

Development of a Scale: Barriers to CBT Homework Completion Scale

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Submitted to the Graduate Faculty of
University of Pittsburgh in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

University of Pittsburgh

2007

UNIVERSITY OF PITTSBURGH

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University of Pittsburgh, 2007

Homework (mutually agreed tasks for the patient to complete outside the therapy session) is an important component of Cognitive Behavioral Therapy (CBT). CBT homework disconfirms negative thoughts and beliefs; focuses subjective accounts to more objective detailed accounts; allows therapist and patient to review the past week's activities; and helps the therapist to relate the session to specific tasks (Beck et al., 1979). Compliance with homework has been shown to improve the clinical results of CBT (Persons et al., 1988). At the present time there is no consensus as to the average rate of adherence in completing homework assignments (Detweiler & Whisman, 1999).

The identification and reliable measurement of barriers affecting completion of homework assignments may improve the potency of CBT, thereby producing further reductions in depressive symptoms and improvement in ultimate clinical outcome. It may also assist researchers to identify factors related to variance in treatment outcome, thereby strengthening the generalizability of investigational findings for the clinical community.

A two-phase study was conducted to develop an instrument that may assist CBT patients, therapists, and researchers to ascertain the barriers that may be preventing completion of homework assignments. Phase I involved the interview of 20 depressed patients and 20 therapists to elicit perceived barriers to homework completion in order to develop an item pool for the draft instrument. In Phase II, the draft instrument was administered to 56 subjects on 2

separate occasions.

Factor Analysis revealed a 2-factor solution of “Patient Factors” and “Therapist/Task Factors.” Internal Consistency demonstrated Alpha Coefficients of the Subscale and Entire scales that ranged from .80 to .95. Test-Re-Test correlations demonstrated Pearson correlations of .72 to .95. The only consistent demographic predictors of levels of Barriers to CBT Homework Completion Scale scores were race and marital status. The Patient subscale was able to satisfactorily classify patients (75 to 79 %) with low and high adherence to homework assignments. There were no consistent predictors of assignment compliance. The Barriers to CBT Homework Completion Scale scores did correlate significantly with Assignment Compliance (.32 to .46). Sample size most likely limited the ability to fully evaluate the psychometric properties of this draft instrument. Future studies will expand upon this pilot study of the Barriers to CBT Homework Completion Scale.

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PREFACE

A project this large cannot be accomplished without numerous contributors. First and foremost I would like to thank my entire family and all of my friends who have provided endless love, support, patience, and encouragement over the many years of this journey.

Secondly, I would like to thank Dr. Jacqueline Dunbar-Jacob who, many years ago, encouraged me to seek this goal and has been the supreme role model both as a professional and a person. She is the template of character, kindness, achievement, and mentorship.

I would like to thank my dissertation committee who, each in their own way, provided direction, support, and information. Drs. Stone and Sereika for their statistical and psychometric guidance; Dr. Olshansky for her guidance in qualitative research, and Dr. Michael Thase for his guidance in the area of mood disorders research, CBT, and research in general. I would like to thank Drs. Michael Thase, Robin Jarrett, Jesse Wright, Steve Hollon, Sander Kornblith, Michael Greenwald, Larry Glanz, Karen Woodall, Linda Ewing, and Carol Hughes, ACSW for allowing me to recruit subjects from their clinical and academic settings. This was most generous and will be appreciated for many years to come.

I would like to thank everyone that participated in the study process. Most emphatically I would like to thank Ms. Jessica Wilson and Mr. James Moorehead who served as the research assistants for this project and participated with great dedication and energy. I would also like to

acknowledge the supreme efforts of Ms. Amy Fasiczka in her invaluable statistical support and patience. Ms Cindy Kidner, from UT Southwestern generously contributed her time and effort to make sure all of the data from Texas was obtained and sent. Finally, Ms. Christine Johnson for her guidance and assistance in preparing the dissertation.

I would also like to acknowledge the raters in Phase I who volunteered their time to review the transcripts and develop the concepts. They are Maureen Callan MSW, Kathleen Bowler PhD, RN, LuAnn Shutt RN, MSN, Crystal Spotts MEd, and Susan Dillon RN for the interview reviews and Robert Howland MD, Randi Taylor PhD, and Jacqueline Stack RN, MSN as the concept raters. Their generosity in giving of their time is greatly appreciated. Finally, I would like to thank David J. Kupfer M.D. as the Principal Investigator of the MHIRC at Western Psychiatric Institute and Clinic, which sponsored the Seed Monies Grant that provided the necessary funds that allowed me to conduct this study.

1.0 INTRODUCTION

1.1 BACKGROUND OF THE PROBLEM

Major Depression, considered a common disorder, has been reported to have a lifetime prevalence ranging from 5 to 17.1% (National Institute of Mental Health, 2000; Regier et al., 1988; Regier et al., 1993; Kessler et al., 1994; Blazer et al., 1994). The National Institute of Mental Health (2000) documented this disorder as affecting 9.9 million American adults. General conclusions that were drawn from these epidemiologic surveys were that depression is a common disorder and occurs more frequently in women than men, and its prevalence is reduced as individuals get older. Being married offers some protection against depression and Caucasian and Hispanic individuals appears to be more vulnerable.

Primary care centers serve as a principal venue in the treatment of depression. Approximately one half of those seeking treatment for Major Depressive Disorder receive it through a non-specialty physician (Narrow et al., 1993). The prevalence of Major Depressive Disorder in primary care patients ranges from 2.8% to 33% (Schwenk et al., 1998; Kessler, 1985; Barrett et al., 1998; Kamerow, 1988; Zung, 1983), with reported differences dependent on setting, i.e., urban vs. rural, and diagnostic methodology.

Increased comorbidity of Major Depressive Disorder with various physical disorders has been clearly documented in the literature (Roder & Voshart, 1986; Stein et al., 1991; Felker et al., 1996; Cassem, 1990). This comorbidity has often been associated with poor outcome and increased rates of mortality (Felker et al., 1996). Under-treatment of the psychiatric as well as the physical illness occurs due to the complexity of providing collateral treatment for depression in the context of the medical disorder. Patient factors such as non-completion and systems issues, including poor evaluation and follow-through, contribute to this under-treatment.

Major depression results in significant functional impairment in multiple domains. They include physical, emotional, occupational, and family functioning (Schonfeld et al., 1997; Wells et al., 1989; Mintz et al., 1992; Kessler & Frank, 1997). This impairment in functioning is equal to or greater than many common debilitating physical disorders. There is conflicting evidence whether remission from Major Depressive Disorder returns an individual to full functioning.

An additional burden of depression to the country is economic. Stoudemire et al. (1986), estimated the direct and indirect cost of depression (morbidity, mortality, direct treatment costs, years of major activity lost and years of life lost) to be \$16.3 billion per year. Indirect morbidity costs from lost work years of depression represented more than 75% of the costs of depression to society. Greenberg et al. (1993), expanding upon this earlier research, studied the economic burden of all types of depression, including not only Major Depressive Disorder but also bipolar disorder and dysthymia. Using a human capital approach, they estimated the annual costs of depression in the United States to total \$43.7 billion in 1990 dollars.

Unfortunately, even though treatment has been shown to be effective in treating Major Depressive Disorder, there continues to be a number of people who die each year as a result of suicide. The National Center for Health Statistics (2005) reported the number of suicides in

2002 in the United States were 31,655 (the most recent year surveyed). This resulted in an age-adjusted rate of 11/100,000 and makes it eighth in ranking as the cause of death (overall). Psychopathology (mental and addictive disorders) is considered a central risk factor for suicide (Moscicki, 1995). Of those assessed through psychological autopsy, 90% were found to have had a mental or addictive disorder at the time of suicide. Affective disorder, especially Major Depressive Disorder, has been implicated as the most common diagnostic risk factor.

Major Depressive Disorder is not only a disorder with a potentially fatal outcome, but other fundamental clinical implications related to its cyclical and/or chronic nature. Mueller and Leon (1996) identified Major Depressive Disorder as a life-long episodic disorder with multiple recoveries and recurrences, averaging one episode per five-year period.

Depression continues to be an undertreated disorder, despite the multiple effects that it has on an individual and society due to the often recurrent/chronic course (Davidson & Meltzer-Brody, 1999). The Epidemiological Catchment Area Study (Robins & Regier, 1991) reported only one in ten persons suffering from depression received adequate treatment, of the one-third of depressed patients who actually sought treatment.

The National Depressive and Manic-Depressive Association, in a consensus statement, (Hirschfeld et al., 1997) concluded that individuals with depression are being seriously undertreated even though safe, effective, and economic treatments are available. Notwithstanding, Friedman (1997) reported that standard treatments for depression produce substantial improvements in 60 to 80% of patients.

Antidepressant medications are effective across the full range of major depressive episodes in Major Depressive Disorder (American Psychiatric Association, 1993; Depression Guideline Panel, 1993; Frank et al., 1993). Approximately 50% of patients respond to the first trial of antidepressant (Thase & Rush, 1997).

Two time-limited therapies, Interpersonal Therapy (Klerman et al., 1984) and Cognitive Behavioral Therapy (CBT; Beck et al., 1979), have been demonstrated through research to be effective for mild to moderate depression (National Institute of Mental Health, 2001). Meta-analyses of randomized clinical trials document the relative equivalence of CBT and Interpersonal Therapy to pharmacotherapy in treating mild to moderate depression (Dobson, 1989; Depression Guideline Panel, 1993).

Interpersonal therapy is a weekly face-to-face present-oriented short-term therapy for the acute treatment of depression (Klerman et al., 1984). This therapy emphasizes the current interpersonal problems of the patient. More specifically, Interpersonal Therapy manages the four basic interpersonal problem areas of unresolved grief: role transitions; interpersonal role disputes; and interpersonal deficits. Interpersonal Therapy relates symptom onset to overt or covert disputes with significant others with whom the person is currently involved (Frank & Spanier, 1995).

The form of Cognitive Behavioral Therapy developed by Aaron T. Beck (1979), also known as Cognitive Therapy, has taken the view that an individual's appraisal of a situation, thought, or feelings affect the coping process and thereby the resulting behaviors. This therapeutic paradigm, used in a wide variety of problems and clinical populations, has the following key points. First, perception and experiencing, in general, are active processes that

involve both inspective and introspective data. Second, the patient's cognitions represent a consequence and synthesis of internal and external stimuli. How a person appraises a situation is generally evident in his/her cognitions, thoughts, and visual images. These cognitions constitute a person's "stream of consciousness" or phenomenal field, which reflects the person's configuration of him/her, the world, his/her past, and future. Alterations in the content of the person's underlying cognitive structures affect his or her affective state and behavioral pattern. Through therapy a patient can become aware of his/her cognitive distortions. Lastly, correction of these faulty dysfunctional constructs can lead to clinical improvement. The focus of CBT, then, is on the patient's thinking (especially automatic thoughts) and how that thinking affects the patient's mood and behavior.

Several meta-analyses or reviews of existing CBT studies (Miller & Berman, 1983; Dobson, 1989; Robinson, 1990; Gaffan et al., 1995; Gloaguen et al., 1990; Butler et al., 2005) demonstrated CBT to be an efficacious treatment, especially when compared to a control condition, i.e., waiting list for treatment, pharmacotherapy, and other miscellaneous therapies. Meta-analyses, using more stringent inclusion criteria to reflect Beck's original model and a standard outcome measure, evidence more robust findings for the efficacy of CBT. CBT is one of only two psychotherapies considered efficacious such that they are recommended by the Agency for Health Care Policy Research (AHCPR) in their published practice guidelines.

Beck (1979) views homework, in particular, as a critical vehicle from which data, which disconfirms many of the patient's negative beliefs and distortions can be obtained. It makes therapy more concrete by examining the week that has gone by, and enhances the therapeutic communication with the patient. Homework reinforces and serves as a supplemental educational aspect of the therapy itself. Rush (1983, p.110) further states its critical nature: "homework

assignments help the patient develop objectivity about situations that are otherwise stereotypically misconstrued; identifies underlying assumptions; and develops and tests alternative conceptualizations and guiding assumptions.”

CBT practitioners reported use of homework is 66% of sessions as compared to 48% of sessions in non-CBT therapists [$t(174.64) = 5.28, p < .001$] (Kazantzis & Deane, 1999). They further evaluated the therapist’s perception of the importance of homework for various patient problems and found that 69% believed homework was rated as having great importance in the treatment of depression; 19% rated it as moderately important and only 4% rated it as having little importance.

Depressed patients who comply with homework assignments in CBT have been shown to have an early response to treatment (Fennell & Teasdale, 1987; DeRubeis & Feeley, 1980; and Startup & Edmonds, 1994). Other researchers (Persons et al, 1988; Neimeyer & Feixas, 1990; Bryant et al., 1999; Burns & Spangler, 2000; Addis & Jacobsen, 2000; Burns & Nolen-Hoeksema, 1991) have demonstrated that completion with homework assignments in CBT was associated with an overall better outcome. Homework was shown to make an independent contribution to treatment outcome, above and beyond the overall CBT intervention (Addis & Jacobsen, 2000; Burns & Nolen-Hoeksema, 1991). Burns and Spangler (2000) showed, through structural equation modeling, that for every unit of homework completion, the Beck Depression Inventory (Beck et al, 1961) dropped 4.35 points. Persons et al. (1988) showed that those who complied with homework improved three times as much as those who did not, with a mean reduction of 16.6 points. Neimeyer and Feixas (1990) showed homework completion to produce significant mean reductions in both the Beck Depression Inventory [24.03 (SD= 7.29) to 14.68 (SD=9.38)] and the Hamilton Rating Scale for Depression (Hamilton, 1967) [17.27 (SD= 5.89)

to 8.13 (SD=4.37)]. Bryant et al. (1999) showed mean reductions in the Hamilton Rating Scale for Depression [21.08 (SD=3.59) to 4.35 (SD= 4.40)] at treatment outcome. Thus, completion with homework is associated with improved outcome when measured by well established self-report (Beck Depression Inventory) and interviewer-administered (Hamilton Rating Scale for Depression) measures of depression severity.

Non-adherence to homework assignments has been broadly explained by an inter-relationship among task, therapist, and patient variables (Detweiler & Whisman, 1999). Adherence is reduced when the task is excessively difficult, inappropriate or ill defined, not built on client strengths, and not clearly associated with the identified problem or complaint.

Therapist behavior has been identified as a critical element related to adherence in completing CBT homework. These behaviors include: inappropriate goal setting and mismatch between patient ability and assignment (Shelton & Levy, 1981); failure to explain the rationale and importance of an assignment (Burns & Auerbach, 1992; Worthington, 1986); therapists negative cognitions about homework completion (Beck, 1995), and therapists “giving up” on homework due to patient’s repeated non-adherence (Newman, 1994).

Patient factors that have been related to homework non-completion can be broadly characterized as: Lack of Understanding; Emotional; Cognitions; Resistance; Environmental; and Characteristics of the Patient (See Appendix A for a list of relevant patient factors). Self-efficacy has been posited as a patient variable that may impact homework completion in a profound manner. Bandura’s Social Learning theory (Bandura, 1977) defines self-efficacy as “judgment of how well one can execute courses of action required to deal with prospective situations” (Bandura, 1982, p. 122).

Whether an action is undertaken, according to Bandura (1977), is dependent upon “outcome expectancy” and “efficacy expectation.” Outcome expectancy is a person’s estimate that a given behavior will lead to certain outcomes. Efficacy expectancy, in contrast, is the belief that one can execute an action successfully so as to produce the outcomes. Efficacy determines how much effort, as well as how long, a person will persist when faced with barriers, i.e., people with higher efficacy expectations will persist to success in the face of obstacles. Conversely, low efficacy expectancy leads to fear and avoidance of particular situations that are judged as threatening, while high efficacy expectancy leads to affirmative behavior.

Failure to carry out corrective experiences, i.e., to perform homework assignments, may be related to problems with both efficacy and outcome expectations. A patient may have low efficacy expectation and not believe in his own ability to carry out the assignment and/or he may not believe the homework assignment will produce the desired result (outcome expectancy). Thus, self-efficacy may interact with CBT homework non-completion in a circular manner. A patient with low self-efficacy may be less likely to complete a homework assignment believing he/she is incapable of completing the task and/or alternately disbelieving it will produce the desired outcome. Repeated non-completion with homework assignments, then, may deprive the patient of corrective learning experiences designed to improve beliefs of self-efficacy.

At the present time there is no consensus as to the average incidence of non-adherence with homework assignments (Detweiler & Whisman, 1999). Furthermore, Shelton and Levy (1979) expressed concern that in a survey of four behavioral journals spanning a five-year time frame, sixty percent of the articles reported homework use as a part of the treatment protocol, yet few gave information regarding the frequency, duration, setting where assignments were given,

and completion rate of the given task. Primakoff (1986) also noted the lack of research studies that investigate homework completion as a variable that could affect outcome, in particular, the specification, standardization and statistical analysis of homework use. Additionally, they called into question the existing published CBT research with respect to a failure to explore homework as a predictor variable. This omission, they argue, has resulted in several potential sources of error variance that may make interpretation of the results difficult. There is, unfortunately, no consistent systematic or psychometrically valid method to measure homework completion or to appraise potential patient, therapy, and task factors contributing to non-adherence with homework assignments.

1.2 STUDY PURPOSE

The long-term objective of this study was to assist therapists and patients to identify barriers that may reduce the likelihood of completion of CBT homework. The purpose of this study was to develop and psychometrically evaluate an instrument to measure barriers that may deter adherence to CBT homework. The instrument, to be administered after an assignment of homework in each CBT session, was designed to assist therapists to identify and clinically intervene with patient's perceived barriers to homework completion at that session. It was also intended to assist CBT researchers to identify sources of variance in treatment outcome by comparing populations, i.e., those with high or low perceived barriers in relation to homework completion and treatment outcome.

