously, even if the consumers were not interested in participating in the study, these measures would give the treatment provider potentially
useful clinical information, assuming that the staff training in the measures and their interpretation was provided, either in advance or parallel to implementation.

Fifth, the loss of funding used to provide financial compensation to participants potentially hampered recruitment at the secondary site. Unlike the primary site, which only provided case management and medication services, the secondary site provided therapy services as well. Few consumers expressed interest in participating in the study at intake. Presumably, this is because consumers at this site would receive therapy services regardless of their participation in the study. In fact, choosing to participate in the study could actually lead to a temporarily denial of therapy services for those individuals assigned to conditions other than the two cognitive-behavioral therapy conditions. For a number of reasons, some of which may have included the absence of financial compensation and a lack of desire to participate in research solely for the benefit of scientific knowledge, many individuals at this site refused participation. However, this view is not consistent with the perspective of the Clinical Director and Senior Psychologist at the agency, both of whom didn’t feel as though the financial incentives mattered one way or another as a motivator for participation. At the primary site, lack of interest in participation because of the risk of not receiving therapy services was not an identified difficulty, as the only clinical services routinely offered at this site could be categorized as treatment-as-usual. As such, individuals at this site were often interested in participating because of the possibility of receiving some type of therapy services.

Finally, this study has raised questions about whether the assessment tools used, namely the combination of the Beck Depression Inventory – II, the Revised Hamilton Rating Scale for Depression, and the Structured Clinical Interview for DSM-IV
Diagnoses are accurate at assessing the presence of diagnoses necessary for inclusion. Many inconsistencies were observed between these measures across participants in the study, as will be discussed later in more detail.

Session Attendance and Retention of Participants

Although less of a challenge than identification and recruitment of potential participants, retention of participants was also a difficulty encountered in the implementation of this project. At the primary site, consistent session attendance and retention after assignment to a treatment condition was the primary difficulty encountered, whereas at the secondary site, attendance rates for the initial assessment session posed the greatest challenge. Previous literature examining intake and therapy session attendance at two rural community mental health clinics reported no-show rates of 22% to 43% for intake appointments and 21% to 26% for therapy sessions (Shoffner, Staudt, Marcus, & Kapp, 2007), suggesting that attendance rates at community mental health agencies are an issue that continues to need to be addressed. At the primary site in this study, no show rates for appointments for the study were approximately 25% and at the secondary site in this study, no show rates for appointments for the study were approximately 26%. These numbers are very consistent with those found in previous studies. At the primary site, two issues seem to account for the attendance and retention rates after assignment to treatment condition. First, participants at the primary site had a number of substantial life stressors that accounted for drop-outs and repeated no-shows. These included, but are not limited to, homelessness, frequent changes in residence,
serious interpersonal conflicts, chronic physical illness, and difficulties scheduling appointments around work obligations. These are characteristics that are realistic for and likely to be encountered when working with consumers at a community mental health agency that can be addressed through other services provided at the agency, such as employment services, housing services, and case management services. Doing so requires substantial effort on the part of the agency however, in terms of identifying consumers in need of such services and connecting consumers to these services once they have been identified. Second, transportation problems were also a prevalent issue at the primary site. Many of the participants in the study did not have their own form of transportation. To address this issue, the agency provided transportation in a number of ways, including providing bus tokens, cab rides, and rides provided by the agency staff. Reminder phone calls were also made to help keep participants connected to the study and to allow the nurse to problem-solve attendance and transportation issues with participants. These issues were discussed as a part of initial project planning and were readily identified by agency administrators as likely to assist in an effort at acquiring and retaining participants. In fact, most of the assistive measures were already in existence at the agency due to known problems associated with services to this population and were not constructed primarily for purposes of the research project.

At the secondary agency, session attendance for the initial assessment session was the primary difficulty. At the most recent count, seven of the thirty individuals who scheduled for initial assessment appointments had their files closed because of repeated no-shows. Despite repeated reminder phone calls, this difficulty persisted at this agency. Only one of the aforementioned depression treatment outcome studies alluded to the
degree of contact necessary to encourage participants to attend an initial assessment appointment. Miranda and colleagues (2003) reported that participants in their study were contacted a mean of 4.1 times before they completed a telephone diagnostic interview and an additional 7.8 times before they completed an in-person clinical interview. This finding suggests that researchers must be fairly persistent about contacting participants to encourage participation. It is possible that in the present study, the researchers were not persistent enough about continuing to contact clients to encourage participation, even after repeated no-shows. Future researchers may also want to consider involving case managers or other individuals with whom potential participants have contact with at the agency and utilize these individuals in problem-solving how to get potential participants to their initial assessment appointments. However, what would be involved in carrying out this suggestion might be viewed as additional work for the case manager. As such, the researcher would need to take into account the potential burden on the agency and staff in terms of costs and employee time.

Project Implementation

Although recruiting and retaining participants has been challenging in the present study, very few difficulties have been encountered in the implementation of the two cognitive-behavioral therapy conditions. The face-to-face cognitive-behavior therapy condition was implemented with relative ease. However, there are two aspects of implementation that should be considered by future researchers. First, therapists administering this condition commented that there was too much paperwork associated
with this condition and commented as though they felt the large amount of paperwork made the flow of therapy less fluid than desirable. Future researchers should minimize the amount of paperwork involved in the administration of treatment or develop systems to make sure that the involvement of paperwork is less cumbersome for therapists.

Researchers could potentially consider eliminating the brief anxiety and depression measure, the levels of distress measure, and the internal/external attribution measure, as the information obtained from these measures was either captured by other measures used in treatment (e.g. the Beck Depression Inventory – II) or did not provide information that was useful in terms of understanding the outcome of treatment or guiding the course of therapy. Other psychoeducational paperwork items, such as the breathing cycle worksheet, could potentially be conveyed verbally to participants to minimize the amount of paperwork as well. Second, because each face-to-face therapy session covered a great deal of information, therapists had to be very careful about the management of session time. Future researchers should ensure that therapists have practice administering the treatment prior to seeing participants to guarantee that therapists have a sense of how session time should be managed.

The interactive multimedia assisted cognitive-behavioral therapy condition was also implemented with relative ease. The nurse administering the program at the primary site had no difficulties in implementation and was able to engage in other nursing tasks for the agency while simultaneously running a participant through the treatment, which is consistent with the information obtained in prior studies (e.g. Van Den Berg, et al, 2004). Measures of the time the nurse spent with participants who were in this condition during each session suggests that nurse help is needed only at the beginning and end of the
session, as would be expected with any other routine appointment at the agency. The only observation of note with implementation of this treatment condition was the wide variation in the amount of time participants required to complete treatment sessions. While some participants required approximately one hour to complete a session, other participants required nearly two hours to complete a session. This was consistent with observations of the face-to-face cognitive-behavioral therapy condition as well. Future researchers should be sure to take this issue in to account in order to prevent double-booking participants if a high rate of patient flow is anticipated or occurs.

Systemic Issues

Finally, a number of difficulties were encountered at an agency level that future researchers should be aware of and consider when attempting to conduct similar studies in community mental health settings. First, staff turnover in terms of involvement with this project was relatively high at the primary agency, which were no doubt influenced by employee turnover and restructuring processes that occurred at the agency more generally. Almost none of the individuals who were involved in the study at its inception were involved in the later portions of the study. The high turnover rates observed at the agency are consistent with previous research that suggests that the entire public mental health workforce experiences a turnover every five to seven years (Blankertz & Robinson, 1997). Inconsistency in staff members involved in the study poses two primary difficulties. First, a substantial amount of time is spent bringing new individuals involved in the study “up to speed”, which means that meetings may feel redundant to
those individuals who have been consistently involved in the study. Second, this
prevents a loyalty to the study from being established through long-term participation.
Efforts were made to establish positive working relationships with all individuals
involved in the study, but decisions at an agency level led to many of these individuals no
longer being involved in the study over time. Future researchers should work with
agency administration to identify and involve employees who are likely to be remaining
at the agency over long periods of time and who are also likely to be committed to
involvement in the project. However, researchers should also have plans in place to
retrain new agency staff as necessary, as it is unlikely that there will be no agency
turnover even among carefully selected staff. Future researchers might also consider
simply bringing staff resources to the agency, rather than utilizing the staff available at
the agency.

Second, it is important to establish continued interest on the part of the agency
staff to be involved in the project. Over the course of this study, the interest in the study
on the part of agency staff waned, and its status as a priority decreased. Part of the reason
for the loss of interest likely came from large protocol changes that were made midway
through the study at the primary site, which stagnated recruitment and progress over the
span of a few months. The primary protocol change that interfered with continuous
recruitment was a Human Subjects Institutional Review Board change that was requested
to include all agencies within the community mental health system in recruitment, rather
than merely the specific site where recruitment was initially taking place. Future
researchers should spend a great deal of time considering all possible obstacles and
identifying ways to address such obstacles in an efficient and timely manner, should they
occur. The frequency of meeting times with agency staff also decreased over the course of the project, which may have also led to a decrease in agency interest in the project. Future researchers should ensure that weekly or bi-weekly meetings are maintained over the course of the study, even if it appears that regular meetings may not be needed, unless it appears that additional meetings are hampering agency interest in the project (e.g. because of the time demands involved in regular meetings), in which case such meetings should be limited accordingly. Finally, future researchers should consider ways in which unnecessary additional work on the part of agency staff members can be minimized.