The primary aim of Phase I of the study was to develop the initial item pool and to draft the instrument “Barriers to CBT Homework Completion Scale.” This was accomplished via interview of depressed patients currently engaged in CBT and expert CBT clinicians.

The primary aims of Phase II were to conduct a pilot study of the initial version of the “Barriers to CBT Homework Completion Scale” and the Assignment Completion Rating Scale (Primakoff, et al., 1986 & Bryant et al., 1999) in a sample of depressed patients.

This pilot investigated the preliminary psychometric properties, i.e., reliability and internal structure of the instruments as well as the external structure evidence of the instrument in terms of its ability to predict homework completion.

The initial secondary aim of Phase II was to investigate whether level of depression (as measured by the Beck Depression Inventory), length of depression in weeks, length of CBT in weeks, dysfunctional attitudes (as measured by the Dysfunctional Attitudes Scale), and level of therapist training (as measured by years of education and degree of supervision) were related to “Barriers to CBT Homework Completion Scale” scores.

Additionally, subjective level of depression (as measured by the Beck Depression Inventory), length of depression in weeks, depression episode subtype (single, recurrent, or chronic), length of depression in weeks, length of CBT in weeks, dysfunctional attitudes (as measured by the Dysfunctional Attitudes Scale), and level of therapist training (as measured by years of education and degree of supervision) and “Barriers to CBT Homework Completion Scale” scores were examined in relation to their ability to predict completion of homework assignments as measured by the “Assignment Compliance Rating Scale.”

Finally, the demographic variables of gender, age in years, income, and educational level in years, marital status, and ethnic background were evaluated in terms of their ability to predict

the scale and subscale scores of the “Barriers to CBT Homework Completion Scale” and final CBT homework completion as measured by “The Assignment Compliance Rating Scale.”

1.3 RESEARCH QUESTIONS

1. Can the construct “barriers to completion in completing CBT homework” be measured in a reliable and valid manner in a group of depressed patients receiving CBT?
2. Do subjectively measured level of depressive symptoms (as measured by the Beck Depression Inventory), dysfunctional attitudes (as measured by the Dysfunctional Attitudes Scale), length of time in CBT in weeks, length of depression in weeks and level of therapist training (years of training and degree of supervision) account for significant variance in the level of “Barriers to CBT Homework Completion Scale” scores?
3. Do the “Barriers to CBT Homework Completion Scale” scores, subjectively measured level of depressive symptoms (as measured by the Beck Depression Inventory), length of time in CBT in weeks, dysfunctional attitudes (as measured by the Dysfunctional Attitudes Scale), length of depression in weeks, and level of therapist training (years of training and degree of supervision) account for significant variance in resulting homework completion?

Previous research (see literature review) has indicated that increased severity of depressive symptoms, longer length of depression, decreased length of time in CBT and recurrent or chronic subtype of depression, and greater expertise of the CBT

therapist may account for significant variance in “Barriers to CBT Homework Completion Scale” scores and homework completion as measured by “The Assignment Compliance Rating Scale.”

4. Is there a demographic profile associated with higher “Barriers to CBT Homework Completion Scale” and lower “Assignment Completion Rating Scale” scores?

A demographic profile defined by female gender, older age, higher level of education, and marital status (being married) was expected to be associated with lower scores on the “Barriers to CBT Homework Completion Scale” and greater levels of homework completion as measured by the “Assignment Completion Rating Scale.”

1.4 DEFINITION OF TERMS

The terms for the purpose of this study are defined as follows:

1. Major Depression

Major depression, as defined by the *Diagnostic and Statistic Manual of Mental Disorders – Fourth Edition (DSM-IV)*, is a clinical disorder that has five (or more) of the following symptoms during the same two-week period and represents a change from previous functioning (American Psychiatric Association, 1994, p. 327). At least one of these symptoms must be depressed mood or loss of interest or pleasure. Other symptoms include: depressed mood most of the day, nearly every day; markedly diminished interest or pleasure in all or almost all activities, most of the day, nearly every day; significant weight loss or gain or an increase or

decrease in appetite nearly every day; insomnia or hypersomnia nearly every day; psychomotor agitation or retardation nearly every day; fatigue or loss of energy nearly every day; feelings of worthlessness or excessive or inappropriate guilt nearly every day; diminished ability to concentrate or indecisiveness nearly every day and recurrent thoughts of death or suicidal ideation with or without a plan.

2. Cognitive Behavioral Therapy

Cognitive Behavioral Therapy (CBT) is a structured, short-term, present-oriented psychotherapy, directed towards solving current problems and modifying dysfunctional thinking and behavior (Beck, 1995). It is based on the underlying theoretical rationale that an individual's affect and behavior are largely determined by the way in which he structures the world (Beck, 1967, 1976)

3. Completion/Adherence

Completion refers to the extent to which patients are obedient and follow the instructions, proscriptions, and prescriptions of the health care providers. Adherence implies a more active, voluntary, collaborative involvement of the patient in a mutually acceptable course of behavior to produce a desired preventative or therapeutic result (Meichenbaum & Turk, 1987, p. 20) compared to completion. For the purposes of this study, adherence referred to full completion of the agreed upon homework assignment. This included categories five (The patient did the assigned homework) and six (The patient did more of the assigned homework than was necessary) of the "Assignment Completion Rating Scale" (Primakoff, 1986; Bryant et al., 1999).

4. Homework

Homework is a task that is mutually agreed upon by the CBT therapist and patient to be completed in the time period after a session and before the subsequent session. Homework is

considered a vehicle from which data may disconfirm negative thought and beliefs. It is uniquely tailored to each patient's goals and the content of the session (Beck, 1979; 1995). Thus, across patients, homework assignments varied each session (except session one). Session one, however, characteristically included reading the brochure "Coping with Depression" (Beck & Greenberg, 1974). Variations included type of assignment, how much time is required to prepare and complete the assignment, and general difficulty (some assignments are inherently more difficult). Homework assignments were broadly characterized as educative (bibliotherapy), affective (mood management techniques), cognitive (recording automatic thoughts), behavioral (response prevention), or organizational (constructing activity schedules). See Appendix B for a more comprehensive list of CBT homework assignments.

5. Barriers

Barriers referred to any patient variable, belief, treatment variable, illness and symptom variable, relationship variable, organizational/structural variable that may affect patient adherence (Meichenbaum & Turk, 1987). Barriers were broadly organized according to patient, therapist, and task barriers (Detweiler & Whisman, 1999).

1.5 SIGNIFICANCE TO THE FIELD

The care and treatment of major depression occurs at various venues including inpatient, outpatient and primary care settings. CBT, both in Beck's (1979) classic paradigm and in modified versions and applications, is one of the most prominent and efficacious treatments for major depression. Nurses deliver CBT as advanced professionals and as primary nurses on inpatient settings.

Completion with homework assignments has been demonstrated to be an important component of the overall effectiveness of CBT. The identification and reliable measurement of barriers affecting completion with homework assignments may improve the potency of CBT, thereby producing further reductions in depressive symptoms and improvement in ultimate clinical outcome.

It may also assist CBT researchers to identify factors related to variance in treatment outcome, thereby strengthening the generalizability of investigational findings for the clinical community. Findings from this study will broadly contribute to the body of knowledge on adherence with self-care assignments through further knowledge about barriers affecting CBT homework completion in a depressed population.

2.0 REVIEW OF THE LITERATURE

The literature review demonstrated the extent and consequences of Major Depressive Disorder in the United States. Basic epidemiologic information regarding the prevalence of Major Depressive Disorder was examined as well as prevalence in primary care settings, where Major Depressive Disorder is often treated. Major depression was appraised in relation to comorbidity, misdiagnosis, under-diagnosis, and under-treatment. Consequences of this illness, including reduced quality of life, significant economic impact, and the worst possible outcome, suicide, were detailed. The overall effectiveness and cost-effectiveness of treatment was highlighted. Efficacious treatment for Major Depression for this disorder was reviewed, most specifically, pharmacologic treatment, and two psychotherapeutic interventions Interpersonal Therapy and Cognitive-Behavioral therapy. Efficacy of CBT, in particular, was examined in relation to its theoretical constructs and mechanisms. The integral nature of CBT homework to its efficacy was reviewed as well as the critical need to appraise barriers to the successful completion. The literature review demonstrated the deficiency in CBT, both clinically and in the conduct of research, to validly measure perceived barriers to successful homework completion.

2.1 EPIDEMIOLOGY OF DEPRESSION

Major Depression, considered a common disorder, has been reported to have a lifetime prevalence ranging from 5 to 17.1% (National Institute of Mental Health, 2000; Regier et al., 1988; Regier et al., 1993; Kessler et al., 1994; Blazer et al., 1994). The National Institute of Mental Health (2000) documents this disorder as affecting 9.9 million American adults. Epidemiological estimates for Major Depressive Disorder have changed over time in relation to the nosology of the disorder itself. It was not until the introduction of the third *Diagnostic and Statistical Manual for Mental Disorders*, by the American Psychiatric Association on Nomenclature and Statistics, those explicit diagnostic criteria, a multi-axial system, and a descriptive approach that attempted to be neutral with respect to theories and etiology, were made available for the diagnosis of depression and other psychiatric disorders. The revised third and fourth volumes of the *Diagnostic and Statistic Manual* identified inconsistencies and used empirical evidence to further specify diagnoses (American Psychiatric Association, 1994). Thus, more recent epidemiologic research, the Epidemiologic Catchment Area study of the early 1980's and the National Comorbidity Survey of the early 1990's, relied on the clustering of signs and symptoms rather than simple presentation of signs and symptoms.

The Epidemiological Catchment Area survey, funded by the National Institute on Mental Health, was a multi-site general population survey of the epidemiology of psychiatric disorders and use of health services. The five sites included: New Haven, Connecticut; Baltimore, Maryland; St. Louis, Missouri; Durham, North Carolina and Los Angeles, California. This survey, conducted between 1980 and 1985, assessed need for, seeking, and obtaining mental health services in household and institutional residents age 18 years and older. The initial wave was conducted in 20,291 adults; six months later they were re-interviewed via telephone and one

year later 79.1% of the sample was re-interviewed. The Epidemiological Catchment Area study used the Diagnostic Interview Schedule (Robins et al., 1981) to identify mental health problems (Regier et al., 1984; Howard et al., 1996) and provided epidemiologic statistics on one month, six month, one year, and lifetime rates.

One-month prevalence of Major Depressive Disorder was 2.2 % (0.2). The female rate was 2.9 % to the male rate of 1.6%. Rates of affective disorder at different ages ranged from 3.1 to 4.5 years with an abrupt decrease to 1.4% at age sixty-five years.

The overall one-month prevalence rate was arrived at from a sample of 18,571, with each of the sites contributing between 3004 and 5034 subjects. Adults aged eighteen years and over were selected from a probability sample of households, one adult being interviewed from each of these households. Completion rates were from 68 to 79 %, the majority from 77 to 79 %. Forty one percent of the sample was men and 59 % women. The largest proportion of age ranges fell in the 65+ years plus range (30.7%) and the 25+ to 34 years ranges (21.9%). Sixty nine percent were non-black, 23 %, and 8% Hispanic. Forty-seven percent were married, 20% single, and 33% divorced, separated, or widowed (Regier et al., 1988).

At the wave two follow-ups, 12 months later, 4442 (21.9 %) of the original sample were not available to be re-interviewed. A one-year prevalence rate of 5% (0.2) was found for unipolar depression. It had the highest annual incidence rate of any of the evaluated affective disorders at 3.2 % (Regier et al., 1993).

In an initial report, analyzing lifetime prevalence of psychiatric disorders in three sites (Robins et al., 1984), the following lifetime prevalence by site for Major Depressive Disorder was found: New Haven 6.7% (0.5); Baltimore 3.7% (0.3); and St. Louis 5.5% (0.6). The average was 5.3%. Robins and Regier (1991) later identified the lifetime prevalence of Major

Depression at 5% when all five groups were considered. There was a tendency of Major Depressive Disorder to decrease with advancing age, to occur in women more than twice as often as men (7.0% vs. 2.6%), and to occur in whites more often than non-whites.

The second major epidemiologic study, the National Comorbidity Survey was conducted between 1990 and 1992 (Kessler et al., 1994). The National Comorbidity Study made use of a structured interview, the Composite International Diagnostic Interview (Robins et al., 1988; World Health Organization, 1990), to assess non-institutionalized civilians age 18 to 54 in the United States. This congressionally mandated study surveyed the comorbidity of substance use and non-substance psychiatric disorders in the United States. The National Comorbidity Study made three advances. Diagnoses were based on the revised third edition of the Diagnostic and Statistic Manual rather than the third edition of the Diagnostic and Statistic Manual. Risk factors as well as incidence and prevalence were assessed. Lastly, a national sample was utilized allowing regional comparison.

The sample included 8098 respondents with a total response rate of 82.6%. The sample is based on a stratified multi-stage probability sample in the non-institutionalized civilian population in the 48 coterminous states. Weighted sample characteristics nearly replicated the United States population with the majority of the sample being white, less than high school graduates or high school graduates, married, and from large urban centers. Sex and age ranges were equally matched.

The 12-month prevalence of Major Depressive Disorder was 10.3% (0.6). There continued to be gender differences with women having an increased rate of depression (12.9% (0.8) vs. 7.7% (0.8) for males. Other demographic correlates for affective disorder included younger age, Hispanic origin, lower income and lesser education.

Lifetime prevalence was 17.1% (0.7). A similar pattern of females to males arose with a rate of 21.3 % (0.9) for females and 12.7% (0.9) for males (odds ratio of 1.82 to 1.00, $p < .05$). Demographic correlates for affective disorder that demonstrated significance were race (blacks having less affective disorder) and low income (\$0-19,000) having increased affective disorder.

Blazer et al. (1994) reported 4.9% as the one-month prevalence for Major Depressive Disorder. Female to male odds ratio was 1.57 to 1.00, $p < .05$. Lower educational level, race (Hispanic), lower income (\$0 to 19,999), marital status (married and never married), homemaker status, household composition (lives with another), were associated with greater levels of Major Depressive Disorder at the .05 significance level (Blazer et al., 1994).

The National Comorbidity Study reported higher levels of Major Depressive Disorder as compared to the Epidemiological Catchment Area, conducted just ten years earlier. While it is doubtful that a historical effect for changing levels of depression could have resulted, several alternative explanations have been posited for the difference. First, the National Comorbidity Study used the Composite International Diagnostic Interview, a structured instrument relying on greater numbers of stem questions per disorder than the Diagnostic Interview Survey. Patients were offered three initial stem questions for Major Depressive Disorder with the Composite International Diagnostic Interview compared to one with the Diagnostic Interview Survey. The National Comorbidity Study concerned about false positives conducted a small validating study of those who reported Major Depressive Disorder. It was found that the diagnosis was replicated in 14 out of 20 subjects given a more systematic instrument (Structured Clinical Interview for Diagnostic and Statistic Manual) (Spitzer et al., 1992). Eight out of ten who were not classified as Major Depressive Disorder were classified as such with the Structured Clinical Interview for

Diagnostic and Statistic Manual. These results were comparable to similar follow-up studies of the Diagnostic Interview Survey.

Secondly, the National Comorbidity Study upper age limit was 54 while the Epidemiological Catchment Area was 64 and over. It has been shown in both studies that higher age levels are correlated with lower rates of depression. This difference in samples may have artificially elevated the prevalence of Major Depressive Disorder in the National Comorbidity Study. Finally, methodological differences, i.e., the use of a nationwide sample and a more sensitive instrument, may have resulted in a more valid determination (Blazer et al., 1994).

Regier (1998) further hypothesized that high rates of disorders found in community samples, (both Epidemiological Catchment Area and National Comorbidity Study), may be milder cases of the same disorders seen in clinical settings. He notes that these syndromes may actually signify temporary homeostatic responses to internal or external stimuli and may not represent true psychopathology, i.e., similar to a grief reaction.

Angst (1992) provided further epidemiologic data on depression with a prospective study that included multiple assessments over ten years of a community sample of 20 to 30. The results were a one-year prevalence of 9.4%, a ten-year prevalence of 16.7%, and a lifetime period prevalence of 14.4%.

General conclusions that can be drawn from these epidemiologic surveys are that depression is a common disorder, occurs more frequently in women than men, and its prevalence is reduced as individuals get older. Marital status offers some protection against depression, and race, especially white and Hispanic individuals appear to be more at risk.

The issue of depression in the older age groups has remained controversial and to some extent unclear. The prevalence of Major Depressive Disorder in the elderly from previous studies has been varied with rates from 1.7 % to 16% (Kanoski, 1994).

Mirowsky and Ross (1992), in a sample gathered through random dialing of 2,840 persons, investigated age and depression using the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977). A fall and then successive rise in successive age groups was demonstrated with the lowest rate of depression in the 30 to 39 age groups. The highest rate was in individuals greater than 80 years. The U shaped curve in the survival model showed that depression was lowest among the middle aged and higher among the oldest. When the regression curve was adjusted, however, for life-cycle differences in marital, employment, and economic status, the age curve of depression flattens. Thus, life cycle changes may explain the age curve of depression. These results vary with the National Comorbidity Study and Epidemiological Catchment Area, which demonstrated a decreasing rate of depression with advancing age. Heithoff (1995), in a study investigating the Epidemiological Catchment Area estimates of Major Depressive Disorder in elderly respondents, found that recoding the somatic symptoms of depression, originally attributed to physical or medical explanations, to psychiatric symptoms, did not result in a disproportionate rise in diagnosable depression in the older age groups.

The Epidemiological Catchment Area and National Comorbidity Study findings regarding age, however, continue to be questioned (Karel, 1997) especially given that the suicide rates were highest in the eighty to eighty four age groups at 72.6/100,000 while the general population was 12.4/100,000 (1988 statistics). She further notes that diagnostic criteria may differ in later life with the use of measurement tools that may produce invalid results. Additional

factors related to misdiagnosis of Major Depressive Disorder in the elderly include symptoms being incorrectly attributed to medical causes, the elderly being less likely to be viewed as functionally impaired, and sampling bias, i.e., they may have died or are unable to participate in surveys due to disability or institutionalization.

An important issue that has arisen in relation to age and Major Depressive Disorder is the notion of a “cohort effect” and temporal trends in the prevalence of the disorder. Klerman & Weissman (1989), in a review of studies with a total sample of 38,172, found that depression does not increase with age (current and lifetime prevalence) in both clinical and community samples. They did, however, find a period-cohort, age-period interaction with increasing rates in younger age cohorts with those born after 1940, except for three studies examined. The Cross National Collaborative Group (1992) examined nine epidemiologic and three family studies (approximately 39,000 subjects) with population samples from North America, Puerto Rico, Western Europe, the Middle East, Asia and the Pacific Rim. Their findings were nearly identical with increasing rates in the cumulative lifetime prevalence of Major Depressive Disorder with each successively younger birth cohort (at all sites but one). The Hispanic sample had rates of Major Depressive Disorder in the older cohort that was equal to the younger cohorts. Lewinshohn et al. (1993) supported these findings in a sample of 2032 adults and 1710 adolescents. The Schedule for Affective Disorders and Schizophrenia-Lifetime Version (Endicott & Spitzer, 1978) and K-Schedule for Affective Disorders and Schizophrenia-Lifetime Version were completed and the trend for Major Depressive Disorder and age were examined using survival analyses as a function of birth cohort in each data set.

Artefactual explanations for these cohort effects have been offered by Hasin & Link (1988) i.e., older individuals lessened ability to recognize depression and mental disorders. They

confirmed their hypotheses, to some extent, by analyzing responses from 152 randomly selected community residents on whether a vignette describing Diagnostic and Statistic Manual-III Major Depressive Disorder represented psychological problems. Notwithstanding, it remains unclear whether increased rates of Major Depressive Disorder in younger cohorts represents a temporal shift, is related to noxious variables in the socio-cultural environment, or is related to greater psychological awareness in progressively younger cohorts.

There are no reported gender effects related to cohort and Major Depressive Disorder. Klerman and Weissman (1989) confirmed a higher risk for females with higher prevalence across all birth cohorts. In fact, across all of the studies reported thus far, it remains clear that gender is the most stable risk factor for depression with an approximate ratio of two: one for females to males (Kizilay, 1992). Many risk factors/predictors have been identified for depression in women, yet no clear-cut evidence for a specific etiology has been elucidated. (Hauenstein, 1991 & Nolen-Hoeksema, 1987).

These findings, regardless of controversy regarding prevalence in older age groups and changes among cohorts, demonstrate the frequent rate of Major Depressive Disorder in the general population. This common disorder affects more than nine million Americans each year.

The Epidemiologic Catchment Area Survey (Narrow et al., 1993) found that one half of all persons receives treatment from a primary care physician. The National Ambulatory Medical Survey (Schurman et al., 1993) mirrored these findings noting that nearly one half of all office visits for mental illnesses are to non-psychiatrists.

2.2 MAJOR DEPRESSIVE DISORDER IN PRIMARY CARE

The prevalence of Major Depressive Disorder at primary care has ranged from 2.8% to 33% (Schwenk et al., 1998; Kessler, 1985; Barrett et al., 1998; Kamerow, 1988; Zung, 1983), the variance often attributed to diagnostic methodology. The Michigan Depression Project (Schwenk et al., 1998) used the Structured Clinical Interview for Diagnostic and Statistic Manual-III-R (SCID) and attained a 13.5% prevalence rate for Major Depressive Disorder, with high levels of comorbidity with anxiety and substance abuse disorder. Kessler (1985) attained a prevalence of 33%, in a sample of 1072, using the Schedule for Affective Disorders and Schizophrenia-Lifetime Version. The majority did not, however, meet diagnostic criteria in a six-month follow-up. Barrett et al., (1998) used the Schedule for Affective Disorders and Schizophrenia (Endicott & Spitzer, 1978) with patients in a rural primary care practice (N=260) and found the prevalence of Major Depressive Disorder to be 2.8%. Kamerow (1988) reported a 30% prevalence rate of Major Depressive Disorder. Zung (1983), using his self-report instrument (Zung et al, 1965), reported a 13.2% rate.

In an examination of 32 studies that used depression self-report scales, i.e., Zung, CES-D, Beck Depression Inventory, etc., and 11 studies that used structured interviews, i.e. Diagnostic Interview Survey, PSE (Bedford College Criteria), Schedule for Affective Disorders and Schizophrenia, etc., (Katon & Schulberg, 1992), the prevalence rates of Major Depressive Disorder at primary care centers was found to range from 9 to 30% and 4.8% to 8.6%, respectively. The authors concluded that structured instruments provided more uniform results while self-reports tended to be more variable.

Misdiagnosis and under-diagnosis of Major Depressive Disorder has been reported as a serious issue (Katon, 1987) as it leads to aggressive medical testing and treatment that carries

iatrogenic injury such as poly-surgery, multiple tests and procedures. The results of under-diagnosis are evident with many patients not receiving treatment for depression and the worst consequence being suicide. Under-diagnosis may result from primary care patient's initial somatic presentation as well as a decreased likelihood to identify them as depressed (Munoz et al., 1994).

Schwenk et al. (1998) reported primary care physicians as only being able to identify 35% of patients with Major Depressive Disorder, presumably the more severe cases. Schulberg et al. (1985) reported only an 18% diagnosis rate of cases by primary care physicians of patients that had previously been identified as depressed through the Diagnostic Interview Survey. Nelson (1980) reported a 50% misdiagnosis rate. Perin et al. (1997) distributed four vignettes of Major Depressive Disorder with subtypes of melancholia, atypical, and psychotic features to 45 internal medicine and thirty-two adult psychiatric residents. They noted widespread difficulty identifying Major Depressive Disorder and its subtypes in medicine house staff and attending physicians who subsequently prescribed incorrect or questionable treatments. Finally, Zung et al. (1983) found that of the one 143 patients who were identified as depressed through the Zung Self-Rated Depression scale from a sample of 1086, primary care physicians were only able to identify 41 as symptomatically depressed.

Thus, it is clear that primary care centers serve as a principal venue in the treatment of depression with approximately one half of those seeking treatment for Major Depressive Disorder receiving it through a non-specialty physician. The prevalence of Major Depressive Disorder in primary care patients ranges from 2.8% to 33% with reported differences dependent on setting, i.e. urban vs. rural and diagnostic methodology. Major Depressive Disorder, nonetheless, remains one of the most common disorders treated at primary care centers. This

notwithstanding, Major Depressive Disorder continues to be under-diagnosed or misdiagnosed due to the clinical presentation of medical patients as well as lack of psychiatric diagnostic expertise in primary care physicians.

2.3 MAJOR DEPRESSIVE DISORDER AND CO-MORBIDITIES

The increased comorbidity of Major Depressive Disorder with various medical disorders has been clearly documented in the literature (Roder & Voshart, 1986; Stein et al., 1991; Felker et al., 1996; Cassem, 1990). Additionally, this comorbidity has often been associated with poor outcome, including increasing rates of mortality (Felker et al., 1996). Major Depressive Disorder has a higher prevalence with the following medical illnesses/conditions: stroke (Schubert et al., 1992; Harrington and Salloway, 1997); Diabetes (Padgett, 1993); Goodnick et al., 1995); Cardiovascular disease (Friechione & Vlay, 1986; Glassman & Shapiro, 1998, Musselman et al., 1998); Cushings Syndrome (Krystal et al., 1990); hypothyroidism (Roose et al., 1999); Cardiovascular Disease (Jackson, 1998); cancer (Massie & Holland, 1990); Parkinson's Disease (Mayeux, 1990); pregnancy and the puerperium (Llewellyn et al., 1997; Pariser, 1993); cigarette smoking (Covey et al., 1998); Rheumatoid Arthritis (Revenson et al., 1991; Pincus et al., 1996); Meniere's Disease (Sanastano et al., 1996) and HIV disorder (Fernandez & Ruiz, 1989).

The lack of thorough medical evaluation and inadequate treatment of physical illness in psychiatric patients is documented (Felker et al., 1996). Psychiatric patients may receive less than optimum care for a variety of reasons including emotional and behavioral problems influencing the type of care they receive, patients' inadequate skills to use the health care system

effectively, and poor completion with appointments and physician recommendation. Felker et al., (1996) discuss the difficulties manifested when psychiatric patients are unable to communicate and follow treatment plans, complicating medical work-ups and differential diagnosis. Psychotropic medications also serve to complicate the medical diagnostic process. Hirschfeld et al., (1997), identify patient adherence and willingness to stay with recommended medical regimen as leading to poor treatment by those psychiatric patients treated at primary care centers.

In summary, major depression has an increased comorbidity with numerous medical illnesses/conditions. This comorbidity results in both under-treatments of the psychiatric as well as the medical illness due to the complexity of providing collateral treatment for depression in the context of the medical disorder. Related to this under-treatment are patient factors such as non-completion and systems issues including poor evaluation and follow-through.

2.4 MAJOR DEPRESSIVE DISORDER AND FUNCTIONAL IMPAIRMENT

Schonfeld et al. (1997) studied the impact of untreated depression on functioning and well being, using the Rand Short Form (SF-36: Stewart et al., 1988), in depressed primary care patients. They delineated Major Depressive Disorder as the greatest factor in the reduction of functional status, both as a single disorder and when co-morbid with another disorder. Using regression modeling, an estimate of the impact of various Diagnostic and Statistic Manual-III-R disorders on functioning and well being, in a sample of 6307 primary care patients, was studied. Major depression had the most effect on SF-36 scores for five of the eight scales (social functioning,

role emotional, mental health, vitality and general health). This was comparable to chronic physical illness, even when controlling for physical comorbidity.

This finding was mirrored in an inpatient group of 63 depressed adults. When compared to a matching non-depressed group, adaptive functioning, as measured by the Community Living Skills Scale (Smith & Ford, 1990) was significantly lower in the depressed group (Zauszniewski, 1994).

Functioning in 48 depressed inpatients, at one-year follow-up, was not found to be fully restored even though depressive symptoms were remitted. Ability to carry out job responsibilities, socialization, rest, recreation and mobilization, as measured by the Sickness Impact Profile (Goethe & Fischer, 1995), were impaired at follow-up in the depressed group. The Medical Outcome Study (Wells et al., 1989) described the functioning and well being of depressed patients compared to patients with and without chronic medical conditions. Three health care provision systems (N=11,242) in the United States participated in the Medical Outcomes Study. Both depressive disorder and depressive symptoms (as evaluated through the Diagnostic Interview Survey) were associated with limitations in multiple dimensions of well being and functioning when compared to patients with no chronic disorders. They concluded that functioning was comparable or worse than that of patients with major chronic medical conditions. Six domains of functioning were explored. They included physical functioning, role execution, social activities, bed days, perception of current health, and being free of pain. Pyne et al., (1997) supported these findings with research using the Quality of Well Being Scale (Endicott et al., 1993). The severity of depressive symptoms, as measured by the Hamilton Scale and Beck Inventory, was inversely related to quality of life as measured by the Quality of Well Being Scale. The physical functioning of patients with Major Depressive Disorder was

significantly worse than four of the major chronic medical disorders. Furthermore, depressive symptoms and medical conditions effects on functioning were found to be additive.

Occupational impairment was examined in a meta-analysis of ten published treatment studies (N = 827) (Mintz et al., 1992). The sample was found to have 10% unemployment and 40% impaired workers. In these treatment studies, it was clear that patients who achieved remission and avoided relapse had good work outcomes while those with continuing symptoms or re-hospitalization continued to be work-impaired. Work impairment was most notable at moderate to high levels of depression.

Kessler and Frank (1997) examined the impact of psychiatric disorders on work loss days using data from the National Comorbidity Survey. Major Depressive Disorder was found to have a bivariate relationship between 30 days National Comorbidity Study/Diagnostic and Statistic Manual-III-R disorder and psychiatric work/impairment days of .45 (.33) for work loss days and 2.77 (.67) for work cutback days ($p < .05$). Pure affective disorder was associated with larger average number of work loss days and work cutback days than any other pure disorders examined for a national projection of four million work loss days and 20 million work cutback days in the United States per year. Higher levels of work cutback days were concentrated in the professional categories while there was similarity in work loss days across occupational categories.

Unipolar major depression was rated as the highest source of burden of disease in the mental illness category in the Global Burden of Disease Study (Murray C.L. & Lopez A.D. eds., 1996). This study, conducted by the World Health Organization, the World Bank, and Harvard University, used a measure named Disability Adjusted Life Years. They found major depression only second to ischemic heart disease in magnitude of disease burden in established market

economies. Disability Adjusted Life Years, measuring lost years of healthy life, found unipolar major depression higher in disease burden than cardiovascular disease, alcohol use, road traffic accidents, lung cancer, dementia, osteoarthritis, diabetes, and Chronic Obstructive Pulmonary Disease.

In a review of family functioning and Major Depressive Disorder, Kertner and Miller (1980) identified the following key manifestations of disturbed family/marital functioning: increased friction with spouses and children; decreased problem solving with spouses and resulting overall marital difficulties; negative relationships between parent's depressive mood and children's functioning; increased parental rejection; difficulty coping with unruly behavior in children; and an overall self-evaluation of decreased functioning by families of depressed patients.

In summary, major depression and depressive symptoms are falling short of full disorder criteria, in outpatients and inpatients, results in significant impairment of functioning in multiple domains including physical, emotional, occupational, and family functioning. This impairment in functioning is equal to or greater than many common debilitating physical disorders. There is conflicting evidence regarding return of full functioning in individuals who have remitted from Major Depressive Disorder.

2.5 MAJOR DEPRESSIVE DISORDER AND ECONOMIC IMPACT

An additional burden of depression to the country is economic. Stoudemire et al. (1986) estimated the direct and indirect cost of depression (morbidity, mortality, direct treatment costs, years of major activity lost, and years of life lost) to be \$16.3 billion per year. Using data from

the Epidemiologic Catchment Area Study and a variety of methodological assumptions and estimates, it was determined the direct costs of depression were \$2,113,325,528. This takes into consideration the costs of inpatient; outpatient, pharmaceutical costs and other non-health care costs. Indirect morbidity costs from lost work years of depression were \$10,028,000,000, more than 75% of the costs of depression to society.

Greenberg et al. (1993) expanded upon this earlier research and studied the economic burden of all types of depression, including not only Major Depressive Disorder but also bipolar disorder and dysthymia. Using a human capital approach, they estimated the annual costs of depression in the United States to total \$43.7 billion. Direct costs were estimated at \$12.4 billion (28%); \$7.5 billion (17%) mortality costs arising from depression related suicides; and \$23.8 billion (55%) derived from morbidity costs related to depression in the workplace. Of the morbidity costs related to affective disorders, \$11.7 billion of the costs reflected excess absenteeism from work during episodes of the illness and about \$12.1 billion in costs due to reductions in productive capacity while at work.

In subsequent studies (Greenberg et al., 1993) (Greenberg et al., 1996), revised the economic burden to \$ 52.9 billion and \$77.4 billion in 1990 (inflation adjusted dollars). The author's most recent study (Greenberg et al., 2003) reports a 7% increase in the economic burden of depression to \$83.1 billion.

Although the researchers use a somewhat different methodology and calculation, using the value of a dollar in different time frames, they both arrive at similar conclusions regarding the preponderance of the cost of depression (Major Depressive Disorder or all affective disorder) coming from indirect categories, i.e., absenteeism and lost productivity. Hall and Wise (1995) additionally reported an employee assistance program survey showing, in any calendar year,

13% of employees experience a clinically significant depression that necessitates time off from work with an average multi-year reduction in earnings of 26%

Comorbidity of Major Depressive Disorder with medical disorders has been correlated with increased cost of health care. Comparisons of primary care patients with a disorder of Major Depressive Disorder (n=6257) and a matching sample (N=6257) showed that annual health care costs were higher (\$4246 vs. \$2371, $p < .001$) for those with depression. After adjustment for greater chronic medical illness in the depressed group, there continued to be large cost differences (\$3971 vs. \$2644). These cost differences continued to persist at least 12 months after initiation of treatment.

Patients screened as “high utilizers” of medical care were screened for Major Depressive Disorder using the Medical Outcomes Survey screen (Henk et al., 1996). A diagnosis of Major Depressive Disorder was associated with \$1498 in higher medical costs (\$5,764 vs. \$4,227, $p < .001$). The authors argue that the average cost of treatment for depression in a primary care setting (\$1400), easily offsets the high utilization of medical care.

In inpatient settings, patients identified with greater levels of psychopathology (anxiety, depression, cognitive dysfunction, or pain) by the Medical Inpatient screening test, demonstrated 40% longer median length of hospital stay and 35% greater mean hospital costs than those with lesser degrees of psycho-pathology. The increased stay and resulting higher costs were attributed to a greater amount of medical procedures. It should be noted that patients were medically equivalent, i.e., the increased pathology group were not more physically ill. The mean length of hospital stay in the depressed group was 11.1 (SD=11.1), compared to 8.8 with those of low levels of pathology ($z = 2.43, p < .01$).