While some of the previous suggestions for future researchers would appear to increase the work of agency staff, these suggestions are hypothesized to also be crucial to the successful implementation of such a project. This recommendation seeks to avoid additional work that results from the failure of such a project to work within agency protocols or to bring in additional staff to aid with the project when possible. This project addressed this issue successfully in two ways. First, attempts were made to fit the study in to the standard practices of the agency as much as possible. This includes using language familiar to the agency, using agency scheduling practices as much as possible, and so forth. Second, outside individuals were brought in to administer treatments as much as possible. Doctoral student therapists were used to administer the face-to-face cognitive-behavioral therapy condition and student nurses from a local community college were used as much as possible to administer the interactive multimedia assisted cognitive-behavioral therapy condition. As much as it is important to consider the agency’s involvement in the research study, it is also important to consider the researcher’s involvement with the agency. Researchers should introduce themselves to
agency staff members, attend meetings to promote and discuss the project with agency staff members, and find other ways to become integrated within the agency.

Finally, establishing agency staff time availability is crucial to successfully running a study of this nature. This was done fairly successfully in this study through a few different methods. First, as mentioned previously, individuals outside of the agency should be utilized as much as possible to fill treatment and coordination roles. For those roles that cannot be filled, a few individuals within the agency should be identified who will have consistent, clearly defined roles in the project. Finally, this study identified a "research day" at each agency to ensure that appointments would only be scheduled for individuals involved on the project on that day. This minimized the risk of double-booking agency staff and also allowed agency staff to clear off blocks of time for their involvement in the research project.

A number of observations have been made that suggest aspects of conducting research in community mental health settings with low-income populations that researchers should be aware of, including identifying potential participants, recruiting participants, retaining participants, minimizing research team turnover, maintaining agency interest, and minimizing the excessive use of agency resources, while at the same time maximizing the likelihood of success of the research project. Careful attention to these factors and other factors that may arise is likely to increase the success of a research project, even under the most challenging of circumstances.
CHAPTER VII
CASE HISTORIES

Eight case histories of participants involved in the two cognitive-behavioral therapy conditions in this study demonstrate some of the unique features and challenges of conducting a randomized controlled trial in a community mental health setting with participants with demographic characteristics that are not common in large randomized controlled trials.

Face-to-Face Cognitive Behavior Therapy Participant #1

Participant number one in the face-to-face cognitive-behavioral therapy condition was a thirty-three year-old, divorced, unemployed, Caucasian female, who had obtained her GED. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received a diagnosis of 296.32 Major Depressive Disorder, Recurrent, of Moderate Severity. This diagnosis was inconsistent with her Revised Hamilton Rating Scale for Depression score, which suggested that her depression was of minor severity, and her Beck Depression Inventory – II score, which suggested that her depression was severe. Her self-reported anxiety and depression ratings are consistent with the assessment that her level of depression was severe. Despite very high ratings of satisfaction with treatment, averaging 7.6 out of 8 across measures of a variety of features of treatment, and increasing Beck Depression Inventory – II scores, participant number one dropped out of treatment after two sessions. Based on the report of her therapist, it is
likely that the reason she dropped out of treatment was related to the loss of her place of residence.

Face-to-Face Cognitive-Behavioral Therapy Participant #2

Participant number two in the face-to-face cognitive-behavioral therapy condition was a sixty year-old, widowed, Caucasian female on disability, with a seventh grade educational level. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received a diagnosis of 296.33 Major Depressive Disorder, Recurrent, Severe, Without Psychotic Features, which was consistent with her Revised Hamilton Rating Scale for Depression score, but inconsistent with her Beck Depression Inventory – II score, which suggested her depression was only of moderate severity. Her self-reported anxiety and depression ratings at the beginning of treatment also suggested relatively severe levels of symptoms. Interestingly, almost all of the improvement in participant number two’s depression symptoms, as measured by the Beck Depression Inventory – II, occurred between her initial assessment appointment and the beginning of session number one of treatment. In contrast, participant number two’s self-reported anxiety and depression ratings indicated some improvement over the course of treatment. Participant number two did not complete session number eight of treatment because she reported that she was no longer experiencing symptoms and did not wish to continue treatment. At post-treatment, participant number two’s Structured Clinical Interview for DSM-IV Diagnoses interview indicated that the Major Depressive Disorder episode she was experiencing at pretreatment was in remission, which was consistent with her score
on the Beck Depression Inventory – II. Her score on the Revised Hamilton Rating Scale for Depression indicated that she was still experiencing minor symptoms of depression. Participant number two’s follow-up appointments at one-month and three-months post-treatment indicated a maintenance of improvements in her symptoms of depression. Interestingly, at her three-month follow-up assessment, she met criteria for a lifetime diagnosis of 309.81 Posttraumatic Stress Disorder, a diagnosis that had not been previously given at other assessment points over the course of the study. At her six-month follow-up appointment, substantial inconsistencies emerged between the measures of her symptoms of depression. Her Structured Clinical Interview for DSM-IV Diagnoses interview indicated she was not currently experiencing a Major Depressive Disorder episode and her Beck Depression Inventory – II score was the lowest it had been over the course of her participation in the study, however her Revised Hamilton Rating Scale for Depression score was the highest it had been over the course of her participation in the study, suggesting she was experiencing major depressive symptoms. She also met criteria for current 300.01 Panic Disorder With Agoraphobia on the basis of her Structured Clinical Interview for DSM-IV Diagnoses. Participant number two’s ratings of treatment satisfaction across treatment sessions averaged 6.81 out of eight, with her highest rating being the relevance of homework assigned to her problems and the lowest rating being the ease of following the information presented during therapy sessions. Participant number two’s consumer satisfaction survey scores averaged four out of five.
Participant number three in the face-to-face cognitive-behavioral therapy condition was a thirty-four year-old, divorced, Caucasian female on disability, with some college education. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received diagnoses of 296.2 Major Depressive Disorder, Single Episode, Lifetime, and 300.21 Panic Disorder With Agoraphobia, Lifetime. These diagnoses were consistent with her Revised Hamilton Rating Scale for Depression, which indicated she was not currently depressed, but inconsistent with her Beck Depression Inventory – II score, which suggested she was experiencing moderate to severe levels of depressive symptoms. Her self-reported anxiety and depression ratings taken early in treatment also suggested she was experiencing relatively severe levels of symptoms.

Participant number three’s therapy took place over the course of six months, due to repeated no-shows. Interestingly, her Beck Depression Inventory – II score from her first session of therapy was the lowest score she obtained over the course of treatment. After her first session, her Beck Depression Inventory – II scores increased and then began to decline toward the middle of therapy. Her anxiety self-reported anxiety and depression scores were inconsistent with this trend. Her self-reported anxiety scores remained extremely high throughout the course of treatment, with the exception of a large decrease for session seven only. Her self-reported depression scores had a great deal of variability, increasing at the beginning of treatment, decreasing substantially for two sessions toward the end of treatment, and then increasing again at the end of treatment. Participant number three was unable to complete a post-treatment follow-up assessment because of
the holiday season, however she did complete a one-month follow-up appointment. At one-month follow-up, participant number three’s Beck Depression Inventory – II was higher than it had been at pre-treatment. Similarly, her Revised Hamilton Rating Scale for Depression score also increased. She also received diagnoses of 296.7 Bipolar I Disorder, Most Recent Episode Unspecified, Current and 300.01 Panic Disorder Without Agoraphobia, Current. These data suggest that her symptoms worsened since the end of treatment. Participant number three failed to attend her three-month follow-up assessment appointment. Participant number three’s rating of treatment satisfaction across treatment sessions averaged 7.99 out of eight, with every category of treatment satisfaction being an eight out of eight, with the exception of feeling as though therapy was tailored to her as an individual. Participant number three’s consumer satisfaction ratings averaged a 4.26 out of five.

Face-to-Face Cognitive-Behavioral Therapy Participant #4

Participant number four in the face-to-face cognitive-behavioral therapy condition was a thirty-three year-old, divorced, unemployed, Caucasian female on disability, with some college education. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received diagnoses of 296.31 Major Depressive Disorder, Recurrent, Mild, Current and Lifetime, and 300.01 Panic Disorder Without Agoraphobia, Lifetime. The diagnosis of the severity of her Major Depressive Disorder was consistent with her Revised Hamilton Rating Scale for Depression score, which also indicated mild depression. However, her Beck Depression Inventory – II score at this
assessment indicated she was experiencing severe levels of depression symptoms. Her self-reported anxiety and depression ratings at the beginning of treatment suggested a somewhat higher level of symptoms in comparison to the data obtained from her Structured Clinical Interview for DSM-IV Diagnoses and her Revised Hamilton Rating Scale for Depression scores, although fairly substantial variability in these scores was also observed. Participant number four had a sudden improvement in her depression symptoms according to her Beck Depression Inventory – II scores between session four and five, although this sudden gain was not observed with her self-reported depression rating. She also experienced a sudden gain in her symptoms of anxiety between session five and session six according to her self-reported anxiety rating. Participant number four repeatedly missed her post-treatment assessment appointment, but data obtained at her one-month follow-up assessment indicated some maintenance of improvement of her depression symptoms. Her Beck Depression Inventory – II score was the lowest it had been over the course of the study and below the cutoff for remission. Similarly, her Revised Hamilton Rating Scale for Depression score indicated that she was no longer depressed. However, she continued to meet criteria for 296.31 Major Depressive Disorder, Recurrent, Mild, Current and Lifetime. At her three-month follow-up, participant number four continued to meet criteria for 296.3x Major Depressive Disorder, Recurrent, Current. She also experienced a slight increase in her Beck Depression Inventory – II score, although it continued to remain below the cutoff for remission and a slight increase in her Revised Hamilton Rating Scale for Depression, which indicated she was experiencing a mild level of symptoms of depression. Participant number four’s ratings of treatment satisfaction across treatment sessions averaged 6.65 out of eight, with
her highest rating being that therapy was clear in its rationale and goals and the lowest rating being that therapy was responsive to her needs and that therapy was paced appropriately. Participant number four’s consumer satisfaction survey scores averaged 4.43 out of five.