Treatment-resistant depression (defined by two or more unsuccessful trials of antidepressant medication at adequate dose levels for at least four weeks) has been shown (Russell et al., 2004) to significantly raise economic burden. In a study of 7737 patients using MEDSTAT market scan Private Pay Fee Data Base, the researchers found an increase of medical health care expenditures with the degree of treatment resistance and severity. Mean total health care expenditures increased by 104% from \$571 per month to \$1165 per month from the second to the eighth depression medication trial.

It is clear, that a diagnosis of Major Depressive Disorder alone or with comorbid medical disorder creates economic burden. These costs include the indirect (mortality, morbidity, and reduced work productivity), as well as the direct costs of treatment. The indirect costs have been shown to be more profound, ranging from \$10 billion to \$31.3 billion/year. Additionally, comorbid depression, is clearly associated with increased cost of care in both inpatient and outpatient medical settings.

Adequate treatment, however, has been shown to be cost-effective. Revicki and Wood (1998) showed that patients receiving antidepressant medications, from the dosage guidelines of the Agency for Health Care Policy Research, for ninety days or more, had lower mean total medical costs over six months ($\$1872 \pm \140) compared to patients taking less than the recommended dosages ($\$2622 \pm \413), ($p = .032$). The reduction in costs was attributable to lower non-mental health related inpatient costs in those taking the recommended doses ($\$104$ vs. $\$785$, $p = .004$). Of interest, both groups had similar reductions in the Hamilton Depression Rating scale, causing the authors to conclude the greatest impact of adequate treatment was on the frequency of health care visits and related costs.

Treatments and delivery systems that are traditionally seen as “more expensive,” i.e., therapy or integrated psychotherapy/pharmacotherapy by a psychiatrist, were examined for cost effectiveness in two separate studies (Lave et al., 1998; Goldman et al., 1998). Both studies found that while the treatments or delivery systems may have resulted in higher costs, the results were superior in relation to quality of life year gained or reduced usage of services. When psychotherapy and pharmacotherapy were provided by a psychiatrist, there were fewer outpatient sessions (14.7 vs. 26.2, $p < .001$, $X^2 = -11.12$) and lower costs (\$1336 vs. \$1854, $p < .001$, $X^2 = -5.44$) as compared to the delivery system in which pharmacotherapy and psychotherapy are split (Goldman et al., 1998).

Lave et al. (1998) compared standardized interpersonal therapy and pharmacotherapy with Nortryptaline, as compared to usual treatment at primary care center. While more costly, i.e., \$19,510 to \$11,270 direct cost per quality adjusted year, the standardized treatments led to better outcomes, the costs being comparable with others found in routine practice.

Thus, depression is a costly disorder, resulting in an economic burden to the United States ranging from \$16.4 to \$83.1 billion (depending on the year surveyed). These costs include not only those of direct treatment, i.e. inpatient, outpatient, and pharmacologic intervention, but the more extensive costs of lost productivity and workdays through absenteeism or suicide. Treatment has been shown to be effective in producing symptomatic relief and in reducing the costs of service utilization.

2.6 DEPRESSION AND SUICIDE

Unfortunately, even though treatment has been shown to be effective in treating Major Depressive Disorder, there continues to be a number of people who die each year as a result of suicide. The National Institute of Mental Health (2006) reported the suicide totals/year in the United States to be 30,622 in 2001 (the most recent year surveyed). This resulted in an age-adjusted rate of 10.7/100,000 and makes it eleventh in ranking as the cause of death (overall). The total deaths by suicide has been relatively stable with rates in 1992 at approximately 30,000 (McIntosh, 1992), in 1994 at 31,142 (Moscicki, 1997), and in 1998 at 30,575 (National Center for Health Statistics, 2001).

Socio-demographic risk factors for suicide include gender, ethnicity, marital status, and age. Males are four times as likely to die from suicide as females. White males represent 73% of all suicides (National Institute of Mental Health, 2006). Caucasian ethnicity is a significant risk factor with 90% of all suicides committed by white males and females (National Center for Injury Prevention and Control, 2001). Married individuals display the lowest risks of suicide while divorced and widowed exhibit the highest rates. Those never married fall somewhere between the married and marital disruption group (McIntosh, 1992). Suicide rates are higher in the elderly with approximately 20% (6,000/30,000) of suicides reported in 1992 (McIntosh, 1992). The highest suicide rate in the United States is found in white men over the age of 85 (National Institute of Mental Health, 2001). Older adults are at a 50 % greater risk for suicide than all other age groups (Maris, 1992).

Psychopathology (mental and addictive disorders) is considered a central risk factor for suicide (Moscicki, 1995). Of those assessed through psychological autopsy, 90% were found to have had a mental or addictive disorder at suicide. Specifically, affective disorder, especially

Major Depressive Disorder, has been implicated as a major risk factor. Earle et al., (1994), in a survey of the New York Office of Mental Health between April 11, 1988 and August 31, 1991, found that of the 104 suicides reported, the primary diagnosis was affective disorder, 24.1 % compared to 10.6 % for all outpatients ($X^2=16.72$, $df=1$, $p<.001$).

Pokorny (1983), in a prospective study attempting to predict suicide in psychiatric patients (N=4800), found that there was an over-representation of affective disorders and schizophrenia in the completed suicide group ($X^2=24.5$, $p=.001$). Valente (1995) suggests that 40 to 60% of all suicides may be related to major depression. Marin (1992) mirrors this statement by concluding that depressive illness is the single highest predictor in adult suicide (ages 30 to 65). Co-morbid diagnoses are found in a high proportion of those who suicide, especially depression and other affective disorders associated with substance abuse (Moscicki, 1995).

Marin (1997) notes that absent or negative relationships, loss of support, and social isolation are associated with a higher suicide rate. He points out the greater number of people living together in one area the lower the suicide rate.

Genetics and/or family history of suicide have also been identified as an important risk factor for suicide. Mitterauer (1990) found that 100 of 342 depressed patients with a family history of suicide had themselves attempted suicide compared with nine of 80 depressed patients without such a history ($p<.001$). In a comprehensive review of genetic/family studies of suicide, Roy et al., (1997) demonstrated a familial/genetic risk to suicidal behavior (both attempted and completed), with overall risk. These studies include the Iowa 500 study, the Amish study, and various twin, adoption, and molecular genetics studies.

While socio-demographic risk factors have been established, and other moderating variables have been made apparent, i.e., loss of social support and genetic/familial predisposition, attempts to predict individuals who may suicide have been faulty. Pokorny (1983) in a prospective study, attempted to identify those who would attempt or complete suicide. Consecutive inpatient admissions (N=4,800) to a VA hospital were examined on a range of variables thought to be predictive. Discriminant analyses proved inadequate for correctly classifying the subjects. While 20 out of 63 suicides (31.7%) were correctly classified, as were 63 out of 174 attempters (36.2%), there were a large number (1206) of false positives (25.2%). The overall sensitivity was 55.5%, specificity 74.0%, predictive value 2.8% and efficiency 73.8%.

In summary, suicide is the worst possible outcome for any affective episode. The average suicide rate hovers around 30,000/year in the United States with an average age-adjusted rate of 10-11/100,000. Socio-demographic risk factors include gender (male), age (older persons), race (Caucasian), and marital status (divorced or widowed). Psychopathology, specifically affective disorder or comorbid depression and substance abuse are, perhaps, the most significant risk factors. Social environment, i.e., inadequate social support, as well as a family history of suicide or suicide attempt is predictive of future suicidal acts. Overall, efforts to predict who will suicide or make an attempt have been inadequate. Moscicki (1995) identifies prior suicide attempts as being the single best predictor of suicide.

2.7 MAJOR DEPRESSIVE DISORDER AS A RECURRENT AND POTENTIALLY CHRONIC DISORDER

Major Depressive Disorder is not only a disorder with a potentially fatal outcome, but carries other fundamental clinical implications related to its cyclical and/or chronic nature. Mueller and Leon (1996) identify Major Depressive Disorder as a life-long episodic disorder with multiple recoveries and recurrences, averaging one episode per five-year period. In 1988, the MacArthur Foundation Research Network on the Psychobiology of Depression convened a task force to clarify terms related to the specific change points in the course of major depressive illness. These change point terms include “remission, recovery, relapse, and recurrence.”

Frank et al. (1991) identify “remission” as an improvement of sufficient magnitude such that the patient no longer meets syndromal criteria for the disorder or has only minimal symptoms. “Recovery” implies a longer time period and can last indefinitely. In the Diagnostic and Statistic Manual-IV nosology, “recovery” exists when a patient has been asymptomatic for eight weeks. If a patient returns to full syndromal criteria for Major Depressive Disorder prior to the end of this eight-week period, he/she has had a “relapse.” If a patient returns to full syndrome criteria during a period of “recovery” he/she has had a “recurrence.” A “recurrence” is by definition a new episode of Major Depressive Disorder. Prior to 1991, the terms of “remission” and “recovery” as well as “relapse” and “recurrence” were used interchangeably. The authors emphasize the importance of clarity in terms for consistent conceptualization and empiric validation of these events in the course of Major Depressive Disorder.

Much of what is known about the course of Major Depressive Disorder has been made available through analysis of data from the National Institute of Mental Health Collaborative Program on the Psychobiology of Depression (Keller et al., 1982). This naturalistic prospective

study observed and recorded treatment received by those in the study. Clinical course was monitored using the Schedule for Affective Disorders (Spitzer et al., 1978) at various follow-up interviews throughout this longitudinal study. Life tables allowed full use as to the duration of each patient's remission. Estimates of the probability of relapse as a function of time from recovery were calculated, even in the presence of censored data. Predictors of relapse were explored in each separate analysis of the data.

In one of the first published reports from the study (Keller et al., 1982) data from 75 patients who relapsed after a period of remission of the index Major Depressive Disorder episode was examined. The sample included 42 females and 33 males with a median age at entry of 32. The median age at the onset of the first affective episode was 22.5 years. The median score of the Hamilton Rating Scale for Depression, when symptoms were at their worst, was 27.

Of these patients, 24% had relapsed within 12 weeks at risk, 12% of patients relapsing within the first four weeks at risk. Predictors of relapse included an underlying chronic depression (Major Depressive Disorder associated with dysthymia) and three or more previous affective episodes. Those with a superimposed affective disorder of dysthymia were at much greater risk to relapse in the first four weeks at risk compared to those with Major Depressive Disorder alone, 30% vs. 4%, $p < .01$. In fact, more than half of those with the superimposed dysthymia relapsed within the first four weeks at risk. Of those with three or more affective episodes, there was a 43% relapse rate by the twelfth week compared to 11% for those with less than three episodes ($X^2 = 4.96$, 1 df, $p = .026$).

Relapse was further examined in a sample of 141 patients who had Major Depressive Disorder but did not have the pre-existing dysthymic disorder (Keller et al., 1983). Through use of life tables and regression methods, three predictors related to relapse were elucidated. They

included a secondary subtype of Major Depressive Disorder, i.e., comorbid non-affective disorder such as substance dependence, older age at onset of first Major Depressive Disorder, and three or greater prior episodes. Older age at onset of first affective episode and secondary subtype increased the likelihood of relapse. Those with three or greater episodes predicted a significantly shorter time to the first and second prospectively observed relapses (log-logistic regression model, $p = .044$). In fact, doubling the number of prior episodes had the effect of halving the predicted time from recovery to relapse. Those with three or more episodes had 18% second relapse rate by 26 weeks after recovery compared with 73 % who had greater than three episodes.

Lavori et al. (1984), in an extensive review of nine previously published studies on relapse after recovery with re-analysis using life tables, showed that the hazard of relapse declined steadily after the first three years following recovery, especially after the first year. They hypothesize that there may be “healing mechanisms” that come into play when the patient is stabilized over time.

Recovery was examined in a sample of 101 patients with a definite RDC diagnosis of Major Depressive Disorder that included 56 females and 45 males whose median age at entry into the study was 35.3 (Keller et al., 1982). The median age for onset of the first affective episode was 23. The median worst score on the Hamilton Rating Scale for Depression was 28. Again, using life tables and regression models, it was found that the probability of recovering within one year from the onset of the affective episode was 50%. Approximately 85% of those who did recover did so within the first four months. The probability of recovering in the second year was 28%; in the third year 22% and in the fourth year 18%, demonstrating a steady decline in the annual rates of recovery.

Predictors of recovery from entry into the study included acute onset of depressive episode, duration of episode prior to entry into the study, and chronic superimposed depression (Major Depressive Disorder plus dysthymia), $X^2= 9.59$, $df =1$, $p=. 002$. Predictors from actual onset of the depressive episode only included underlying chronic superimposed depression, $X^2=6.02$, $df=1$, $p=. 014$.

Long-term outcomes were examined in a sample of 97 subjects with Major Depressive Disorder but without a history of chronicity or other affective characteristics such as being mixed or cycling (Keller et al., 1984). In this sample with no history of dysthymia but with definite Major Depressive Disorder, 20 out of 97 had not recovered after two years of follow-up. The rate of recovery was the highest after three month of entry and substantially decreased after one year. The rates of recovery are 64 % at six months; 74 % at one year; and 79 % at two years. Of the patients still depressed at six months, 28 % recovered by one year. In the next six months this rate of recovery decreased to 15 % and then to 10 % for those still ill at 18 months.

Predictors of outcome were determined through log regression analysis. Patients seen considerably after the onset of the episode were at considerable risk for remaining ill, $X^2 = 4.04$, $df =1$, $p=. 04$. The first episode of Major Depressive Disorder occurring after the onset of an Research Diagnostic Criteria non-affective disorder, i.e. alcohol or drug dependence, was associated with a poor outcome, $X^2 = 4.48$, $df = 1$, $p=. 03$. Being married increased the chances of a chronic outcome, $X^2 = 6.29$, $df = 2$, $p = .04$. Finally, lower income predicted a poor course, $X^2 = 5.75$, $df =1$, $p = .02$. The probabilities for remaining ill were 19% (seen well after onset of illness), 23% (secondary RDC affective disorder), 23% (married), and 22% (low income).

The risk of chronicity was examined in recurrent episodes in a sample of one hundred one patients with an episode of depression that began while they were in the prospective follow-

up in the Collaborative Depression Study (CDS; Keller et al., 1986). The sample included 37 males and 64 females with a mean age of 38 +/- 15 years. The median duration of well period in the sample was 32 weeks.

The probability (Kaplan-Meyer estimate) for remaining ill for at least one year was 22 %. They also report that the recurrent 20% per episode likelihood of chronicity increases to nearly 30% (the cumulative risk that a member of the cohort of patients with a major depression will eventually fall into an unremitting state of depression). A long time to recovery of the first prospective major depression was examined through Cox regression. Predictors of chronicity included a long prior episode measured from entry ($t= 2.79$, $p=.005$), older age at relapse ($t=2.31$, $p=.018$) and lower family income ($t=2.31$, $p= .034$).

Lavori et al., (1994) using data from the CDS study, found that in non-bipolar patients, the probability that a patient could sustain a recovery for as long as five years was only 22 %. By one year, 40 % had a recurrence, by two years 60 %, and by three years 80 % of the subjects in the study had a recurrence. They note that even those with long remissions continued to be at risk for recurrence. Predictors of recurrence included number of prior episodes, the index episode being a secondary subtype, and a longer index episode from intake. After a substantial period of wellness, endogenous subtype also emerged as a factor in the analysis of recurrence.

Analyses from the Medical Outcomes Study (MOS; Wells et al., 1992) confirmed many of the findings of the Psychobiology of Depression Study regarding the course of Major Depressive Disorder. This observational study of adult patients who received care in a large health maintenance organization, large multi-specialty mixed pre-paid and fee for service group practices, and single-specialty small group and solo practices also examined the course of illness and functional outcomes. The Diagnostic Interview Survey based telephone interview was used

to determine the presence of depression. Current depressive disorder was found in 775 subjects and 1420 subjects had depressive symptoms but no disorder. From these patients a probability sample was drawn for the longitudinal phase of the study. The Course of Depression Interview, based on the Diagnostic Interview Survey (Robins et al., 1981) was administered at 12 and 24-month follow-up intervals.

The findings of the MOS echoed those of the CDS and confirmed the increased probability that Major Depressive Disorder superimposed on dysthymia (double depression) was associated with relapse and worse outcomes. The probability of remission in the first or second year of follow-up was significantly lower among patients with Major Depressive Disorder plus dysthymia than those with Major Depressive Disorder alone at baseline ($p < .01$), especially those who were highly symptomatic at baseline. In fact, if no remission had occurred by year one, those with a double depression had only a 13 to 16% probability of remission by the second year. This was less than one third of the corresponding rate for those with Major Depressive Disorder alone (54 to 65%).

Thus, Major Depressive Disorder is often a cyclical disorder with multiple recoveries and recurrences. The longitudinal prospective observational National Institute of Mental Health study CDS provided much of the information regarding the course of Major Depressive Disorder. The relapse rate was 24 % within the first 12 weeks with the hazard of relapse declining steadily after the first three years, especially after the first year. The probability of recovery declines annually, especially after the first year. The probability of remaining ill for one year was 22% with a 30% risk of falling into an unremitting state of depression. It was estimated that only 22 % of non-bipolar patients were able to sustain a recovery for as long as

five years. Major Depressive Disorder, then, is a much more chronic disorder than had been originally thought.

Predictors of relapse included: Major Depressive Disorder superimposed on dysthymia (double depression); three or more past affective episodes; secondary sub-type of Major Depressive Disorder (comorbidity); and older age at onset. Predictors of recovery included: acute onset of depressive episode; shorter duration of episode prior to entry into the study; Major Depressive Disorder superimposed on dysthymia; secondary subtype of Major Depressive Disorder, being married and low income (increases the chances of chronicity and poor outcome).