Interactive Multimedia Assisted Cognitive-Behavioral Therapy Participant #1

Participant number one in the interactive multimedia assisted cognitive-behavioral therapy condition was a thirty-nine year-old, single, Caucasian female on disability, with a ninth grade educational level. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received diagnoses of 296.2 Major Depressive Disorder, Single Episode, Lifetime, 293.83 Mood Disorder Due to a General Medical Condition, Current and Lifetime, and 309.81 Posttraumatic Stress Disorder, Current and Lifetime. This was consistent with her Beck Depression Inventory – II score, which suggested a severe level of depression symptoms, but inconsistent with her Revised Hamilton Rating Scale for Depression score, which suggested she did not meet criteria for a diagnosis of depression. Her self-reported anxiety and depression scores indicated moderate to severe levels of anxiety and depression symptoms. Participant number one’s Beck Depression Inventory – II symptoms were inconsistent over the course of treatment, although she had a sharp decrease in scores between session number six and session number eight. A similar phenomenon was observed with her self-reported anxiety and depression scores, which both peaked at session six as her Beck Depression Inventory – II score had, and then dropped by session seven and remained low through session eight.
At post-treatment, participant number one’s measures of depression were extremely inconsistent. Her Structured Clinical Interview for DSM-IV Diagnoses interview indicated that she met criteria for 296.3x Major Depressive Disorder, Recurrent, Current and Lifetime and 300.4 Dysthymic Disorder, Current. Similarly, her Revised Hamilton Rating Scale for Depression score indicated symptoms of major depression. However, her Beck Depression Inventory – II score was almost the lowest it had been over the course of her participation in the study, although still suggesting a moderate level of depression symptoms. At her one-month follow-up, she met criteria for 296.35 Major Depressive Disorder, Recurrent, In Partial Remission, Lifetime, 300.4 Dysthymic Disorder, Current, 305.00 Alcohol Abuse, Lifetime, and 309.81 Posttraumatic Stress Disorder, Lifetime, suggesting some improvement in her symptoms of depression and possibly anxiety since her pretreatment assessment and her post-treatment follow-up. Her Revised Hamilton Rating Scale for Depression score also dropped substantially to below the cutoff for meeting criteria for any level of depression symptoms. However, her Beck Depression Inventory – II score remained steady, suggesting a continuing level of moderate depression symptoms. At her three-month follow-up, she met criteria for 296.3x Major Depressive Disorder, Recurrent, Current and Lifetime, and 309.81 Posttraumatic Stress Disorder, Lifetime, suggesting an increase in the severity of her symptoms of depression. Similarly, her Revised Hamilton Rating Scale for Depression score indicated that she was experiencing a minor level of depression symptoms and her Beck Depression Inventory – II score continued to remain steady. At six-month follow-up, she met criteria for 296.2x Major Depressive Disorder, Single Episode, Current and Lifetime, and 300.4 Dysthymic Disorder, Current, suggesting that she was continuing to
experience a return of her symptoms of depression. Her Revised Hamilton Rating Scale for Depression score also increased slightly, as did her Beck Depression Inventory – II score. Participant number one’s rating of treatment satisfaction across treatment sessions averaged 6.77 out of eight, with her highest rating being feeling as though she had adequate choice and input in to her therapy and the lowest rating being an extremely low rating (1.88 out of eight) for the ease of following the information presented during therapy sessions. Participant number one’s consumer satisfaction survey scores averaged 3.78 out of five.

Interactive Multimedia Assisted Cognitive-Behavioral Therapy Participant #2

Participant number two in the interactive multimedia assisted cognitive-behavioral therapy condition was a forty-two year-old, divorced, African-American female, who was unemployed and had graduated from a two-year college or technical school. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received diagnoses of 296.33 Major Depressive Disorder, Recurrent, Severe, Without Psychotic Features, Lifetime, 300.4 Dysthymic Disorder, Current, and 300.21 Panic Disorder Without Agoraphobia, Current and Lifetime. Her Beck Depression Inventory – II score and her Revised Hamilton Rating Scale for Depression score both suggested that she was severely depressed, suggesting a higher level of symptoms than was likely captured in her pretreatment interview. Similarly, her self-reported anxiety and depression scores indicated severe levels of anxiety and depression symptoms. Participant number two’s Beck Depression Inventory – II scores dropped
substantially between session one and session two, but then increased by session three and dropped only slightly over the course of treatment. Her self-reported anxiety and depression scores remained high throughout treatment. At post-treatment, participant number two’s measures were somewhat inconsistent. Her Structured Clinical Interview for DSM-IV Diagnoses interview indicated that she met criteria for 300.4 Dysthymic Disorder, Current, 311 Depressive Disorder Not Otherwise Specified, Current and Lifetime, and Panic Disorder With Agoraphobia, Current and Lifetime, suggesting her symptoms of depression had not improved since pretreatment. However, her Revised Hamilton Rating Scale for Depression score suggested she was only experiencing a minor level of depression symptoms and her Beck Depression Inventory – II score had dropped substantially since pretreatment in to the moderate level of depression symptoms range, although this drop could not necessarily be attributed to treatment itself given the trajectory of her early Beck Depression Inventory – II scores. At her one-month follow-up, she met criteria for 296.33 Major Depressive Disorder, Recurrent, Severe, Without Psychotic Features, Lifetime, 300.4 Dysthymic Disorder, Current, and 300.21 Panic Disorder With Agoraphobia, Current and Lifetime, suggesting some improvement in symptoms of depression. Her Beck Depression Inventory – II score also continued to decline in to the mild level of symptoms range, although her Revised Hamilton Rating Scale for Depression score increased to major depression levels. At her three-month follow-up, she met criteria for 296.3 Major Depressive Disorder, Recurrent, Current and Lifetime, suggesting some worsening in depression symptoms. However, her Beck Depression Inventory – II score remained the same since the last assessment and her Revised Hamilton Rating Scale for Depression score decreased such that she was in the
minor depression range. At her six-month follow-up, participant number two met criteria for 296.4 Bipolar I Disorder, Most Recent Episode Manic, Lifetime, and 296.55 Bipolar I Disorder, Most Recent Episode Depressed, In Partial Remission, Current, which was inconsistent with the data that had been obtained during prior assessments. Her Revised Hamilton Rating Score declined from her three-month follow-up, however it remained in the minor depression range. Inconsistent with this data, her Beck Depression Inventory – II score increased from the mild to the moderate range. Participant number two’s rating of treatment satisfaction across treatment sessions averaged 4.47 out of eight, with her highest rating being feeling as though therapy was tailored to her as an individual and her lowest rating being the ease of following the information presented during therapy sessions. Participant number two’s consumer satisfaction survey scores averaged 3.57 out of five.

Interactive Multimedia Assisted Cognitive-Behavioral Therapy Participant #3

Participant number three in the interactive multimedia assisted cognitive-behavioral therapy condition was a forty-four year-old, divorced, employed Caucasian female, with a degree from a four-year college. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received diagnoses of 296.2x Major Depressive Disorder, Single Episode, Lifetime, and 300.4 Dysthymic Disorder, Current. This was consistent with her Beck Depression Inventory – II score, which suggested she was experiencing a mild level of symptoms of depression, and inconsistent with her Revised Hamilton Rating Scale for Depression score, which
suggested she was not depressed. Her self-reported anxiety and depression ratings were consistent with experiencing a mild level of symptoms of depression and anxiety early in treatment. Participant number three’s Beck Depression Inventory – II scores dropped in to a range of only minimal symptoms by her first treatment session and continued to drop and remain low over the course of treatment. Her self-reported anxiety and depression ratings had some variability over the course of treatment, although both scores dropped slightly by the end of treatment. Of note, participant number three consistently missed therapy sessions and as such, therapy took place over the course of nearly four months. Participant number three repeatedly missed her post-treatment follow-up assessment appointment, although eventually she attended a follow-up assessment just short of three months post-treatment. At three-month follow-up, she no longer met criteria for any diagnoses according to the Structured Clinical Interview for DSM-IV Diagnoses. Consistent with this measure, her Beck Depression Inventory – II score was a two and her Revised Hamilton Rating Scale for Depression Score was a three. Participant number three declined to attend her six-month follow-up assessment appointment. Participant number three’s rating of treatment satisfaction across treatment sessions averaged 6.99 out of eight, with her highest rating being feeling as though the homework assigned was relevant to her problems and the lowest being the ease of following the information presented during therapy sessions. Participant number three’s consumer satisfaction ratings averaged a four out five.
Interactive Multimedia Assisted Cognitive-Behavioral Therapy Participant #4

Participant number four in the interactive multimedia assisted cognitive-behavioral therapy condition was a forty-seven year-old, engaged, Caucasian female on disability, with a degree from a four-year college. Based on her Structured Clinical Interview for DSM-IV Diagnoses interview at pretreatment, she received a diagnosis of 296.3 Major Depressive Disorder, Recurrent, Current and Lifetime. This diagnosis was consistent with Revised Hamilton Rating Scale for Depression score, which indicated major depression, her Beck Depression Inventory – II score, which suggested she was experiencing severe levels of depression symptoms. These scores were also consistent with her self-reported anxiety and depression ratings, which also suggested fairly severe levels of symptoms. Participant number four’s Beck Depression Inventory – II scores and self-reported anxiety and depression scores were somewhat variable over the course of treatment, although all three scores appeared to slightly increase over the course of treatment. Participant number four repeatedly missed her post-treatment follow-up assessment appointment, however she did attend her one-month follow-up assessment. At one-month follow-up, she met criteria for 296.31 Major Depressive Disorder, Recurrent, Mild, Current, 300.01 Panic Disorder, Without Agoraphobia, Current, and 309.81 Posttraumatic Stress Disorder, Current. These diagnoses suggest the maintenance of depression symptoms and a worsening of anxiety symptoms since treatment. This was consistent with her Beck Depression Inventory – II and Revised Hamilton Rating Scale for Depression score, both of which suggested no improvement in depression symptoms since pre-treatment. Participant number four repeatedly no-showed for her three-month
follow-up appointment and as such, did not complete her final assessment. Participant number four’s rating of treatment satisfaction across treatment sessions averaged 6.79 out of eight, with her highest rating being feeling as though she had adequate choice and input into her therapy and the lowest ratings being the relevance of and ease of following the information presented during therapy sessions. Participant number four’s consumer satisfaction ratings averaged 4.2 out of five.