It should be noted that much of the information gathered about the change points during Major Depressive Disorder were from a naturalistic, non-randomized study in a pre-selective serotonin reuptake inhibitor era. Thus, it is possible that newer antidepressants with a lower side effect profile may have resulted in different recovery/recurrence rates. Lack of randomization may have resulted in the bias that may affect the results of any clinical trial.

2.8 UNDER-TREATMENT OF DEPRESSION

Depression continues to be an under-treated disorder, regardless of the multiple impacts on the individual and society and its recurrent/chronic course (Davidson & Meltzer-Brody, 1999). Keller (1982) first reported the under-treatment of depression in 217 patients from a community sample in the Psychobiology of Depression Study. Of the entire sample, 67% received psychotherapy while 55% received anxiolytic medication. Prior to entering the study, only 34% were treated with four consecutive weeks of medication and only three% were treated with the most intensive dose of imipramine hydrochloride or its equivalent for a minimum of four weeks.

Only 12% received greater than 150 mg or its equivalent. At least 66% were treated in the lower dose range of 150 mg or less.

During the first eight weeks of this naturalistic study, the inpatients received either no antidepressant treatment or very low sustained levels. Only 49% received 200 mg of imipramine hydrochloride or its equivalent for four consecutive weeks. Of these patients only 19% received 30 minutes of psychotherapy/week. Of the 88 who entered the study as outpatients, 29% received no antidepressants, 24% received very low or brief trials, and only 19% received at least 200 mg of imipramine for at least four consecutive weeks. Of these patients, 52% received less than 30 minutes of psychotherapy/week. Only 44% were seen at least one hour weekly.

Following a series of univariate and multivariate regression analyses on socio-demographic and clinical variables that were identified as contributors to the intensity of treatment, it was shown that the most important determinant to the level of somatic treatment was “university medical center” ($X^2 = 52.7$, $df = 20$, $p \# .001$). The researchers concluded that this supported the view that the treating clinicians’ decisions were the most important factor in low levels of treatment in the community.

The Epidemiological Catchment Area Study (Robins and Regier, 1991) reported only one in ten persons suffering from depression received adequate treatment of that one-third of depressed patients who actually sought treatment.

Using the pooled data from the Epidemiological Catchment Area Study, the National Medical Care Utilization, the National Health Interview Survey, and the National Survey of Access to Health Care, Vessel and Howard (1993) examined the probability of making a mental health visit and of subsequently entering psychotherapy.

The most educated are most likely to make a visit and most likely to enter psychotherapy. Whites are consistently more likely than non-whites to make a mental health visit and to then subsequently enter psychotherapy. While the wealthy were not necessarily most likely to make a mental health visit, they were more likely to engage in subsequent psychotherapy. There was a curvilinear relationship between age and the probability of making a mental health visit. The youngest and the oldest were least likely to make a visit but the youngest (eighteen to 20) were most likely to enter therapy. Males and females were equally likely to enter psychotherapy even though women were more likely to visit a mental health specialist. The separated or divorced are most likely to visit a mental health specialist followed by the never married, those currently married and the widowed. The same ordering holds true for the probability of entering therapy.

Regarding diagnosis, it was found that persons with depression were more than ten times more likely to make a mental health visit than any other Diagnostic and Statistic Manual-III diagnosis. The probability of having a Diagnostic and Statistic Manual-III diagnosis was increased in the least educated, non-whites who are poor. Thus, it appears that many of those socio-demographic groups in most need of treatment are often those who seek out mental health visits and the subsequent psychotherapy the least.

In fact, the Surgeon General reports that less than one third of adults with a diagnosable mental disorder receive any mental health services in a given year (National Institute of Mental Health, 2001). The National Depressive and Manic-Depressive Association in a consensus statement (Hirschfeld et al., 1997) concluded that individuals with depressions are being seriously under-treated even though safe, effective, and economic treatments are available. Reasons for this under-treatment, they concluded, are patient, provider, and health care system factors. Patient factors include a failure to recognize the symptoms, underestimating the

severity, limited access, stigma, non-completion, and inadequate or no health insurance. Provider factors include poor training about depression, inadequate training in interpersonal skills, inadequate time to treat and access depression, failure to apply or prescribe psychotherapeutic approaches, and inadequate dosing and duration of antidepressant medications. Mental health care systems may also inadvertently create barriers to receiving optimal treatment.

2.9 TREATMENT OF MAJOR DEPRESSIVE DISORDER

2.9.1 Pharmacotherapy

Standard treatments for depression produce substantial improvements in 60 to 80% of patients (Friedman, 1997). The Surgeon General (National Institute of Mental Health, 2001) reports that research conclusively demonstrates that treatment are more effective than placebo. The most widely used treatments include somatic treatment such as antidepressant and electroconvulsive therapy as well as various forms of psychotherapy.

Antidepressant medications are effective across the full range of Major Depressive episodes in Major Depressive Disorder (American Psychiatric Association, 1993; Depression Guideline Panel, 1993; Frank et al., 1993). At least 50% of patients usually respond to the first trial of antidepressant (Thase & Rush, 1997).

Antidepressant treatments are most effective under the following conditions: 1) depression is severe; 2) depression with psychotic features; 3) depression has melancholic or atypical features; 4) patient preference; 5) psychotherapy by a competent trained psychotherapist

in one of the depression specific therapies is not available; 6) prior positive response to medication; and 7) for prophylactic maintenance treatment in recurrent Major Depressive Disorder (Frank et al., 1993).

At present there are a wide array of antidepressants with proven safety and efficacy. They include monoamine oxidase inhibitors, tricyclic antidepressants, selective serotonin reuptake inhibitors, adrenergic modulators, serotonin-norepinephrine reuptake inhibitors, and serotonergic antagonist reuptake inhibitors (Stahl, 1996). No antidepressant, thus far, has proven superiority; therefore decisions regarding selection of an antidepressant are based on co-morbid medical condition, drug-induced side effects, medication cost, lethality of overdose, and depression subtype. Antidepressants, in addition, are used in combination with other antidepressants or with another medication in an augmentation strategy (Schatzberg & Nemeroff, 1998).

Patient preference regarding antidepressant and the associated health state has been shown to be an important factor in lower discontinuation rates, despite comparable efficacy (Revicki & Wood, 1998). These researchers found there were consistent preferences for Fluoxetine and Nefazadone hypothetical health states compared to Imipramine health states, regardless of depression severity. Thus, the overall outcome includes not only measures of antidepressant efficacy but also of patient preference for overall health state.

While there are a variety of psychotherapeutic approaches, two time-limited therapies, Interpersonal Therapy (Interpersonal Therapy) (Klerman et al., 1984) and CBT (Beck et al., 1979) have been demonstrated through research, to be effective in mild to moderate depression (National Institute of Mental Health, 2001). Meta-analyses of randomized clinical trials

document the relative equivalence of CBT and Interpersonal Therapy to pharmacotherapy in treating mild to moderate depression (Dobson, 1989; Depression Guideline Panel, 1993).

2.9.2 Interpersonal Therapy

Interpersonal Therapy is a weekly face-to-face present-oriented short-term therapy for the acute treatment of depression (Klerman et al., 1984). This therapy emphasizes the current interpersonal problems of the patient. More specifically, Interpersonal Therapy manages four basic interpersonal problem areas. They include unresolved grief, role transitions, interpersonal role disputes, and interpersonal deficits. Interpersonal Therapy relates symptom onset to overt or covert disputes with significant others whom the person is currently involved (Frank & Spanier, 1995).

Weissman and colleagues (2000) identify three component processes in the therapy's understanding of depression. They include symptom function (depressive affect and neuro-vegetative signs and symptoms are believed to have biological and psychological precipitants), social and interpersonal relations (interactions are derived from learning based on childhood experiences, concurrent social reinforcement, and personal mastery and competence), and personality and character problems (enduring traits that determine a person's reactions to interpersonal experience and may serve as a predisposition to depressive episodes).

Interpersonal Therapy is time-limited, focused on current interpersonal relationships, and avoids intra-psycho issues and cognitive-behavioral approaches. Personality is recognized but not the focus. The Interpersonal Therapy therapist is a non-neutral patient advocate, with the therapeutic relationship based on an alliance with the patient. The stance of the therapist is active, not passive (Weissman et al., 2000).

The therapy is rooted in the interpersonal school of psychoanalysis founded by Meyer and expanded by Sullivan. Bowlby's attachment theory also provided a framework for Interpersonal Therapy. However, the therapy strictly focuses on current relational dilemmas with the assumption that early childhood experiences are reflected in current interpersonal styles and roles (Frank & Spanier, 1995). Interpersonal Therapy has demonstrated efficacy in the short-term (DiMascio et al., 1979; Elkin et al., 1989; Weissman et al., 1979) and long-term treatments for depression (Frank et al., 1990, 1991; Klerman et al., 1974; Weissman et al., 1974).

Interpersonal Therapy has been modified beyond its original application for acute depression to include a model for maintenance therapy of depression (Frank et al., 1991); depressed geriatric populations (Reynolds et al., 1992); adolescents (Mufson et al., 1993); depressed persons with HIV (Markowitz et al., 1992); dysthymia (Markowitz & Kocsis, 1993); depressed primary care patients (Schulberg et al., 1993); Bipolar patients (Ehlers et al., 1988); depressed patients with marital disputes (Klerman & Weissman, 1993); hospitalized elderly patients (Mossey et al., 1992); bulimia (Fairburn et al., 1991); and drug abuse (Rounsaville et al., 1988). Weissman and Markowitz (1994) conclude from clinical trials that Interpersonal Therapy is a reasonable alternative or adjunct to medication as an acute, continuation, and/or maintenance treatment for Major Depressive Disorder. The other applications detailed thus far are described as promising but not fully tested. It was not useful for drug abuse.

2.9.3 CBT

The form of CBT developed by Aaron T. Beck (1979), has taken the view that an individual's appraisal of a situation, thought, or feelings affect the coping process and thereby the resulting behaviors. This therapeutic paradigm, used in a wide variety of problems and clinical

populations, has the following key points: Perception and experiencing in general are active processes that involve both inspective and introspective data. The patient's cognitions represent a synthesis of internal and external stimuli. How a person appraises a situation is generally evident in his cognitions (thoughts and visual images). These cognitions constitute a person's "stream of consciousness" or phenomenal field, which reflects the person's configuration of him, the world, his past and future. Alterations in the content of the person's underlying cognitive structures affect his or her affective state and behavioral pattern. Through psychological therapy a patient can become aware of his cognitive distortions. Correction of these faulty dysfunctional constructs can lead to clinical improvement.

Cognitive therapy, then, views the individual as an information-processing organism that takes in various types of data from outside and within himself. These cognitions include thoughts, feelings and appraisals of situations. Appraisals are formulated and based upon one's own unique cognitive set that is drawn from beliefs, values, upbringing, previous appraisals and his own formulation of himself and the world (Schema). These formulations may be functional or dysfunctional.

Cognitive therapy takes a "common sense" approach and views every person as being capable of using his/her own problem solving abilities to develop more realistic and alternative ways to formulate his experience. The cognitive therapist assists the patient to examine the distortions that are based upon these erroneous premises and assumptions.

Cognitive therapy is active and structured, collaborative in nature, with a clear focus on the here and now. No interpretation of the unconscious is made and transferences to the therapist are not encouraged, assumed, or interpreted. The focus remains on the patient's thinking (especially automatic thoughts) and how that thinking affects the patient's affect and behavior.

The active therapist assists the patient to become his own therapist through various techniques such as setting the agenda, bridging the gap from last session, Socratic questioning, homework assignments, reviewing of advantages/disadvantages, downward arrow technique, reattribution of responsibility, imagery, active monitoring and scheduling, behavioral experiments, and relaxation training, etc. Therapy is generally seen as "short-term" in comparison to other therapies such as psychoanalysis.

2.9.3.1 Efficacy of CBT

An initial review of the efficacy of CBT (Rush, 1983) concluded from the available outcome studies, that CBT was suitable for unipolar non-psychotic depressives with mild to moderate severity. He also notes that it is most appropriate for patients who have the ability to establish a rapid working alliance. Most patients, he reported, who were able to respond (acute symptom reduction of 50 % in Hamilton Rating Scale for Depression or Beck Depression Inventory), did so within five to seven weeks of twice/week CBT. Of the 10 studies of CBT and 11 group CBT studies that were examined, CBT was equal to or superior to a comparison therapy, pharmacotherapy, or waiting list condition.

Miller and Berman (1983) conducted a meta-analysis of 48 studies that employed broader range cognitive and behavioral interventions. Inclusion in the analysis required at least one component of the therapy to focus on maladaptive beliefs. Forty eight percent of the studies (23) consisted of student volunteers, 27% (13) were volunteers from the community, and 25% (12) were outpatients. Of the studies included, only ten (25%) involved the treatment of depression. There was not a uniform outcome measure.

The authors concluded that CBT therapies were superior to "no treatment" but not to other therapies with the difference averaging less than one quarter of a standard deviation. They

do report a larger mean effect size (1.02, $p < .05$) for the depression diagnostic group ($N = 5$) but conclude that no specific diagnostic group was especially amenable to CBT.

A more stringently applied meta-analysis of the efficacy of CBT in depression (Dobson, 1989), was conducted on 28 studies conducted between 1976 and 1987 that employed Beck's model of CBT and utilized a common outcome measure (Beck Depression Inventory). Ten studies compared CBT to a waiting list or no treatment control. The mean effect size was -2.15 (range = -0.58 to -7.24) showing that the average CBT patient did better than 98% of the controls. Nine studies compared CBT and behavioral therapies with a mean effect size of -0.46 (range = 0.33 to -1.03). The average CBT patient, then, had an outcome better than 67% of behavior therapy patients. Eight studies contrasted CBT with various pharmacotherapies with a mean effect size of -0.53 (range = 0.42 to -1.74). Thus, the average CBT patient did better than 70% of pharmacotherapy subjects. Seven additional studies allowed contrasts between CBT and other psychotherapeutic approaches. The mean effect size was -0.54 (range = 0.32 to -0.90) indicating the average CBT patient did better than 70% of the other psychotherapy patients. Dobson concluded from these effect sizes, that CBT was more effective than no treatment, behavior therapy, pharmacotherapy, and other forms of therapy in the treatment of depression.

Robinson et al. (1990) also conducted a meta-analysis of 58 studies of psychotherapy for depression published between 1976 and 1986. Forms of CBT were identified as significantly more effective than general therapies and antidepressant treatment. However, significance levels were reduced to trend level when investigator allegiance was examined, i.e., investigators who had a particular allegiance to CBT.

CBT is one of two psychotherapies included in the guidelines for the treatment of depression published by the Agency for Health Care and Policy Research (AHCPR), (McGinn,

2000). These guidelines provide information to primary care physicians and the general public on depression and its treatment (Munoz et al., 1994). The Depression Guideline Panel (1993), conducted a meta-analysis informing the AHCPR, and determined that CBT had an overall efficacy rate of 46.6% (\pm 6.9%) with an advantage of 30% (\pm 22%) when compared to waiting list conditions (Thase, 1995). The study incorporated eleven studies with twelve cells: ten adult, two geriatric, eleven outpatients, one inpatient; four-group psychotherapy and eight individual therapies (Frank et al., 1993). Individual CBT had a higher efficacy rate (50.1%) in the AHCPR meta-analysis (Thase, 1995) than group CBT (39.2%).

Gaffan et al. (1995) re-examined those studies in Dobson's meta-analysis, paying particular attention to researcher allegiance to CBT. They confirmed Dobson's original findings that CBT was more effective than control conditions, behavioral therapies, pharmacotherapy, and other psychotherapies. They did, however, find smaller effect sizes and only significant difference when compared to waiting list and attention control groups after taking into account the allegiance of the studies investigators. Larger effect sizes were associated with researchers who had a high allegiance to CBT, although these relationships were non-significant.

Gloaguen et al. (1990) conducted a recent meta-analysis of 78 outcome trials of CBT published between 1977 and 1996. Studies were of Major Depressive Disorder that had been specifically operationalized, used the Beck Depression Inventory as an outcome measure, included a control group, and employed randomization. The results showed that CBT was superior to waiting list or placebo control ($p < .0001$), the average CBT patient doing better by 29% as compared to the average control patient. CBT was superior to antidepressants ($p < .0001$), equal to behavior therapy ($p = 0.95$), and superior to miscellaneous psychotherapies ($p < .01$).

Butler et al. (2005) reviewed the meta-analyses of clinical outcomes in a wide variety of populations receiving CBT. Fifteen methodologically rigorous meta-analyses were reviewed. A total of 332 studies with 9,138 subjects were included. Large effect sizes (.90) were seen for unipolar major depression, generalized anxiety disorder, panic disorder with and without agoraphobia, social phobia, and childhood depressive anxiety and depressive disorders

The preceding meta-analyses included efficacy studies of CBT under, for the most part, well controlled conditions. Seligman (1995) provides results from a large Consumer Reports survey examining perceived effectiveness of existing treatments for psychological problems. He argues that the effectiveness survey yields credible empirical validation of how patients fare under the actual conditions of treatment in the field. Approximately seven thousand subscribers to Consumer Reports specifically responded to the mental health questions included in the 1994 annual questionnaire. Of the 7000, 2,900 saw a mental health professional. Twenty-six questions were asked about type of therapy, presenting problems, satisfaction, etc. Multiple regressions were conducted from the transformed subscales (specific improvement, satisfaction, and global improvement). One of the many findings from the survey suggested that no specific psychotherapy did better than any other for any problem. While Seligman acknowledges the flaws of the survey (sampling bias, no control group, reliance solely on self-report, lack of blindness, retrospective report, and non-random assignment) he touts it as clinically significant information that reflects an unbiased view of treatment in the community.