Themes Across Case Histories

A number of interesting themes emerged across the case histories examined in this study. Many of these themes are consistent with phenomena that have been observed in previous studies, although some of these themes warrant a great deal of further investigation.

Employment Status. Of all the case histories of the participants that were reviewed, only one of these participants was employed, with the remainder of the participants on disability or unemployed. This observation is somewhat unusual in comparison to previous data obtained from studies conducted with community mental health consumers. Only eighteen percent of the participants in the Miranda and colleagues (2003) were unemployed or on disability. However, a study conducted by Kouzis and Eaton (2000) that utilized data from the Epidemiologic Catchment Area (ECA) survey suggested that individuals with a diagnosis of major depressive disorder were at a forty percent greater relative risk of beginning new disability payments over the course of a one-year time frame. This suggests that a relationship exists between
diagnoses of major depressive disorder and the likelihood of receiving disability payments, which may indicate that it is not entirely unusual that such a high percentage of individuals involved in this study were receiving disability payments.

*Educational Level and Ease of Comprehending Information Presented.* Although a great deal of variability was observed in the education level of participants discussed in the case histories, the majority of participants had not completed college. This observation is not uncommon for this population. In the aforementioned study conducted by Merrill and colleagues, 37.1% of their sample had less than a high school education, 32.6% had a high school degree or GED, 23.6% had some trade school or college experience, and only 6.7% had graduated from college. Given the educational level typically attained by community mental health consumers, it is not particularly surprising that the aspect of therapy that participants were least satisfied with was the ease with which they could follow and comprehend the information presented. One participant in the interactive multimedia assisted cognitive-behavioral therapy condition reported that she felt she would need to go through the entire program again to reap all of the potential benefits, as she was being given far too much information to learn and comprehend each week. It is possible that the language and some of the concepts covered in this particular protocol of cognitive-behavioral therapy may not be appropriate for community mental health populations, given their educational level. Additional research is necessary to determine if modifications to therapy protocols should be made when working with community mental health populations in order to ensure that individuals undergoing treatment are able to comprehend and retain the information they are being presented.
Inconsistencies Between Measures of Symptoms of Depression. An examination of these case histories as a whole reveals that the three measures of depression utilized in this study demonstrated inconsistencies in conclusions about the presence and level of depression symptoms across participants. This finding was somewhat surprising given the relatively high correlation between the Beck Depression Inventory – II and the Revised Hamilton Rating Scale for Depression observed in previous studies and given the high interrater reliability scores for major depressive disorder and dysthymic disorder observed in previous studies. It was expected that these measures would be confirmatory of diagnoses of unipolar mood disorders, but instead these measures were often contradictory. Previous studies have discussed the difference in severity of depression symptoms when assessed with self-report measures and clinical ratings and have suggested that it is important to use both kinds of measures when evaluating symptoms of depression (Steer, Beck, Riskind, & Brown, 1987). In the present study, using both measures indeed produced different assessments of the level of severity of depressive symptoms for participants.

Sudden Gains. Through the visual inspection of the Beck Depression Inventory – II score graphs (Appendix F) for each of these case histories, sudden and generally lasting gains in terms of symptoms of depression are observed for Face-to-Face Cognitive-Behavioral Therapy participants number two and number four and Interactive Multimedia Assisted Cognitive-Behavioral Therapy participants number one, two, and three. For Face-to-Face Cognitive-Behavioral Therapy participant number two and Interactive Multimedia Assisted Cognitive-Behavioral Therapy participant number two and number three, these gains occurred primarily during the assessment phase through
the first session of treatment. For Face-to-Face Cognitive-Behavioral Therapy participant number four and Interactive Multimedia Assisted Cognitive-Behavioral Therapy participant number one, these gains occurred approximately midway through treatment.

Sudden gains in therapy are phenomena that have been receiving increased attention in the literature in recent years. Early work by Ilardi and Craighead (1994) suggested that sixty to seventy percent of the improvement in symptoms made during a course of cognitive-behavioral therapy for depression occurs within the first four weeks of therapy, evidence which was used to question the cognitive mediation hypothesis about the mechanism of action in cognitive-behavioral therapy. Tang and DeRubeis (1999) investigated the issue of sudden gains further in a population of adults receiving cognitive-behavioral therapy for depression. Twenty-four of the sixty-one patients involved in their study experienced sudden gains and these individuals were found to be less depressed at posttreatment and follow-up. This finding suggests that the sudden gains experienced during their courses of therapy had lasting positive effects, a result that was replicated in later work (e.g. Tang, DeRubeis, Hollon, Amsterdam, & Shelton, 2007).

Interestingly, the data presented in this study also provided some support for the cognitive mediation hypothesis of cognitive-behavioral therapy, although the authors admitted that many possible confounding variables were not investigated in this study.

Unfortunately, even less work has been conducted investigating pretreatment gains than is available on sudden gains recorded during the course of treatment. Gaynor and colleagues (2003) conducted a study with depressed adolescents in which pretreatment gains were observed for 28% of participants and within-treatment gains were observed for 39% of participants. Similar to what has been previously reported for sudden gains,
pretreatment gains were also associated with superior outcomes on a variety of depression measures. The phenomena observed with the individuals presented in these case histories coupled with the available literature on sudden gains and pretreatment gains suggests this area warrants further consideration and study in order to learn more about potential factors influencing such gains and the mechanisms of action involved in psychotherapy.

*Treatment Session Attendance and Drop-Out.* Although only one of the eight participants presented in these case histories dropped out of treatment, two of the participants received therapy over double the amount of time therapy was intended to take and two of the participants repeatedly missed follow-up appointment sessions. As discussed previously, difficulties with session attendance and drop-out are not uncommon in community mental health populations. However, it is possible that inconsistent session attendance interferes with the maximization of treatment effectiveness. The therapist who provided the face-to-face cognitive-behavioral therapy to Face-to-Face Cognitive-Behavioral Therapy Participant number three noted that she often had to spend sessions “catching up” and reviewing topics that had previously been covered because of the large gaps of time in between therapy sessions. The data obtained from this participant suggests that poor session attendance may have interfered with treatment effectiveness. Future research investigating ways in which session attendance can be improved in community mental health populations is warranted.
CHAPTER VIII
DISCUSSION

Comparison with Previous Research

The phenomena noted in this study, both at the level of conducting the study and at the level of individual case histories, were not unusual when compared to the limited existing literature on working with low-income individuals in community mental health settings. Challenges had been noted previously at the levels of identifying and recruiting participants, encouraging session attendance, retaining participants, and working in collaboration with community mental health agencies. Similarly, mention had been made in previous literature about the employment status and education level of individuals in community mental health settings, inconsistencies between measure of depression, sudden gains and pretreatment gains, and challenges with session attendance and dropout. Unlike previous studies, however, the present study gave substantially more attention to these issues from a process perspective.

Limitations

This study has two primary limitations. First, in regard to the process analysis portion of the study, the observations and recommendations made are based upon the experiences of one research team conducting a treatment outcome study with low-income individuals in a community mental health setting. While the observations made about
phenomena that may interfere with the research process may give future researchers some guidance in the design and implementation of their studies, these observations may have been unique to the experience of this research team. The limited number of treatment outcome studies conducted with a similar population in a similar setting poses a challenge in ascertaining if the observations made in this study are unique to this study alone. In addition, the recommendations made to address the phenomena that may interfere with the research process have not been empirically tested. It is possible, for example, that the reminder calls provided by the nurse to participants in the study did not in fact increase session attendance. This can not be known, as all study participants received reminder phone calls as requested. Second, similar to the first limitation, the preliminary data presented about study participants cannot be generalized to a broader population. This data simply outlines interesting phenomena that were observed, but should not be used to make broader judgments about population characteristics, challenges with assessment, or treatment effectiveness.