Even more controversial, has been the findings of the National Institute of Mental Health's Treatment of Depression Collaborative Research Program study (Elkin et al., 1989). The efficacy of CBT, Interpersonal Therapy, Imipramine plus case management, or placebo plus case management was examined in this randomized 16-week multi-site trial of 250 unipolar

depressed patients. The study also included a longitudinal follow-up. The Treatment of Depression Collaborative Research Program study found that CBT only exceeded pill placebo by 9.4% (SD=8.3) in its efficacy. In addition, the Treatment of Depression Collaborative Research Program study results indicated that pharmacotherapy was superior to CBT in the treatment of more severely depressed outpatients in the study. Issues regarding pre-treatment severity of depression and response to CBT were, at least, partially supported in subsequent studies (Thase et al., 1991; Hollon et al., 1992).

The findings of the Treatment of Depression Collaborative Research Program Study significantly influenced practice guidelines for the treatment of Major Depressive Disorder (American Psychiatric Association, 1993; Agency for Health Care Policy Research, 1994) suggesting CBT to be most appropriate for mild to moderately severe Major Depressive Disorder. Persons et al., (1996) argues this point, with a presentation of other studies underscoring the results of CBT's efficacy in severe patients, as mixed rather than conclusive.

Finally, evidence from multiple CBT clinical trials indicates that CBT may offer some protection against relapse (Evans et al., 1992; Blackburn et al., 1986; Kovacs et al., 1981; Simons et al., 1986; Fava et al., 1998; Thase et al., 1992; Paykel et al.). Thase and colleagues (1992) showed that patients who had fully recovered during a 16 week CBT program were less likely to relapse (9%) during a one-year follow-up compared to patients with residual symptoms at the end of treatment (52%). Even the controversial Treatment of Depression Collaborative Research Program Study (Shea et al., 1992) evidenced lower rates of relapse at 12 months (9% for CBT vs. 28% for TCA + CM) and 18 months (36% for CBT vs. 50 % for TCA + CM).

Conversely, Parker et al. (2003) vigorously argue that CBT is only of equivalent, not superior, efficacy to other psychotherapies. CBT's general efficacy, they judge, has been

overblown and misrepresented due to methodological errors and misinterpretations in several of the meta-analyses reported in the literature, i.e., Gluaguen et al., (1998). Specifically, incorporation of placebo control and wait list patients into one composite group, disallows analysis of a placebo effect.

They dismiss claims that CBT has demonstrated relapse prevention properties. They further argue that CBT in combination with pharmacotherapy (a synergistic effect) may, in fact, be its most suitable use.

Additionally, the authors identify CBT researcher's inability to conclusively validate the model or to demonstrate efficacy in a wide range of depression severities and subtypes as factors that decrease its purported usefulness. Non-specific factors such as structure, patient participation, behavioral components, initial hope, etc., may be possible mechanisms of action separate from the theoretical model.

The heterogeneity of Major Depressive Disorder, they argue, requires a uniquely "prescribed" therapy or intervention. The treatment, the authors conclude, should match the patient signs and symptoms rather than the practitioner obliging a patient's disorder to fit a homogeneous therapeutic model.

In summary, several meta-analyses or reviews of existing CBT studies have demonstrated CBT to be an efficacious treatment, especially when compared to waiting list, pharmacotherapy, and other miscellaneous therapies. Meta-analyses, using more stringent inclusion criteria, i.e., a standard outcome measure, evidence more robust findings for the efficacy of CBT. Issues of concern and/or controversy include lack of control groups in Rush's initial findings comparing CBT and medication (Hollon et al., 1993), investigator allegiance to CBT and subsequent results (Robinson et al., 1990; Gaffan et al., 1995), issues of real world effectiveness of CBT as

compared to other psychotherapies (Seligman, 1995), the methodological validity of meta-analyses done thus far (Parker et al., 2003) and the ongoing controversy regarding CBT's efficacy in more severe patients in relation to its poor showing in the Treatment of Depression Collaborative Research Program Study. These issues notwithstanding, CBT is one of only two psychotherapies considered efficacious such that they are recommended by the APCHR in their published practice guidelines. Finally, CBT appears to offer some protection against relapse in this often chronic and recurring disorder.

The efficacy of CBT, to at least some degree, is evidenced by the modifications that have been made to various other clinical populations. They include: Borderline Personality Disorder (Linehan, 1993; Lee & Overholser, 2004); use; Substance Abuse (Beck et al., 1993); Personality Disorder (Beck et al., 1990); Computer Administered CBT (Selmi et al., 1990); Panic Disorder (Shear et al., 1994); depressed adolescents (Wilkes & Rush, 1988); Depressed Inpatients (Scott, 1988; Shaw, 1981; Thase & Wright, 1991); Suicidal Behavior (Freeman & Reinecke, 1993; Ellis, 1996); Anxiety disorders and Phobias (Beck et al., 1985) and Bipolar Disorder (Zaretsky et al., 1999; Scott, 2001). In addition to these specific modifications, CBT has been examined in a multitude of psychiatric and non-psychiatric studies with largely positive results. Some of these groups and applications include: EEG sleep patterns in Major Depressive Disorder (Thase et al., 1992; Thase et al. 1996); nocturnal penile tumescence in Major Depressive Disorder (Nofzinger et al., 1993); gender and CBT response in CBT (Thase et al., 1994); chronic depression (Thase et al., 1994; Scott, 1992); of diaries in well older adults (Campbell, 1992); religious/non-religious CBT (Propst et al., 1992); group CBT for panic disorder (Telch et al., 1993); social phobia (Bruch et al., 1991; Gelertner et al., 1991); generalized anxiety disorder (Borkovec & Costello, 1993; Power et al., 1990; Butler et al., 1991); bulimia nervosa (Wilson, 1991; Agras et al., 1992;

Wilfrey et al., 1993; Leitenberg et al., 1994; Garner et al., 1993; Fairburn et al., 1991); anorexia nervosa (Channon et al., 1989); Nursing Home residents (Abraham et al., 1992); rheumatoid arthritis (Keefe & Van Horn, 1993); chronic fatigue syndrome (Lloyd et al., 1993; Surawy et al., 1995; Sharpe et al., 1996); body image disturbance (Fisher & Thompson, 1994); dental anxiety (Getka & Glass, 1992); male spousal abusers (Faulkner et al., 1992); insomnia in older adults (Edinger et al., 1992); recurrence of duodenal ulcer (Wilhelmsen et al., 1994); primary care depressed patients (Teasdale, 1985); marital therapy (Teichman et al., 1995); medically unexplained symptoms (Speckens et al., 1995); depression in type II diabetes mellitus (Lustman et al., 1998); and obsessive compulsive disorder (Emmelkamp et al., 1991).

2.9.3.2 CBT Homework

Beck (1979) views homework, in particular, as a critical vehicle from which data, which disconfirms many of the patient's negative beliefs and distortions can be obtained. As it makes therapy more concrete by examining the week that has gone by, it enhances the therapeutic communication with the patient. Homework reinforces and serves as a supplemental educational aspect of the therapy itself. Rush (1983, p.110) further states its critical nature: "homework assignments help the patient develop objectivity about situations that are otherwise stereotypically misconstrued; identifies underlying assumptions, and develops and tests alternative conceptualizations and guiding assumptions." Kovacs (1980) suggests homework assignments are a testing ground to help the patient test the validity of negative notions and to provide mastery experiences as well. Homework is not only viewed as an experiment to test out faulty ways of thinking but to also learn new types of compensatory skills that decrease depressive relapse (Barber & DeRubeis, 1989). Homework is considered particularly relevant to the treatment of depression as the characteristics of the disorder itself (motivational, cognitive, and

behavioral disturbances) interact to reduce the effectiveness of typical therapeutic interventions such as psychoeducation, advice, and the development of insight (Thase & Callan, 2006). Types of homework assignments for the depressed patient are detailed in Appendix B.

While homework is described as an integral approach in CBT and other therapies with a behavioral component, only one published study was found examining the frequency to which clinicians actually incorporate it into everyday practice. Kazantzis and Deane (1999) sent a survey inquiring about demographics, frequency of homework (homework) use, frequency of procedures used in recommended homework, and perceived importance of homework assignments in the treatment of different patient populations to clinical psychologists registered with the New Zealand Psychologist Board (N=358). Of the 221 usable returns, it was found that CBT practitioners reported use of homework in 66% of sessions as compared to 48% of sessions in non-CBT therapists [$t(174.64) = 5.28, p < .001$]. They further evaluated the therapists' perception of the importance of homework for various patient problems and found that 69% believed homework was rated as having great importance in the treatment of depression; 19% rated it as moderately important and only 4% rated it as having little importance.

Several studies have presented data that homework assignments, assigning and adherence, predicted improvement in depressive symptoms in samples of Major Depressive Disorder. Fennell and Teasdale (1987), in a study of 34 moderately to severely depressed patients randomly assigned to either CBT or treatment as usual, evaluated treatment response through use of the Beck Depression Inventory, either bi-weekly for the CBT patients, or weekly for the treatment as usual patients. The researchers found that CBT led to a rapid reduction in depression. The change on the Beck Depression Inventory for the CBT group between pretreatment assessment and week two correlated significantly with changes on the Beck

Depression Inventory over the whole treatment period [$r(15) = .58, p < .02$]. They examined the process in therapy to elucidate this early treatment change for those in CBT. They found that patients who responded positively to the conceptualization of depression presented in the “Coping with Depression” booklet and of the success of homework tasks carried out between session two and three showed immediate reductions in depression and a positive long term outcome. The authors concluded that homework empirically validated the rationale offered in the booklet.

Zettle and Hayes (1987) conducted a component and process analysis of CBT in a 12-week therapy course with twelve depressed women between the ages of 22 and 64 years. Subjects were required to have a 20 or above on the Beck Depression Inventory. The three components of distancing (recognizing that depressive beliefs were hypotheses not facts), cognitive restructuring, and behavioral homework were included. Subjects were randomly assigned into one of four treatment cells within a two X two factorial design. They included: cognitive restructuring vs. distancing plus cognitive restructuring X absence or presence of behavioral homework. All subjects received 12 sessions of CBT with varying lengths of the assigned component. They were rated with the Beck Depression Inventory and Hamilton Rating Scale one week post-treatment and two months later.

No significant differences were found between the therapeutic trends of the two cognitive components. Subjects receiving behavioral homework, however, reported lower depression than those who did not (adjusted M of 11.59 vs. 20.17). Additionally, subjects who received behavioral homework reported greater enjoyment from engaging in pleasant activities than did the group who was not assigned behavioral homework.

Persons et al., (1988), in an examination of the efficacy of CBT in 70 private practice patients with Major Depressive Disorder, found that along with initial Beck Depression Inventory score and endogenous symptoms, homework completion and interaction between homework completion and initial Beck Depression Inventory significantly predicted end of treatment Beck Depression Inventory scores. Patients who did homework improved three times as much as those who did not. The mean initial Beck Depression Inventory score for completers was 21.61. Homework led to a reduction to 13.92 or a 64.4% reduction in the group that did homework (when other factors were held constant). When not controlling for other effects, the actual mean reduction was 16.6 points for those who did homework with a percentage change of 73.4. Those who did not do homework had a reduction of 22.7% on the Beck Depression Inventory.

Neimeyer and Feixas (1990) conducted a study in which group members were randomly assigned to either group CBT with homework (N=32) or CBT with no homework (N=31). A repeated measures two X three ANOVA (homework vs. no homework X pre vs. post vs. follow up) on the entire sample showed a robust reduction in the Beck Depression Inventory between the two groups ($F = 34.43, p < .0001$). An additional two X three repeated measures ANOVA (pre vs. post X homework vs. no homework demonstrated Hamilton Rating Scale for Depression scores decreased significantly from pre-therapy to post-therapy ($F = 59.56, p < .0001$). A multiple regression procedure was performed and ratings by an independent clinician post-therapy also showed substantial improvements for the group assigned to homework.

In an attempt to understand the processes of change in the CBT treatment of depression, DeRubeis and Feeley (1990) conducted a factor analytic study of data from 25 adult outpatients with Major Depressive Disorder. One factor representing “concrete” symptom focused methods

of CBT, predicted subsequent symptom reduction when assessed early in treatment but not later. These concrete methods included encouraging patients to undertake straightforward focused tasks between sessions as well as discussing these tasks in session. The authors concluded that adherence to this aspect of theory specified procedure was an important factor in the success of CBT. They replicated this finding in a subsequent study (Feeley et al. 1999).

Startup and Shapiro (1993) conducted a confirmatory analysis of DeRubeis and Feeley's (1990) model as well as that of Hollon (1988) derived from the Treatment of Depression Collaborative Research Program Study results. Hollon's factor analysis produced a model that clearly differentiated "cognitive and behavioral" components, especially those that focus on homework. From ratings of one hundred twelve sessions, the final model clearly validated the Hollon model. They failed to validate the DeRubeis and Feeley model of the "concrete and abstract" cognitive features.

Ilardi and Craighead (1994) reviewed the role of non-specific treatment factors in several studies of CBT. They concluded that homework was a non-specific treatment factor that promoted a decrease in depression through increased hope and self-efficacy. The authors also comment on the importance of homework assignments in validating the "treatment rationale" of CBT.

In a study comparing a related model of cognitive/behavioral therapy and psychodynamic/interpersonal therapy, Startup and Edmonds (1994) examined 235 sessions of therapy in 25 patients. Patients had scored at least 16 on the Beck Depression Inventory and met Diagnostic and Statistic Manual III criteria for Major Depressive Disorder. The mean age was 41.8 years (SD=9.1 years) and the mean Beck Depression Inventory score was 25.5 (SD=7.1). At the end of treatment the mean Beck Depression Inventory score had dropped to 10.0

(SD=8.1). Therapists categorized the type of homework assignment given for each session and rated completion with homework on a seven point scale (one = the assignment was not completed to seven = the assignment was completed as agreed). The mean number of assignments per session was 1.81 (SD= .99). The mean of the therapist's rating of completion was 4.59 (SD=2.24).

Two multiple regression analyses, one using Beck Depression Inventory scores at the end of treatment as the dependent variable, the other using Beck Depression Inventory scores at three month follow-up, were performed to test the relationship between completion and outcome. The model included age, sex, Beck Depression Inventory at session one, and early and late completion. The multiple R for the complete model at the end of treatment was .89, $F = 7.25$, $p < .004$, and the adjusted $R^2 = .68$. Early completion accounted independently for 13% of the variance.

The multiple R at the three-month follow-up was reduced to .77 (adjusted $R^2 = .42$, $F = 3.28$, $p = .05$). Only initial symptom severity made a significant independent contribution to the prediction. Thus, early completion was most important in predicting outcome at post-treatment. These findings support Fennell and Teasdale's earlier findings regarding early completion and homework assignment.

Three areas concerning homework completion were examined in a study of endogenous major depressives with a Hamilton Rating Scale for Depression score of 15 or greater (Bryant et al., 1999). They included relationship of homework completion to treatment completion, relationship of therapist behavior to completion, and relationship of selected patient variables to completion. The subjects included 26 outpatients (8 men and 18 women) with a mean age of 37.38 years (SD= 9.64) and an average of 1.77 previous episodes (SD = 2.23). The mean pre-

treatment Hamilton Rating Scale for Depression was 21.08 (SD = 3.59) and the Beck Depression Inventory was 24.77 (SD = 7.72). The Assignment Completion Rating Scale (Primakoff et al., 1986) was used to assess quantity of homework completion to each therapy assignment. This operationally defined scale ranged from one (the patient did not attempt the assigned homework) to six (the patient did more of the homework than was requested). The Therapist Homework Assignment Competency Scale was developed by the first author of the study to assess homework related therapist behaviors. Specifically, the Therapist Homework Assignment Competency Scale rated: reviewing previous week's assignments; providing a rationale for the assignments; clearly assigning and tailoring the homework to the patient problems and seeking reactions to the assignment as well as developing strategies to deal with completion issues. The Hamilton Rating Scale for Depression and Beck Depression Inventory were assessed weekly while the Assignment Compliance Rating Scale and the Therapist Homework Assignment Competency Scale assessed in sessions in the beginning, middle and end phases of this 16-week, 20 session course of CBT.

For all sessions the mean Assignment Compliance Rating Scale was 4.01 (SD=1.38). Homework completion was high with 51.6% of sessions characterized by subsequent homework completion and only 10 % of sessions that the patient did not attempt to complete assigned homework. There was significant improvement on symptom measures. The Hamilton Rating Scale for Depression fell from a mean of 21.08 (SD = 3.59) to 4.35 (SD = 4.40) at termination and on the Beck Depression Inventory from 24.77 (SD = 7.72) to 6.25 (SD = 7.18).

Correlations were computed between the averaged Assignment Compliance Rating Scale and the Hamilton Rating Scale for Depression indexes of change. Mean Assignment Compliance Rating Scale scores significantly predicted percentage of change in Hamilton Rating Scale for

Depression scores from pre to post-treatment [$r(12) = .66, p < .01$] and residual change in Hamilton Rating Scale for Depression scores [$r(12) = -.71, p < .01$]. Beck Depression Inventory scores, however, were not significantly related to percentage change, [$r(12) = .35, p = ns$] or residual change in scores [$r(12) = -.29, p = ns$]. There was also a significant relationship between therapist review of previous week's session homework (Therapist Homework Assignment Competency Scale item 1) and completion at next session [$r(60) = .39, p = .002$].

Thus, completion with homework was significantly related to patient outcome but only when measured by the Hamilton Rating Scale for Depression scale. The therapist behavior most robustly connected to patient outcome was review of previous session's homework assignment. The author's conclude the lack of a correlation between completion and Beck Depression Inventory may have been related to sample size. There was a sizable portion (22.8%) of homework assignments not followed up or reviewed in the next session, precluding Assignment Compliance Rating Scale ratings.

Burns and Spangler (2000) examined the causal relationships linking homework completion with depression using structural equation modeling. Two groups of depressed outpatients from Dr. Burn's clinic were included in the analyses. The first had a sample of 122. The second, the replication group, had a sample of 399. Patients were studied using a variety of assessments including the Beck Depression Inventory, Hopkins Symptom Checklist-90 (Derogatis et al., 1974), Empathy Scale (Burns & Nolen-Hoeksema, 1992), and Willingness Scale (Burns & Nolen-Hoeksema, 1991). Specific to completion were the therapist and patient's estimates of homework completion. Patients were randomly assigned to therapist and received CBT alone or CBT with medication.

A model was tested to examine three causal paths: 1) the causal effect of depression (DEP) prior to treatment and then at the end of treatment (DEPF); 2) the causal effect of depression at post-treatment to homework; and 3) the causal effect of homework at the end of treatment (DEPF). The causal effect of homework on DEPF was -4.32 ($CR = -2.89$, $p < .01$) but the causal effect of DEPF on homework was not significant ($CR = 0.19$). The effect of homework on DEPF indicates there was an average 4.35-point drop on the Beck Depression Inventory for every unit change of homework. The authors concluded that homework had a causal effect on depression severity but that depression severity did not influence homework completion.

Kazantzis et al., (2001) argue the above authors interpretation of causal inferences when the overall study design was descriptive with correlation analyses. They further identify the methodological deficits of retrospective ratings, which may inflate compliance ratings and failure to adjust for therapist competence levels. In a reply to this criticism, Burns and Spangler (2001) reviewed the general methodology of structural equation modeling to negate the implication of causality in the initial report.

Homework completion, as well as acceptance of treatment rationale (ATR), was examined in relation to within treatment change and outcomes of CBT in depression in a sample of 150 (Addis & Jacobsen, 2000). Patients were included if they had a Diagnostic and Statistic Manual III-R diagnosis of Major Depressive Disorder; a score of 20 or higher on the Beck Depression Inventory; and a score of 14 or higher on the Hamilton Rating Scale for Depression. ATR was measured after each session by a single question, "To what degree does the treatment you are receiving match with your ideas of what helps people in psychotherapy?" on a scale from 0 (not at all) to 100 (completely). Depressive symptoms were measured with the Beck

Depression Inventory pre-treatment and before each session. The Hamilton Rating Scale for Depression (17- item scale) and the Beck Depression Inventory were administered at the post-treatment assessment. Homework completion was measured on a seven-point scale after each session.

A three-step mediation regression analysis was performed. Semi-partial correlations done from step-wise regressions showed early completion was correlated at .23, $p < .01$; mid-change at .12 (NS); and final outcome at .17, $p < .05$. Mid-completion was associated with mid-change at .18, $p < .05$ and with final outcome at .17, $p < .05$. Separate and independent contributions of ATR and completion in predicting treatment change and outcome were demonstrated. The authors concluded that the findings supported a multi-process model of change in CBT, i.e., ATR may promote involvement in treatment while completion with homework contributes to additional change.

To explore factors contributing to homework completion and eventual outcome, Burns and Nolen-Hoeksema (1991) used the Self-Help Inventory (Burns et al., 1987) in a group of mixed affectively disordered patients diagnosed by the Structured Clinical Interview for DSM-IV. The authors examined the frequency with which subjects used active coping strategies when depressed, as well as the perceived helpfulness and willingness to learn new coping strategies. They predicted initial coping scores and subsequent homework completion would be correlated with outcome following a 12-week CBT course. They also predicted initial coping scores and homework completion would be simultaneously correlated with outcome.

Frequency of the use of coping strategies (pretreatment) did not predict completion with homework (as estimated by the therapists): $r(123) = .06$, ns, and $r(168) = .06$, ns (post-treatment at week 12). Neither was patient's willingness to try new coping strategies significant with

therapist's or patient's estimates of completion with homework assignments: $r(167) = .14, p < .06$ (therapist's estimates) and $r(122) = .12, p = .17$ (patient's estimate). Contrary to their initial predictions, the frequency at which patients used active coping strategies before treatment was not correlated with completion with homework or with the degree of improvement at outcome.

A regression analysis was performed to determine the additive effects of homework completion (as measured by patients) and coping factors on twelve-week outcome, measured by the Beck Depression Inventory, controlling for depression severity pre-treatment. The R^2 for the equation was 43.2%, $F(5,116) = 17.67, p < .0001$, showing the homework completion variable contributing 6.6 % of the unique variance in the outcome, above and beyond what was accounted for by the three coping factors and the initial Beck Depression Inventory. Burns and Nolen-Hoeksema concluded that findings from the regression analysis cross-validated Persons et al. (1988) earlier findings that patients completing homework assignments had a better clinical outcome than those who did not.

Kazantzis et al. (2000) used meta-analytic technique to examine the effects of homework assignments on therapy outcome and the relationship between homework compliance and outcome. Studies were included if they were: published in English; reported the assessment of homework compliance or examined the effects of homework assignments on therapy outcome or the relationship between homework compliance and outcome. Of the 719 studies that were initially surveyed, only 31 met criteria. The sample was further reduced, as sufficient statistical information was not provided in the four studies that were excluded.

Effect sizes were calculated using coefficient r . Eleven of the studies examined the effect of homework assignments in therapy and sixteen examined the relationship of compliance and treatment outcome. The sample included ten Major Depressive Disorder studies. The mean

effect size of homework assignments on therapy outcome was $r = .36$. The mean effect size for the depression studies in this analysis was .38. Weighted average correlation ($r=.22$) indicated that homework compliance is a significant predictor of therapeutic outcome. The mean effect size for the depression studies in the compliance analysis was .22. The authors conclude the results are a clarification of homework's contribution to therapeutic outcome.

Additionally, homework completion has been shown to be an important factor to outcome in other clinical populations such as in the development of assertiveness (Kazdin & Mascitelli, 1982); agoraphobia (Edelman & Chambless, 1993); Social Phobia (Edelman & Chambless, 1994); and in elderly depressed persons dealing with developmental losses (Campbell, 1992).

In summary, homework is viewed as critical in the theory of CBT as it disconfirms negative beliefs and distortions (Beck et al., 1979). It also extends exposure time to therapeutic elements beyond the time in the session, allowing for "practice" of what was learned in therapy (Rush, 1983; Kovacs, 1980). Homework has been shown to be a frequently used tool of CBT therapists, one study showing its use in 66 % of sessions (Kazantzis & Deane, 1999).

Depressed patients who comply with homework assignments in CBT have been shown to have an early response to treatment (Fennell & Teasdale, 1987; DeRubeis & Feeley, 1980; Startup & Edmonds, 1994). Fennell and Teasdale (1987) hypothesized the response associated with early completion to homework was based on validation of the rationale and theory behind CBT.

Other researchers (Persons et al., 1988; Neimeyer & Feixas, 1990; Bryant et al., 1999; Burns & Spangler, 2000; Addis & Jacobsen, 2000; Burns & Nolen-Hoeksema, 1991) have demonstrated that completion with homework assignments in CBT was associated with an

overall better outcome. Homework was shown to have an independent contribution to treatment outcome, above and beyond the overall CBT intervention (Addis & Jacobsen, 2000; Burns & Nolen-Hoeksema, 1991). Burns and Spangler (2000), showed, through structural equation modeling, that for every unit of homework completion, the Beck Depression Inventory dropped 4.35 points. Persons et al., (1988) showed that those who complied with homework improved three times as much as those who did not, with a mean Beck Depression Inventory reduction of 16.6. Neimeyer and Feixas (1990) showed homework completion to produce significant mean reductions in both the Beck Depression Inventory [24.03 (SD= 7.29) to 14.68 (SD=9.38)] and the Hamilton Rating Scale for Depression [17.27 (SD= 5.89) to 8.13 (SD=4.37)] while Bryant et al., (1999) showed mean reductions in the Hamilton Rating Scale for Depression [21.08 (SD=3.59) to 4.35 (SD= 4.40)] at treatment outcome. Kazantzis et al. (2000), through meta-analysis demonstrated a significant effect size, when analyzing 27 studies with homework as an intervention, for the effects of homework on treatment outcome and the relationship between homework compliance and treatment outcome.

Thus, completion with homework is associated with improved outcome when measured by well established self-report (Beck Depression Inventory) and interviewer administered (Hamilton Rating Scale for Depression) measures of depression severity. The exact mechanism for change associated with homework completion in CBT has not been clearly demonstrated. Ilardi and Craighead (1994) suggest the assignment and subsequent completion of homework creates hope and feelings of self-efficacy. Therefore, they see homework as a non-specific moderator integral to symptom improvement in CBT. Finally, the symptom improvement associated with homework completion, has been demonstrated in other clinical populations including social skills training (Kazdin & Mascitelli, 1982); agoraphobia (Edelman &

Chambless, 1993); social phobia (Edelman & Chambless, 1994); and elderly depressed persons dealing with developmental losses (Campbell, 1992).

2.9.3.3 Barriers to Homework Completion

Non-adherence to homework assignments has been broadly explained by an inter-relationship among task, therapist, and patient variables (Detweiler & Whisman, 1999). The authors later tested this theory (2005) using audiotapes from the CPT project (Hollon et al., 1992) and coding specific patient, task, and therapist variables as present/not present or within a given factor's specific range, i.e., from one, the patient did not attempt homework up to a range of three, did most or all of homework assignment. 20-four outpatients who were in the CBT protocol and had between two and six codable audiotaped sessions in the first month of treatment were included. Four coders identified as "advanced undergraduates from Yale" coded the tapes along the specific patient, task, and therapist variables: Level of client adherence to homework; level of client involvement in assignment and discussion of homework; therapist setting of concrete goals; therapist initiation of discussion of barriers to completing homework assignments and use of written reminders of homework assignment.

They found clients who had greater levels of involvement in the assignment of homework had better outcomes mid-treatment compared to clients who exhibited higher levels of involvement in the review of homework, who had a better two year outcome. Therapist discussion of barriers to involvement in homework with less involved clients, setting of concrete goals, and use of written homework reminders was correlated with positive outcome. The study demonstrated that all three variables were significant to outcome.

2.9.3.4 Task

Difficulty of homework assignment has been identified as an important variable in non-adherence or failure to adopt health-promoting behaviors (Broder, 2000; Conoley et al., 1994; Beck, 1995; Sennott- Miller & Miller, 1986). Task difficulty, in particular, has been identified as an often-neglected consideration in the adoption of health promoting behaviors. Difficulty is often viewed as a constant rather than variable (Sennott-Miller & Miller, 1986). These factors in addition to inappropriate and ill-defined assignments have been identified by Beck (1995) as impediments to homework completion.

In a study of 30 men and 30 women (age 26 to 70), chosen randomly from a church directory, Sennott- Miller & Miller (1986) examined the likelihood of adopting a health related task, i.e. eating a diet low in cholesterol, and the perceived difficulty of the task. Subjects were asked to consider ten health promoting behaviors in relation to: 1) the effectiveness a task would have in reducing the risk of heart trouble; 2) how difficult it would be to adopt; and 3) the likelihood of adopting the behavior. Subjects were trained in magnitude estimation. The average amount of the criterion in question was assigned a level of ten. For each behavior subjects were asked to assign a number to the item depending upon how much more or less of the criterion characteristic it had than the behavior chosen to be average.

A regression analysis was performed, using logarithmically transformed data, on likelihood with effectiveness and perceived difficulty: $\text{Likelihood} = 19.9 (\text{Effectiveness}^{.19}) (\text{Difficulty}^{-.50})$ $R^2 = .92$. Difficulty was consistently a stronger predictor of likelihood of adopting a health promoting behavior than perceived effectiveness of the task. In fact, the relationship between the likelihood of adopting the associated behavior and the perceived

difficulty was curvilinear. The likelihood of performing a particular activity decreased substantially when difficulty went from a low to a moderate rating.

Conoley et al. (1994) examined graduate student and faculty counselors (personal, family, social, vocational, and educational issues) with respect to the match between the problem and the recommendation; the difficulty level of the recommendation and the degree to which the recommendation built on client strengths. Seven raters rated 3 tapes. Four raters scored predictor variables. Four scored screening variables, i.e., client/counselor relations. The criterion variable was also scored without knowledge of the predictor variable.

Difficulty was rated as not difficult, moderately difficult, or difficult. How well the recommendation matched the problem was rated on a three-point scale from one (low rating) to three (well explained). Whether it built on client strengths was scored dichotomously (yes or no). Implementation was only considered if it had been partially or completely accomplished. Inter-rater agreement regarding criterion variables ranged from .657 to 1.00 (Kappa).

An overall regression analysis was significant, $F(3, 33) = 22.96, p < .0001, R^2 = .68$, showing all variables predicted implementation. All three predictors added to the model: 1) building on the client's strengths, $\beta = 0.48, t(33) = 4.11, p < .0002$; 2) recommendations matching the problem, $\beta = 0.30, t(33) = 2.83, p < .008$; and 3) difficulty of the recommendation, $\beta = -0.26, t(33) = -2.17, p < .04$.

Thus, adherence is reduced when the task is excessively difficult, inappropriate or ill defined, not built on client strengths and not clearly associated with the identified problem or complaint. The findings, however, are descriptive and/or based on non-CBT counseling or health intervention.

2.9.3.5 Therapist Activity

Behaviors on the part of the therapist have been identified as critical to the implementation of homework assignments. Therapist skill (Thase & Callan, 2006) includes the persuasive abilities of the therapist in relation to convincing patients to try assignments; making homework a part of the regular flow of the therapy session, using positive reinforcement, and dealing with nonadherence, and matching the needs and abilities of individual patients.

Worthington (1986) examined homework completion in a study of 61 adults (older than 21 years of age) who received counseling at an adult community agency operated by the psychology department at a large urban university. Presenting problems involved career, emotional, family, or adult transition problems. Counselors were 16 practicum students with masters' degrees.

Therapist skills were rated by the Ranking of Counselor Skills (RCS), a 38- item form that assessed ability to form therapeutic relationships, conceptualization and assessment, intervention, awareness of the impact of the counselor thoughts, feelings, and behaviors on the counselor/client; openness to supervision and professional demeanor and behavior. Ratings were from one to five on each item. Patient problems were rated on a five-point Likert scale from absent (zero) to severe (four). Client change was rated on a 13-point scale from very much worse (zero) to no change (six) to very much better (twelve). Homework assignments were rated on two separate scales. The first, the Homework Assignment Report (HAR: Martin & Worthington, 1981) had one section to identify and rate the type of homework assigned and a second section that listed 18 counselor behaviors (rated dichotomously as yes or no), associated with behaviors that may have been used during homework assignments. The second section is completed the following week and rated as to the degree to which the client completed the

homework. It was rated on a six point scale from (1) did the opposite of what I directed to (6) do exactly what I said and even extended it. Counselor's estimate of clients' reaction to homework was rated on a nine- point scale from (one) unsatisfied to (nine) satisfied.

A MANCOVA was performed, using initial problem severity as the covariate and counselor's rating of clients' completion, reaction to the homework, and final problem severity as dependent variables. It revealed non-significant results, $F(6, 20) < 1$. A MANCOVA using weighted mean completion, weighted mean reaction to homework and final problem severity as dependent variables was significant, $F(3,38) = 15.67, p < .0001$. The locus of effect, identified through univariate ANOVA, was in final severity, $F(1, 40) = 25.70, p < .0001$.

There was a difference in completion dependent upon phase of therapy, $F(2,156) = 4.79, p < .01$) with early phase of therapy demonstrating more client homework completion. Completion was higher with homework related to the use of standardized instruments, $F(1,157) = 5.65, p < .02$.

A stepwise linear regression was done to predict completion with homework assignment. The best model involved counselor-checking attitudes about homework [$R^2 = .08$ (standardized Beta = .30)]; counselor-stressing status as an expert was negatively related to completion ($R^2 = .17$, incremental $R^2 = .09$, Beta = -.22) and the fraction of previous sessions in which homework that was assigned was completed ($R^2 = .21$, incremental $R^2 = .04$, Beta = .29). A fourth variable, counselor stressing the importance of homework did not add to the overall R^2 (incremental $R^2 = .01$. Overall $F(3,100) = 8.96, p < .00003$. Thus, the best predictors of completion were: whether the client stayed in counseling; how counselors treated homework that was assigned the previous week, i.e., did they review homework in the session; when homework was assigned, and the client's previous response to homework.

Bryant et al. (1999) examined follow-up of homework assignments by therapist (subjects and methods described previously). They found a significant relationship between therapist reviews of previous sessions homework, as measured by THACS item one, and homework completion measured at next session [$r(60) = .39, p = .002$]. Furthermore, when examining other therapist variables, i.e., therapist skills, in a hierarchical regression, examining homework predicted subsequent completion, increasing R^2 to .23, a change of .112 [$F(1, 55) = 8.03, p < .01$]. The authors suggest that examining therapist-operating procedures, i.e. reviewing patient homework, may be the most important variable to consider when examining a patient's noncompliance to CBT homework.