Future Directions

The limitations of this study point to two primary future directions for researchers. First, more treatment outcome research needs to be conducted with low-income populations in community mental health settings. Low-income populations and community mental health settings have a number of unique features that may limit the generalizability of results obtained through treatment outcome studies conducted with other populations in laboratory settings. The necessity of additional research in this area
cannot be overemphasized. Second, more empirical work should be conducted that attends to process issues. While lots of research exists that addresses treatment efficacy, little empirical research exists about the process of conducting such research. For example, a future study could investigate the impact of appointment reminder phone calls on session attendance, through randomly assigning participants to receive or not receive phone calls. While reminder phone calls have face validity, in the sense that it appears they should increase session attendance, if research revealed that there was no difference in attendance, this would be an important finding. A great deal of effort can be spent on addressing process issues over the course of a treatment outcome study, yet little evidence exists about whether various strategies utilized to address process issues actually achieve their desired impact. In closing, it is essential that additional treatment outcome research is conducted with low-income populations in community mental health settings and that the processes involved in this research are empirically investigated to help make future research processes more efficient and applicable in treatment practices in the real world.
Appendix A

DSM-IV-TR Diagnostic Criteria for Major Depressive Episode
DSM-IV-TR DIAGNOSTIC CRITERIA FOR MAJOR DEPRESSIVE EPISODE

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

Note: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

1. depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful). Note: In children and adolescents, can be irritable mood.

2. markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)

3. significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day. Note: In children, consider failure to make expected weight gains.

4. insomnia or hypersomnia nearly every day

5. psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)

6. fatigue or loss of energy nearly every day

7. feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)

8. diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)

9. recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide

B. The symptoms do not meet criteria for a Mixed Episode.

C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized
by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.
Appendix B

DSM-IV-TR Diagnostic Criteria for Dysthymic Disorder
DSM-IV-TR DIAGNOSTIC CRITERIA FOR DYSTHYMIC DISORDER

A. Depressed mood for most of the day, for more days than not, as indicated either by subjective account or observation by others, for at least 2 years. **Note:** In children and adolescents, mood can be irritable and duration must be at least 1 year.

B. Presence, while depressed, of two (or more) of the following:

- (1) poor appetite or overeating
- (2) insomnia or hypersomnia
- (3) low energy or fatigue
- (4) low self-esteem
- (5) poor concentration or difficulty making decisions
- (6) feelings of hopelessness

C. During the 2-year period (1 year for children or adolescents) of the disturbance, the person has never been without the symptoms in Criteria A and B for more than 2 months at a time

D. No Major Depressive Episode has been present during the first 2 years of the disturbance (1 year for children and adolescents); i.e., the disturbance is not better accounted for by chronic Major Depressive Disorder, or Major Depressive Disorder, In Partial Remission.

**Note** There may have been a previous Major Depressive Episode provided there was a full remission (no significant signs or symptoms for 2 months) before development of the Dysthymic Disorder. In addition, after the initial 2 years (1 year in children or adolescents) of Dysthymic Disorder, there may be superimposed episodes of Major Depressive Disorder, in which case both diagnoses may be given when the criteria are met for a Major Depressive Episode.

E. There has never been a Manic Episode, a Mixed Episode, or a Hypomanic Episode, and criteria have never been met for Cyclothymic Disorder.

F. The disturbance does not occur exclusively during the course of a chronic Psychotic Disorder, such as Schizophrenia or Delusional Disorder.

G. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

H. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
Specify if:

**Early Onset:** if onset before age 21 years

**Late Onset:** if onset is age 21 years or older

Specify (for the most recent 2 years of Dysthymic Disorder):

**With Atypical Features**
Appendix C

Table of Studies
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<th>Authors</th>
<th>Mean Age (Years)</th>
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Appendix D

Informed Consent Documents
Initial consent form for patients NOT on medication at the beginning of the study:

"Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression"

Western Michigan University
Department of Psychology
Informed Consent to Participate in Research

Principal Investigator: C. Richard Spates, Ph.D.
Student Investigator: Alyssa Kalata & Nishani Samaraweera

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

You will be offered a two-stage informed consent process before finally agreeing to participate in this study. The first part of the informed consent process will occur at the first appointment, where you will be given a brief description of the project. The second part of the informed consent process will occur after you have been assessed and found qualified to enter the study. You will have the right to agree or not agree to participate at each stage of the informed consent process.

Participation

If you agree initially to participate in this study, you will be asked to attend a first interview, during which you will be asked to complete one ten-minute questionnaire and a five-minute personal information form. If you qualify for participation based on the information gathered, you will be asked to complete two psychological interviews that will take a total of about one hour to administer. Only those persons who qualify for a
diagnosis of depression or dysthymia will be eligible to participate. Furthermore, a
diagnosis of psychosis, bipolar disorder, or mental retardation will exclude you from the
study. You will also temporarily be excluded if you are found to be suicidal during the
initial assessments before treatment has begun. This exclusion will be until your any
suicidal issues have been addressed or resolved.

Procedures

If you qualify for participation in the study, you will be asked to come in for an additional
appointment approximately one-week after your first appointment. At that time you will
be asked to complete a ten-minute questionnaire and a one and one-half hour interview to
thoroughly evaluate your depression. It is after that assessment, if you agree to
participate, that you will be randomly assigned to one of the four treatments mentioned
above. Based upon your continued agreement to participate, you will be told at that time
which of the four treatments you will receive. The treatment will be described to you by
an experimenter after the assessment is completed. Treatment will begin within two
weeks after this appointment. Upon completion of treatment, you will be asked to come
in for three follow-up appointments, the last of which will occur three months after
treatment has been completed. However if you are still experiencing depressive
symptoms at the end of the primary treatment phase of the study (at the end of eight
treatment sessions), you will be given the opportunity to select a treatment from among
those being tested used in the study, as a means of addressing your continuing symptoms.
The treatment provided to you at that time will be at no costs to you if approved by the
Kalamazoo Community Mental Health and Substance Abuse Services Agency.

Risks

As in all research, there may be unforeseen risks to the participant. If an accidental injury
occurs, appropriate emergency measures will be taken; however, no compensation or
treatment will be made available to you except as otherwise specified in this consent
form. 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 clinic is prepared to offer treatment or make a
referral should emergency care become necessary. You will be responsible for the cost
of all emergency care not approved by the Kalamazoo Community Mental Health and
Substance Abuse Services agency, should such care become necessary.

Benefits

The primary potential benefit of participation in the study to you as a participant is the
alleviation of depressive symptoms. Recall that the four treatments are called, (1)
Treatment As Usual, (2) Michigan Medication Algorithm, (3) Interactive Multimedia
Cognitive-Behavioral Therapy, and (4) Face to Face Cognitive-Behavioral Therapy. In
the Treatment as Usual and the Michigan Medication Algorithm groups, this is likely to
occur through continued use of antidepressant medications. In the Cognitive-Behavioral Therapy (either face-to-face or computer assisted) groups, this is likely to occur through the provision of different techniques for addressing depression symptoms, obtained through participation in weekly sessions of Cognitive-Behavioral Therapy and tasks be done outside of therapy. Furthermore, knowledge gained from this study may lead to the development of more effective and accessible treatments for depression, which in turn may help other individuals experiencing depression.

Confidentiality

All of the information obtained from you is confidential. Original forms and progress notes with your name will be maintained in your current patient file at the Kalamazoo Community Mental Health and Substance Abuse Services building. Information in your treatment folder that is outside of this research project belongs to the clinic and may not be used as data for this study without your expressed permission. In the unlikely event that data of such nature is required, your permission will be sought before it is accessed. Forms used in this study may be placed in your treatment folder where they will be retained until they are destroyed along with the rest of the documents in your treatment folder according to the policies of the clinic. All documents outside of the clinic will contain a code number instead of your name and will be stored in a locked cabinet in the laboratory of the researcher. The researcher will maintain a list with your name matched to your corresponding research subject number in a different locked cabinet located within the laboratory. The master list will be maintained for the duration of the study, and then will be destroyed after all the data from the study is analyzed. A signed consent document and data containing no identifying information will also be retained for at least three years in a locked file in the principal investigator’s laboratory. You will be given a signed copy of this consent form for your records.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHSAS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.
Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature ___________________________ Date ____________

Consent obtained by: ___________________________ Signature of researcher ___________________________ Date ____________
Initial consent form for patients on medication at the beginning of the study:

“Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression”

Western Michigan University
Department of Psychology
Informed Consent to Participate in Research

Principal Investigator: C. Richard Spates, Ph.D.
Student Investigators: Alyssa Kalata & Nishani Samaraweera

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments are as follows: treatment as usual (the medication treatment you are currently receiving), a new medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University. You will be offered a two-stage informed consent process before finally agreeing to participate in this study. The first part of the informed consent process will occur at the first appointment, where you will be given a brief description of the project. The second part of the informed consent process will occur after you have been assessed and found qualified to enter the study. You will have the right to agree or not agree to participate at each stage of the informed consent process.

Participation

If you agree to participate in this study, you will be asked to attend an initial interview, during which you will be asked to complete one ten-minute questionnaire and a five-minute personal information form. If you qualify for participation based on the information gathered, you will be asked to complete two psychological interviews that will take a total of about one hour to administer. Only those persons who qualify for a diagnosis of depression or dysthymia will be eligible to participate. Furthermore, a diagnosis of psychosis, bipolar disorder, or mental retardation will exclude you from the study. You will also temporarily be excluded if you are found to be suicidal during the
initial assessments before treatment has begun. This exclusion will be until your any suicidal issues have been addressed or resolved.

Procedures

If you qualify for participation in the study, you will be asked to come in for an additional appointment approximately one-week after your first appointment. At that time you will be asked to complete a ten-minute questionnaire and a one and one-half hour interview to thoroughly evaluate your depression. It is after that assessment, if you agree to participate, that you will be randomly assigned to one of the four treatments mentioned above. Based upon your continued agreement to participate, you will be told at that time which of the four treatments you will receive. The treatment will be described to you by an experimenter after the assessment is completed. Treatment will begin within two weeks after this appointment. If you are already taking medication you will continue to take medication under supervision of the physician. If a new medication is thought necessary in the judgment of your physician, you will be tapered off your existing medication over a period of between 1 and 4 weeks. Any psychological treatment you receive would be added to this medication. Treatment will last for eight sessions scheduled one week apart or in the MIMA condition could take nine to twelve sessions, depending on the tapering process deemed appropriate by your psychiatrist. Upon completion of treatment, you will be asked to come in for three follow-up appointments, the last of which will occur three months after treatment has been completed. However if you are still experiencing depressive symptoms at the end of the primary treatment phase of the study (at the end of eight treatment sessions), you will be given the opportunity to select a treatment from among those being tested used in the study, as a means of addressing your continuing symptoms. The treatment provided to you at that time will be at no costs to you if approved by the Kalamazoo Community Mental Health and Substance Abuse Services Agency.

Risks

As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to you except as otherwise specified in this consent form. 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.

Another risk is associated with the use of any antidepressant medication whether you are a participant in this project or not. In the MIMA and in the Treatment as Usual conditions (the 2 medication treatments), there are risks associated with tapering medications. The treating psychiatrist is aware of these risks and will take appropriate measures to reduce, minimize or prevent them. These steps will be specific to your individual reactions to the tapering process. The clinic is prepared to offer treatment or make a referral should emergency care become necessary. You will be responsible for
the cost of all emergency care not approved by the Kalamazoo Community Mental Health and Substance Abuse Services agency, should such care become necessary.

Benefits

The primary potential benefit of participation in the study to you as a participant is the alleviation of depressive symptoms. Recall that the four treatments are called, (1) Treatment As Usual, (2) Michigan Medication Algorithm, (3) Interactive Multimedia Cognitive-Behavioral Therapy, and (4) Face to Face Cognitive-Behavioral Therapy. In the Treatment as Usual and the Medication Management groups, this is likely to occur through continued use of antidepressant medications. In the cognitive-behavioral therapy (either face-to-face or computer assisted) groups, this is likely to occur through the provision of different techniques for addressing depression symptoms, obtained through participation in weekly sessions of cognitive-behavioral therapy and tasks be done outside of therapy. Furthermore, knowledge gained from this study may lead to the development of more effective and accessible treatments for depression, which in turn may help other individuals experiencing depression.

Confidentiality

All of the information obtained from you is confidential. Original forms and progress notes with your name will be maintained in your current patient file at the Kalamazoo Community Mental Health and Substance Abuse Services building. Information in your treatment folder that is outside of this research project belongs to the clinic and may not be used as data for this study without your expressed permission. In the unlikely event that data of such nature is required, your permission will be sought before it is accessed. Forms used in this study may be placed in your treatment folder where they will be retained until they are destroyed along with the rest of the documents in your treatment folder according to the policies of the clinic. All documents outside of the clinic will contain a code number instead of your name and will be stored in a locked cabinet in the laboratory of the researcher. The researcher will maintain a list with your name matched to your corresponding research subject number in a different locked cabinet located within the laboratory. The master list will be maintained for the duration of the study, and then will be destroyed after all the data from the study is analyzed. A signed consent document and data containing no identifying information will also be retained for at least three years in a locked file in the principal investigator’s laboratory. You will be given a signed copy of this consent form for your records.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or
the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

__________________________  ________________________
Signature                              Date

Consent obtained by: ____________________________  ________________________
Signature of researcher                              Date
For those assigned to the Face-to-Face CBT condition who are NOT taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This is the second stage of the informed consent process. As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you are designated to receive cognitive-behavioral therapy that will be administered by a licensed doctoral student therapist from Western Michigan University. Therapy will take place at 418 Kalamazoo Avenue (KCMH) once weekly for one hour for eight sessions. Your therapy sessions may be monitored through a two-way mirror or video-taped by researchers involved in this study to assure quality control. If you wish to participate but do not wish to have your sessions monitored you may opt out of this part of the study, but still receive the treatment to which you are assigned. In this cognitive-behavioral therapy you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked to complete the same ten-minute questionnaire you completed at the beginning of the study each week. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight sessions of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the
active treatment phase of the study after you qualify. Qualification will be finally
determined after your second assessment visit.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or
penalty. If you have any questions or concerns about this study, you may contact either
Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may
also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-
8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise
during the course of the study. You may also contact the Medical Director of KCMHS or
the Executive Director at (269) 553-9211. This consent document has been approved for
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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 more than one year old. This consent
document has also been approved by the Kalamazoo Community Mental Health Research
Committee.

Your signature below indicates that you have read and/or had explained to you the
purpose and requirements of the study and that you agree to participate.

______________________________
Signature

______________________________
Date

Consent obtained by: ________________________
Signature of researcher

______________________________
Date
For those assigned to the Face-to-Face CBT condition who are taking medication at the beginning of the study:

**Purpose**

As a patient at this agency, you have been invited to participate in a research project entitled "Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression." As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

**Procedures and Compensation**

As a result of the random assignment process, in addition to your current medication treatment, which will continue to be monitored by your physician, you have been designated to receive cognitive-behavioral therapy that will be administered by a licensed doctoral student therapist from Western Michigan University. Therapy will take place at 418 Kalamazoo Avenue (KCMH) once weekly for one hour. Your therapy sessions may be monitored through a two-way mirror or video-taped by researchers involved in this study to assure quality control. If you wish to participate but do not wish to have your sessions monitored you may opt out of this part of the study, but still receive the treatment to which you are assigned. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked to complete the same ten-minute questionnaire you completed at the beginning of the study each week. The therapist will seek to assist you in understanding your depression and how to change your symptoms leading to a positive mood. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid
ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

________________________  ____________________
Signature                          Date

Consent obtained by:

________________________  ____________________
Signature of researcher    Date
For those assigned to the Treatment as Usual Condition who are NOT taking medication at the beginning of the study:

**Purpose**

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

**Procedures and Compensation**

As a result of the random assignment you have been designated to begin a standard medication treatment for depression at KCMH or the current agency at which you are receiving medication services and this treatment will be monitored over the eight-week active treatment phase of the study. This monitoring will take place by you being requested to come to the clinic each week and be seen by a nurse. You will complete the ten-minute questionnaire that you completed at the beginning of the study, at each visit throughout the eight-weeks of active treatment. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature __________________________ Date ______

Consent obtained by: __________________________
Signature of researcher __________________________ Date ______
For those assigned to the Treatment as Usual Condition who ARE taking medication at the beginning of the study:

**Purpose**

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

**Procedures and Compensation**

As a result of the random assignment process you have been designated to continue the medication treatment for depression that you have been receiving at KCMH or the current agency at which you are receiving medication services, and this treatment will be monitored over the eight-week active treatment phase of the study. This monitoring will take place by you being requested to come to the clinic each week and be seen by a nurse. You will complete the ten-minute questionnaire that you completed at the beginning of the study, at each visit throughout the eight weeks of active treatment. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

____________________________________  __________________________
Signature                                      Date

Consent obtained by: ____________________________  __________________________
Signature of researcher                            Date
For those assigned to the IMM-CBT condition who are NOT taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you have been designated to receive the computer-based therapy for treatment of depression. A nurse at the Kalamazoo Community Mental Health and Substance Abuse Services agency will work with you and oversee this computer-administered therapy. You will be asked to attend these sessions at the Kalamazoo Community Mental Health and Substance Abuse Services building, located at 418 West Kalamazoo Avenue once per week and to meet with the nurse who will be working with you, for eight sessions. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked each week to complete the ten-minute questionnaire you completed at the beginning of the study. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature ___________________________ Date __________

Consent obtained by: ___________________________ Date __________

Signature of researcher ___________________________ Date __________
For those assigned to the IMM-CBT condition who are taking medication at the beginning of the study:

**Purpose**

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

**Procedures and Compensation**

As a result of the random assignment process, in addition to your current medication treatment, which will continue to be monitored by your physician, you have been designated to receive a computer-based therapy for treatment of depression. A nurse at the Kalamazoo Community Mental Health and Substance Abuse Services agency will work with you and oversee this computer-administered therapy. You will be asked to attend these sessions at the Kalamazoo Community Mental Health and Substance Abuse Services building, located at 418 West Kalamazoo Avenue once per week and to meet with the nurse who will be working with you. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked each week to complete the ten-minute questionnaire you completed at the beginning of the study. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the
active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_________________________________________  ______________________
Signature                                              Date

Consent obtained by:  __________________________________________
Signature of researcher                                     ______________________
                                                               Date
For those assigned to the MIMA condition who are NOT taking medication at the beginning of treatment:

**Purpose**

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

**Procedures and Compensation**

As a result of the random assignment process, you have been designated to begin a medication treatment for depression, and this treatment will be monitored and adjusted accordingly over the eight-week active treatment phase of the study. This means that your medications may be increased or decreased in dosage or new medications added to your treatment according to the best judgment of the physician. You will make weekly visits to the clinic or the current agency at which you are receiving medication services and be seen by a medical professional for monitoring and continued treatment throughout the eight weeks. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_________________________ Date
Signature

Consent obtained by: ____________________________ Date
Signature of researcher
For those assigned to the MIMA condition who ARE taking medication at the beginning of treatment:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you have been designated to receive the Michigan Medication Algorithm treatment. This means that your medications may be increased or decreased in dosage or new medications added to your treatment according to the best judgment of the physician. Because you are already taking medications, prior to beginning treatment in this project, one to four weeks may be spent tapering off your current medications. This process is necessary in order to assure clinical safety and you will be monitored by the medical staff during this period of tapering. During this tapering process, you will make weekly visits to the clinic or the current agency at which you are receiving medication services and be seen by a medical professional for monitoring. Once the acute treatment phase has begun you will continue treatment throughout eight weeks. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously. You will be paid ten dollars per visit for each assessment and treatment session you attend during the active treatment phase of the study after you qualify. Qualification will be finally determined after your second assessment visit.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Medical Director of KCMHS or the Executive Director at (269) 553-9211. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature

Consent obtained by: ________________________________
Signature of researcher

Date

Date
Initial consent form for patients NOT on medication at the beginning of the study:

"Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression"

Western Michigan University
Department of Psychology
Informed Consent to Participate in Research

Principal Investigator: C. Richard Spates, Ph.D.
Student Investigators: Alyssa Kalata & Nishani Samaraweera

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) has been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University. You will be offered a two-stage informed consent process before finally agreeing to participate in this study. The first part of the informed consent process will occur at the first appointment, where you will be given a brief description of the project. The second part of the informed consent process will occur after you have been assessed and found qualified to enter the study. You will have the right to agree or not agree to participate at each stage of the informed consent process.

Participation

If you agree initially to participate in this study, you will be asked to attend a first interview, during which you will be asked to complete one ten-minute questionnaire and a five-minute personal information form. If you qualify for participation based on the information gathered, you will be asked to complete two psychological interviews that will take a total of about one hour to administer. Only those persons who qualify for a diagnosis of depression or dysthymia will be eligible to participate. Furthermore, a diagnosis of psychosis, bipolar disorder, or mental retardation will exclude you from the study. You will also temporarily be excluded if you are found to be suicidal during the
initial assessments before treatment has begun. This exclusion will be until any suicidal issues have been addressed or resolved.

Procedures

If you qualify for participation in the study, you will be asked to come in for an additional appointment approximately one-week after your first appointment. At that time you will be asked to complete a ten-minute questionnaire and a one and one-half hour interview to thoroughly evaluate your depression. It is after that assessment, if you agree to participate, that you will be randomly assigned to one of the four treatments mentioned above. Based upon your continued agreement to participate, you will be told at that time which of the four treatments you will receive. The treatment will be described to you by an experimenter after the assessment is completed. Treatment will begin within two weeks after this appointment. Upon completion of treatment, you will be asked to come in for three follow-up appointments, the last of which will occur three months after treatment has been completed. However if you are still experiencing depressive symptoms at the end of the primary treatment phase of the study (at the end of eight treatment sessions), you will be given the opportunity to select a treatment from among those being tested used in the study, as a means of addressing your continuing symptoms. The treatment provided to you at that time will be at no costs to you if approved by the Battle Creek Community Mental Health Agency.

Risks

As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to you except as otherwise specified in this consent form. 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 clinic is prepared to offer treatment or make a referral should emergency care become necessary. You will be responsible for the cost of all emergency care not approved by the Battle Creek Community Mental Health agency, should such care become necessary.

Benefits

The primary potential benefit of participation in the study to you as a participant is the alleviation of depressive symptoms. Recall that the four treatments are called, (1) Treatment As Usual, (2) Michigan Medication Algorithm, (3) Interactive Multimedia Cognitive-Behavioral Therapy, and (4) Face to Face Cognitive-Behavioral Therapy. In the Treatment as Usual and the Michigan Medication Algorithm groups, this is likely to occur through continued use of antidepressant medications. In the Cognitive-Behavioral Therapy (either face-to-face or computer assisted) groups, this is likely to occur through the provision of different techniques for addressing depression symptoms, obtained through participation in weekly sessions of Cognitive-Behavioral Therapy and tasks be
done outside of therapy. Furthermore, knowledge gained from this study may lead to the development of more effective and accessible treatments for depression, which in turn may help other individuals experiencing depression.

Confidentiality

All of the information obtained from you is confidential. Original forms and progress notes with your name may be maintained in your current patient file at the Battle Creek Community Mental Health Agency building. Information in your treatment folder that is outside of this research project belongs to the clinic and may not be used as data for this study without your expressed permission. In the unlikely event that data of such nature is required, your permission will be sought before it is accessed. Forms used in this study may be placed in your treatment folder where they will be retained until they are destroyed along with the rest of the documents in your treatment folder according to the policies of the clinic. All documents outside of the clinic will contain a code number instead of your name and will be stored in a locked cabinet in the laboratory of the researcher. The researcher will maintain a list with your name matched to your corresponding research subject number in a different locked cabinet located within the laboratory. The master list will be maintained for the duration of the study, and then will be destroyed after all the data from the study is analyzed. A signed consent document and data containing no identifying information will also be retained for at least three years in a locked file in the principal investigator’s laboratory. You will be given a signed copy of this consent form for your records.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.
Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

Signature ___________________________ Date ___________________________

Consent obtained by: ___________________________ Date ___________________________

Signature of researcher ___________________________ Date ___________________________
Initial consent form for patients on medication at the beginning of the study:

“Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression”

Western Michigan University
Department of Psychology
Informed Consent to Participate in Research

Principal Investigator: C. Richard Spates, Ph.D.
Student Investigators: Alyssa Kalata & Nishani Samaraweera

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments are as follows: treatment as usual (the medication treatment you are currently receiving), a new medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University. You will be offered a two-stage informed consent process before finally agreeing to participate in this study. The first part of the informed consent process will occur at the first appointment, where you will be given a brief description of the project. The second part of the informed consent process will occur after you have been assessed and found qualified to enter the study. You will have the right to agree or not agree to participate at each stage of the informed consent process.

Participation

If you agree to participate in this study, you will be asked to attend an initial interview, during which you will be asked to complete one ten-minute questionnaire and a five-minute personal information form. If you qualify for participation based on the information gathered, you will be asked to complete two psychological interviews that will take a total of about one hour to administer. Only those persons who qualify for a diagnosis of depression or dysthymia will be eligible to participate. Furthermore, a diagnosis of psychosis, bipolar disorder, or mental retardation will exclude you from the study. You will also temporarily be excluded if you are found to be suicidal during the
initial assessments before treatment has begun. This exclusion will be until any suicidal issues have been addressed or resolved.

Procedures

If you qualify for participation in the study, you will be asked to come in for an additional appointment approximately one-week after your first appointment. At that time you will be asked to complete a ten-minute questionnaire and a one and one-half hour interview to thoroughly evaluate your depression. It is after that assessment, if you agree to participate, that you will be randomly assigned to one of the four treatments mentioned above. Based upon your continued agreement to participate, you will be told at that time which of the four treatments you will receive. The treatment will be described to you by an experimenter after the assessment is completed. Treatment will begin within two weeks after this appointment. If you are already taking medication you will continue to take medication under supervision of the physician. If a new medication is thought necessary in the judgment of your physician, you will be tapered off your existing medication over a period of between 1 and 4 weeks. Any psychological treatment you receive would be added to this medication. Treatment will last for eight sessions scheduled one week apart or in the MIMA condition could take nine to twelve sessions, depending on the tapering process deemed appropriate by your psychiatrist. Upon completion of treatment, you will be asked to come in for three follow-up appointments, the last of which will occur three months after treatment has been completed. However if you are still experiencing depressive symptoms at the end of the primary treatment phase of the study (at the end of eight treatment sessions), you will be given the opportunity to select a treatment from among those being tested used in the study, as a means of addressing your continuing symptoms. The treatment provided to you at that time will be at no costs to you if approved by the Battle Creek Community Mental Health Agency.

Risks

As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to you except as otherwise specified in this consent form. 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. Another risk is associated with the use of any antidepressant medication whether you are a participant in this project or not. In the MIMA and in the Treatment as Usual conditions (the 2 medication treatments), there are risks associated with tapering medications. The treating psychiatrist is aware of these risks and will take appropriate measures to reduce, minimize or prevent them. These steps will be specific to your individual reactions to the tapering process. The clinic is prepared to offer treatment or make a referral should emergency care become necessary. You will be responsible for the cost of all emergency care not approved by the Battle Creek Community Mental Health agency, should such care become necessary.
Benefits

The primary potential benefit of participation in the study to you as a participant is the alleviation of depressive symptoms. Recall that the four treatments are called, (1) Treatment As Usual, (2) Michigan Medication Algorithm, (3) Interactive Multimedia Cognitive-Behavioral Therapy, and (4) Face to Face Cognitive-Behavioral Therapy. In the Treatment as Usual and the Medication Management groups, this is likely to occur through continued use of antidepressant medications. In the cognitive-behavioral therapy (either face-to-face or computer assisted) groups, this is likely to occur through the provision of different techniques for addressing depression symptoms, obtained through participation in weekly sessions of cognitive-behavioral therapy and tasks be done outside of therapy. Furthermore, knowledge gained from this study may lead to the development of more effective and accessible treatments for depression, which in turn may help other individuals experiencing depression.

Confidentiality

All of the information obtained from you is confidential. Original forms and progress notes with your name may be maintained in your current patient file at the Battle Creek Community Mental Health Agency building. Information in your treatment folder that is outside of this research project belongs to the clinic and may not be used as data for this study without your expressed permission. In the unlikely event that data of such nature is required, your permission will be sought before it is accessed. Forms used in this study may be placed in your treatment folder where they will be retained until they are destroyed along with the rest of the documents in your treatment folder according to the policies of the clinic. All documents outside of the clinic will contain a code number instead of your name and will be stored in a locked cabinet in the laboratory of the researcher. The researcher will maintain a list with your name matched to your corresponding research subject number in a different locked cabinet located within the laboratory. The master list will be maintained for the duration of the study, and then will be destroyed after all the data from the study is analyzed. A signed consent document and data containing no identifying information will also be retained for at least three years in a locked file in the principal investigator’s laboratory. You will be given a signed copy of this consent form for your records.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_____________________________________________  ______________________
Signature  Date

Consent obtained by: ____________________________  ______________________
Signature of researcher  Date
For those assigned to the Face-to-Face CBT condition who are NOT taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” This is the second stage of the informed consent process. As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you are designated to receive cognitive-behavioral therapy that will be administered by a therapist from the Battle Creek Community Mental Health Agency or a licensed doctoral student therapist from Western Michigan University. Therapy will take place at the Cedar Glen Center (3630 Capital Avenue SW, Battle Creek, MI 49015) once weekly for one hour for eight sessions. Your therapy sessions may be monitored through a two-way mirror or video-taped by researchers involved in this study to assure quality control. If you wish to participate but do not wish to have your sessions monitored you may opt out of this part of the study, but still receive the treatment to which you are assigned. In this cognitive-behavioral therapy you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked to complete the same ten-minute questionnaire you completed at the beginning of the study each week. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight sessions of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

________________________________________  ________________
Signature                                           Date

Consent obtained by: ______________________________  ________________
Signature of researcher                                    Date
For those assigned to the Face-to-Face CBT condition who are taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, in addition to your current medication treatment, which will continue to be monitored by your physician, you have been designated to receive cognitive-behavioral therapy that will be administered by a therapist from the Battle Creek Community Mental Health Agency or a licensed doctoral student therapist from Western Michigan University. Therapy will take place at the Cedar Glen Center (3630 Capital Avenue SW, Battle Creek, MI 49015) once weekly for one hour. Your therapy sessions may be monitored through a two-way mirror or videotaped by researchers involved in this study to assure quality control. If you wish to participate but do not wish to have your sessions monitored you may opt out of this part of the study, but still receive the treatment to which you are assigned. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked to complete the same ten-minute questionnaire you completed at the beginning of the study each week. The therapist will seek to assist you in understanding your depression and how to change your symptoms leading to a positive mood. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey.
One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

______________________________ Date
Signature

Consent obtained by: ____________________________ Date
Signature of researcher
For those assigned to the Treatment as Usual Condition who are NOT taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment you have been designated to begin a standard medication treatment for depression at Battle Creek Community Mental Health Agency or the current agency at which you are receiving medication services and this treatment will be monitored over the eight-week active treatment phase of the study. This monitoring will take place by you being requested to come to the clinic each week and be seen by a nurse or a researcher. You will complete the ten-minute questionnaire that you completed at the beginning of the study, at each visit throughout the eight-weeks of active treatment. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-
8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_________________________  __________________________
Signature                              Date

Consent obtained by:  __________________________  __________________________
Signature of researcher              Date
For those assigned to the Treatment as Usual Condition who ARE taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process you have been designated to continue the medication treatment for depression that you have been receiving at Battle Creek Community Mental Health Agency or the current agency at which you are receiving medication services, and this treatment will be monitored over the eight-week active treatment phase of the study. This monitoring will take place by you being requested to come to the clinic each week and be seen by a nurse or a researcher. You will complete the ten-minute questionnaire that you completed at the beginning of the study, at each visit throughout the eight weeks of active treatment. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may
also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

__________________________  ________________________
Signature                          Date

Consent obtained by: ____________________________  ________________________
Signature of researcher              Date
For those assigned to the IMM-CBT condition who are NOT taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you have been designated to receive the computer-based therapy for treatment of depression. A researcher at the Battle Creek Community Mental Health agency will work with you and oversee this computer-administered therapy. You will be asked to attend these sessions at the Cedar Glen Center (3630 Capital Avenue SW, Battle Creek, MI 49015) once per week and to meet with the researcher who will be working with you, for eight sessions. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked each week to complete the ten-minute questionnaire you completed at the beginning of the study. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

_________________________________________  
Signature

Consent obtained by:  
_________________________________________  
Signature of researcher

Date  

_________________________________________  
Date
For those assigned to the IMM-CBT condition who are taking medication at the beginning of the study:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, in addition to your current medication treatment, which will continue to be monitored by your physician, you have been designated to receive a computer-based therapy for treatment of depression. A researcher at the Battle Creek Community Mental Health and Substance Abuse Services agency will work with you and oversee this computer-administered therapy. You will be asked to attend these sessions at the Cedar Glen Center (3630 Capital Avenue SW, Battle Creek, MI 49015) once per week and to meet with the researcher who will be working with you. In this cognitive-behavioral therapy, you will be guided in how to look at your thoughts and behavior as they affect your mood, and assisted in altering these so that they have more positive effects in eliminating your depressive symptoms. You will be asked each week to complete the ten-minute questionnaire you completed at the beginning of the study. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study. One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

______________________________  ______________________
Signature                      Date

Consent obtained by:  ________________________________  ______________________
Signature of researcher        Date
For those assigned to the MIMA condition who are NOT taking medication at the beginning of treatment:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you have been designated to begin a medication treatment for depression, and this treatment will be monitored and adjusted accordingly over the eight-week active treatment phase of the study. This means that your medications may be increased or decreased in dosage or new medications added to your treatment according to the best judgment of the physician. You will make weekly visits to the clinic or the current agency at which you are receiving medication services and be seen by a medical professional for monitoring and continued treatment throughout the eight weeks. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight-weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.

Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-
8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

______________________________  ____________________
Signature                                           Date

Consent obtained by:  ____________________________  __________________
                                   Signature of researcher                      Date
For those assigned to the MIMA condition who ARE taking medication at the beginning of treatment:

Purpose

As a patient at this agency, you have been invited to participate in a research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Depression.” As indicated to you earlier, this research is intended to measure the effectiveness of four therapies to treat individuals suffering from depression. This is the second stage of the informed consent process. The four treatments being evaluated are as follows: treatment as usual (a medication treatment), a new approach to medication treatment called MIMA (the Michigan Implementation of Medication Algorithms), interactive multimedia assisted cognitive-behavioral therapy (a computer-assisted therapy), and face-to-face cognitive-behavioral therapy. Each of these three alternative treatments (MIMA, interactive multimedia assisted cognitive-behavioral therapy, and face-to-face cognitive-behavioral therapy) have been shown to be effective with many people. We are doing this study because we want to learn which treatment is the most effective for which patients. Portions of this project will serve as Alyssa Kalata’s and Nishani Samaraweera’s thesis and dissertation projects and is sponsored by the Kalamazoo Community Mental Health Board and Western Michigan University.

Procedures and Compensation

As a result of the random assignment process, you have been designated to receive the Michigan Medication Algorithm treatment. This means that your medications may be increased or decreased in dosage or new medications added to your treatment according to the best judgment of the physician. Because you are already taking medications, prior to beginning treatment in this project, one to four weeks may be spent tapering off your current medications. This process is necessary in order to assure clinical safety and you will be monitored by the medical staff during this period of tapering. During this tapering process, you will make weekly visits to the clinic or the current agency at which you are receiving medication services and be seen by a medical professional for monitoring. Once the acute treatment phase has begun you will continue treatment throughout eight weeks. If you are found to be symptomatic at the end of the eight weeks of active treatment you will be offered a treatment from among those tested in this study.

One week after the completion of the eight weeks of treatment, you will again be asked to come in and complete the same ten-minute multiple-choice questionnaire and then you will be interviewed with the one and one-half hour psychological interview given previously. You will also be asked to complete a ten-minute Client Satisfaction Survey. One and three months after the acute phase of treatment (eight sessions), you will be asked to complete the psychological interviews mentioned previously.
Problems or Questions

You may refuse to participate or quit at any time during the study without prejudice or penalty. If you have any questions or concerns about this study, you may contact either Dr. C. Richard Spates at (269) 387-4329 or Alyssa Kalata at (269) 387-4332. You may also contact the Chair of the Human Subjects Institutional Review Board at (269) 387-8293 or the Vice President of Research at (269) 387-8298 if questions or problems arise during the course of the study. You may also contact the Clinical Director of the Battle Creek Community Mental Health Agency at (269) 966-1460. 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 more than one year old. This consent document has also been approved by the Kalamazoo Community Mental Health Research Committee.

Your signature below indicates that you have read and/or had explained to you the purpose and requirements of the study and that you agree to participate.

______________________________  ____________________________
Signature                                           Date

Consent obtained by: ________________________________  ____________________________
Signature of researcher                                           Date
Appendix E

Protocol Clearance from the Human Subjects Institutional Review Board
Date: March 10, 2006

To: Richard Spates, Principal Investigator  
Alyssa Kalata, Student Investigator for thesis  
Nishani Samaraweera, Student Investigator  
Sophie Rubin, Student Investigator  
Sheryl Lozowskisi-Sullivan, Student Investigator  
Sarah VerLee, Student Investigator

From: Mary Lagerwey, Ph.D., Chair

Re: HSIRB Project Number 05-10-16

This letter will serve as confirmation that your research project entitled “Testing the Effectiveness of Cognitive Behavioral and Medication Therapy in the Acute Treatment of Unipolar 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: February 15, 2007
Appendix F

Participant Beck Depression Inventory – II Graphs
Appendix G

Participant Revised Hamilton Rating Scale For Depression Graphs
Interactive Multimedia CBT Consumer #1 - RHRSD Score

Interactive Multimedia CBT Consumer #2 - RHRSD Score
Appendix H

Participant Self-Rated Anxiety Measure Graphs
Face-to-Face CBT Consumer #3 - Anxiety

Face-to-Face CBT Consumer #4 - Anxiety
Appendix I

Participant Self-Rated Depression Measure Graphs
BIBLIOGRAPHY