Therapist follow-up has also been identified by Detweiler and Whisman (1999) as a factor that could affect adherence to homework assignments. Failure of the therapist to follow-up on the previous week's assignment is thought to diminish the importance of homework and contribute to non-completion. Other therapist behavior such as inappropriate goal setting and mismatching the difficulty of the assignment to patient ability creates obstacles for homework completion (Shelton & Levy, 1981). Failure to explain the rationale for a particular assignment as well as the overall importance of homework to the success of CBT promotes non-adherence (Burns & Auerbach, 1992; Worthington, 1986).

Cox et al. (1988), in a study of 30 subjects at an outpatient behavioral clinic, randomly assigned patients to a verbal or written behavioral prescription in a counterbalanced, within subjects, crossover design. They found that written prescriptions led to better recall and adherence to homework assignments ($F = 13.02, p < .001, 89\% \text{ vs. } 71\% \text{ (recall)}$) and ($F = 9.96, p < .005, 78\% \text{ vs. } 62\% \text{ (adherence)}$). Burns and Auerbach (1992) also recommended the practice of carefully listing assignments to improve completion with homework.

Therapist competence has been identified (Shaw et al., 1999; Davis & Hollon, 1999) as a significant variable that must not be overlooked in treatment outcome and the execution of homework assignments. Davis and Hollon (1999) identify therapist insensitivity and inflexibility as impacting compliance with homework assignments. Shaw and colleagues (1999) researched therapist competence in CBT in relation to therapeutic outcome in the multi-site The Treatment of Depression Collaborative Research Program Study. Fifty-nine patients were entered into the CBT condition. Eight CBT therapists were trained and certified across three sites. Measures included the Hamilton Depression Rating Scale, the Beck Depression Inventory, The SCL-90, and the Cognitive Therapy Rating Scale (Young & Beck, 1980). The Cognitive Therapy Rating Scale, an 11-item scale, measures CBT competence. Factor analysis has revealed two factors within the instrument. “Skill” includes general therapeutic ability such as collaboration, interpersonal effectiveness, empiricism, and implementation of strategy. “Structure” included three items: setting an agenda, pacing the session, and homework review and assignment. Scores are attained through expert review of videotaped therapy sessions.

Bivariate correlations and results of multiple regression demonstrated the structure subscale was responsible for results found with the Cognitive Therapy Rating Scale total score. Significance was found for this subscale and Hamilton Rating Scale for Depression-17 ($p < .05$) and the Beck Depression Inventory ($p < .05$). The authors note that the structure subscale had lower internal consistency (.43) than the Cognitive Therapy Rating Scale as a whole (.84) or the skills subscale (.86). Notwithstanding, this subscale consistently correlated with positive outcome measures, indicating the importance of therapist skill in assigning and monitoring homework to treatment outcome.

Finally, therapists may have various negative cognitions that effect non-adherence. Beck (1995), identified frequent therapist cognitions, i.e., the patient is overburdened, too fragile, or was insulted with confrontation about non-adherence about homework, that contribute to patterns of homework failure. Newman (1994) also suggests that therapists may also “give up” with homework when patients continually resist doing homework, i.e. the lack of patient response may actually extinguish the therapist’s correct behavior in relation to homework.

In summary, therapist behavior has been identified as a critical element related to CBT homework adherence. These behaviors include inappropriate goal setting and mismatch between patient ability and assignment (Shelton & Levy, 1981); failure to explain the rationale and importance of an assignment (Burns & Auerbach, 1992; Worthington, 1986); therapists negative cognitions about homework completion (Beck, 1995); and therapists giving up on homework due to patient’s repeated non-adherence (Newman, 1994). These conclusions, however, are anecdotal recommendations from leading CBT authors and not based upon well-designed research. Other non-CBT research on the use of homework in counseling (Cox et al., 1988; Worthington, 1986) has found that homework completion was associated with therapist’s treatment of homework from the previous session and use of written prescription of desired patient activity. These findings are either descriptive or based upon a non-depressed sample. Bryant et al.’s research (1999) in a sample of CBT patients with Major Depressive Disorder is the most compelling evidence that the therapist’s review of homework improves subsequent homework completion.

2.9.3.6 Patients

There have been numerous patient factors related to homework non-completion identified in the descriptive CBT literature. They may be broadly characterized as: 1) Lack of Understanding; 2)

Emotional; 3) Cognitions; 4) Resistance; 5) Environmental; and 6) Characteristics of the Patient. See Appendix A for a listing of these factors.

Patient factors, however, have not been shown in the research literature to be significant in relation to homework completion. Factors such as age, education, depression severity, learned resourcefulness (Bryant et al., 1999); use of active coping strategies (Burns & Nolen-Hoeksema, 1991); and problem severity (Worthington, 1986), were unrelated to homework completion. The descriptive CBT literature, then, appears to be at odds with the sparse research findings that patient factors are not influential when evaluating homework completion. In particular, Davis and Hollon (1999) identify patient attitudes and beliefs as a significant factor in noncompliance with CBT homework. They describe two types of patient noncompliance patterns. “Passive noncompliance” describes the patient who would like to complete the homework task but for a variety of reasons does not. The patient with “active resistance” has a specific reason for not wanting to complete the homework assignment. These patterns as well as unrealistic expectations about the pace of change may affect the degree of homework compliance.

2.9.3.7 Self-Efficacy

Self-efficacy has been posited as a patient variable that may impact homework completion in a profound manner. Bandura’s Social Learning theory (Bandura, 1977) defines self-efficacy as the “judgments of how well one can execute courses of action required to deal with prospective situations” (Bandura, 1982, p. 122).

Whether an action is undertaken, according to Bandura (1977), is dependent upon “outcome expectancy” and “efficacy expectation.” Outcome expectancy is a person’s estimate that a given behavior will lead to certain outcomes. Efficacy expectancy, in contrast, is the belief that one can execute an action successfully so as to produce the outcomes. Efficacy determines

how much effort, as well as how long, a person will persist when faced with barriers, i.e., people with higher efficacy expectations will persist to success in the face of obstacles. Conversely, low efficacy expectancy leads to fear and avoidance of particular situations that are judged as threatening while high efficacy expectancy leads to affirmative behavior.

Efficacy expectations are based upon performance accomplishments, vicarious experience, verbal persuasion, and emotional arousal. Bandura (1977; 1977; & 1982) suggests that performance accomplishments provide the most dependable source of efficacy expectations. Repeated failures will, however, lower mastery expectations, while repeated successes raise them and even allow for periodic failure.

Bandura (1977) suggests that conversation alone, i.e., talk therapy, is not necessarily effective in altering defensive human behavior. Corrective learning experiences that are performance based and allow for mastery experiences may be more powerful. He notes that psychological procedures alter the level and strength of self-efficacy. “Lasting change, however, in self-efficacy and behavior, is best achieved by participant methods using powerful induction procedures to develop capabilities then removing the external aids to verify personal efficacy, then finally using self-directed mastery to strengthen and generalize expectations of personal efficacy” (Bandura, 1977, p.202).

Failure to carry out corrective experiences, i.e., to perform homework assignments, may be related to problems with both efficacy and outcome expectations. A patient may have low efficacy expectation and not believe in his own ability to carry out the assignment and/or he may not believe the homework assignment will produce the desired result (outcome expectancy). Thus, self-efficacy may interact with CBT homework non-completion in a circular manner. A patient with low self-efficacy may be less likely to complete a homework assignment believing

he/she is incapable of completing the task and/or alternately disbelieving it will produce the desired outcome. Repeated non-completion with homework assignments will deprive the patient of corrective learning experiences designed to improve beliefs of self-efficacy.

Kavanagh (1983) advanced a model whereby the development and conclusion of depressive episodes is effected by a reciprocal relationship between self-efficacy, performance accomplishments, and mood. According to the model, immediate change in activities that are viewed as highly significant to a person's depression would be most effective in ending an episode as they take advantage of the mutual influence of the three variables.

A study was conducted to test this model (Usaf & Kavanagh, 1990) with 60 depressed subjects who were randomly assigned to receive CBT or to be on a waiting list. Groups were matched for age and Beck Depression Inventory score, CBT N = 31, waiting list N = 29. Subjects were included if they met Research Diagnostic Criteria for Major Depressive Disorder (Spitzer, et al., 1978); had duration of Major Depressive Disorder of at least one month; a score of at least an 18 on the Beck Depression Inventory; and a raw score of 40 on the Self-Rating Depression Scale (Zung, 1965).

Two separate self-efficacy measures were constructed based on principles outlined by Bandura. In the first set, subjects rated degrees of control or confidence in reaching performance criteria from ten (uncertain) to one hundred (certain). Set two included The Assertion Efficacy Questionnaire (Gambrell & Richey, 1975) and the Athletics Efficacy Questionnaire (Kavanagh & Bower, 1985). Self-monitoring scales corresponded to content areas in self-efficacy scales, i.e., tension, enjoyment, negative thoughts, social confidence, and mood.

The final sample, after attrition, included nineteen in the treatment group (16 females, three males), and 24 in the waiting list group (19 females, 5 males). The mean age of the

treatment group was 37.6 years and in the waiting list group was 40.7 years. Mean educational level of the treatment group was 11.4 years and in the waiting list group 11.6 years. In the total sample, 39.5% were married or in a de facto relationship. All F-tests to compare the groups were non-significant.

Treatment included CBT groups modeled on the Coping with Depression Program (Lewinsohn et al., 1982). Groups were divided into six to eight subjects who received ten, two-hour sessions over eight weeks (twice/week for the first two weeks and once/week for the remaining six sessions). MANOVA results (F-values) Pre vs. Post-treatment are presented in Table 1 (Usaf & Kavanagh, 1990, p.59).

Table 1 MANOVA Results Pre vs. Post Group Treatment

Variable Group	df	Group Across Time	Time	Group X Time
Depression	2, 39	2.01	13.64 ^{***}	1.29
Self-Efficacy (1)	5, 33	0.19	6.52 ^{***}	3.08 [*]
Self-Efficacy (2)	2, 38	1.96	8.98 ^{***}	3.30 [*]
Self-Monitoring	5, 32	0.52	7.12 ^{***}	4.56 ^{**}
ATQ-30	1, 40	1.88	20.42 ^{***}	7.06 [*]

* p < .05
** p < .01
*** p < .001

In a separate MANOVA comparing post-treatment vs. three-month follow-up, gains were maintained or increased, most notably that of depression, $F(2, 15) = 4.66, p < .05$. The mean Beck Depression Inventory post-treatment was 17.76 and at follow-up was 11.94 ($N = 17$). The authors conclude that the results support the reciprocal relationship between mood, performance, and self-efficacy. They explain the lack of effect for depression at post-treatment to be due to the possible weaker effect of a group CBT strategy compared to an individual approach.

Cervone et al. (1994) conducted three separate experiments examining mood induction, self-efficacy, and personal standards of performance. The subjects included 34 to 90 undergraduates (depending on experiment). Each experiment involved mood induction along with a hypothetical situation or simple task examining performance criterion and associated ratings of self-efficacy. In all three studies subjects exposed to the negative mood inductions

required higher performance standards to feel satisfied with their attainments without a specific effect on perceived self-efficacy. Thus, negative mood may affect standards of performance, raising them inordinately, rather than effecting self-efficacy per se. It should be noted that these experiments were conducted on a non-depressed sample and represent hypothetical situations and related performance criterion. The results, therefore, are less robust and should not be generalized to a depressed population.

Teasdale (1985) posits that effective treatment for depression, rather than facilitating a general sense of self-efficacy in controlling depression, instead gives a specific sense of efficacy in dealing with “depression about depression.” He recommends targeting specific depression management skills, i.e., constructive or pleasant activity, exercise, positive social interaction, and modification of thought content to develop this specific sense of efficacy in dealing with “depression about depression.”

Finally, in a study of 66 depressed patients who received treatment focused on interpersonal skill, cognitions, or pleasant events, Zeiss et al. (1979) found no difference in outcome. Patients improved on most of the dependent variables. The authors conclude that these results can be explained from a self-efficacy framework, i.e., as long as a treatment improves a patient’s sense of self-efficacy, it is adequate. Specifically, they detail the following criteria to be necessary for a treatment to be considered adequate (Zeiss et al., 1979, pp. 437-438):

1. “Therapy should begin with an elaborate, well-planned rationale. This rationale should provide initial structure that guides the patient to the belief that he or she can control his or her own behavior, and thereby, his or her depression.

2. Therapy should provide training in skills that the patient can utilize to feel more effective in handling his or her daily life. These skills must be of some significance to the patient and must fit the rationale that has been presented.

3. Therapy should emphasize the independent use of skills by the patient outside of the therapy context and must provide enough structure so that the attainment of independent skill is possible for the patient.

4. Therapy should encourage the patient's attribution that improvement in mood is caused by the patient's increased skillfulness, not by the therapist's skillfulness."

These recommendations support the relation of homework completion and independent skills training to self-efficacy, regardless of the therapy.

In summary, self-efficacy is a potent theoretical construct that is considered when examining patient non-completion with CBT homework assignments. Bandura's theory regarding self-efficacy provides a framework for understanding homework non-adherence. Kavanagh (1983) provides an additional model to illustrate the reciprocal relationship between self-efficacy, performance accomplishments, and depressed mood. Usaf and Kavanagh (1990) conducted a study in depressed patients receiving either group CBT or waiting list conditions to test the model. In separate MANOVA's (pre vs. post-treatment and post-treatment vs. three-month follow-up) nearly all variables examining mood, performance, and perceived self-efficacy were significant in the treatment group. Excessive performance standards were found to be the

result of negative mood induction rather than a change in perceived self-efficacy, suggesting that standards as opposed to self-efficacy was related to low moods. This finding, however, was in a group of non-depressed college students dealing with hypothetical situations. The self-efficacy model was advanced as the rationale for improvement of “depression about depression (Teasdale, 1985), and overall depression, regardless of treatment modality (Zeiss et al., 1979).

2.10 METHODOLOGICAL CONSIDERATIONS

At the present time there is no consensus as to the average failure rate in completing homework assignments (Detweiler & Whisman, 1999). Furthermore, Shelton and Levy (1979) expressed concern that in a survey of 4 behavioral journals spanning a five-year time frame, 60% of the articles reported homework use as a part of the treatment protocol, yet few gave information regarding the frequency, duration, and setting where assignments were given, and the completion rate of the given task. Primakoff et al. (1986) also noted the lack of research studies that investigate homework completion as a variable that could affect outcome, in particular, the specification, standardization, and statistical analysis of homework use.

The information presented thus far presents non-completion as a multi-factorial dilemma. Numerous theoretical explanations, as to why patients may be non-compliant with CBT homework assignments, were discussed. There is, unfortunately, no consistent systematic method to measure homework completion or to appraise potential patient, therapy, and task factors contributing to non-adherence with homework assignments.

Primakoff et al. (1986) called into question the existing published CBT research with respect to a failure to explore homework as a predictor variable. This omission has resulted in

several potential sources of error variance that may make interpretation of the results difficult. In particular they identify these sources or error variance as: Completion Bias; Confounding Third Variable; Completion Decay; Specific vs. Non-specific effects of Cognitive therapy homework and possible negative effects of homework.

Differences in outcome between treatment groups can be due to the degree of completion with the treatment protocol, rather than the protocol itself. This completion bias creates interpretive problems with studies in which this may be factor. Primakoff et al. (1986) call into question the existing CBT research, as the failure to look at homework as a predictor variable in many of the studies creates the possibility of completion, i.e., without studying the degree of homework completion, there can be differential availability of this important ingredient of CBT itself. They criticize CBT researcher's for this critical omission citing the fields use of treatment manuals for therapy and use of the Cognitive Therapy Rating Scale (Young et al., 1983) to rate therapist completion, yet there is no systematic vehicle to measure homework completion. An adequate measurement tool would allow use of inception cohorts to examine within group variability with homework completion.

Completion may be a marker of superior outcome for variables other than the protocol itself, i.e., a third variable that is correlated to increased adherence and a more positive outcome. CBT research has examined process variables such as "learned resourcefulness" as well as other patient moderator variables in the prediction of outcome, yet few studies have included homework completion to detect this possible confound (Primakoff et al., 1986).

Completion decay may also result from a failure to systematically assess homework completion across the entire course of the study, both active and follow-up phases. Differing rates of homework completion over time together with a breakdown in monitoring completion,

creates error variance. The treatment's failure to demonstrate "relapse prevention" may not be related to the CBT itself, but rather, to noncompliance with homework assignments (Primakoff et al., 1986).

Without detailed assessment of homework completion, it is difficult to determine whether the specific as opposed to the non-specific effects of CBT homework assignments are producing a change. Primakoff et al. (1986), identifies some of these non-specific effects of homework such as increased self-efficacy and the increased activity related to action-oriented homework assignments. The indirect results from homework completion may be considerable in effecting a positive outcome. They identify the need to examine the specific cognitions that are targeted from a particular assignment as well as use of "placebo" homework assignments to study the specific vs. the non-specific effects of homework.

Finally, the authors state the importance of assessing for potential negative effects of homework assignments. Not all CBT assignments produce the intended positive results. Deleterious effects such as guilt and self-criticism may inadvertently affect treatment outcome.

Finally, Kazantzis and Lampropoulos (2002) criticize clinical research studies of CBT as not accounting for the possibility that patients may engage in homework that is different from the actual assignment. Researchers, the author's conclude has generally failed to address the quality of homework compliance. In a more recent review of the literature of thirty two CBT research studies, Kazantzis et al. (2004) reported eight studies that used retrospective patient accounts; only 4 that used the same measure of homework compliance, and more than half that relied on a single measure of homework compliance. The vast majority focused of quantity of homework compliance without addressing quality. Additionally, most employed correlational designs that

cannot determine causality and rely on small sample sizes that are inadequate to test hypotheses about moderating effects (Kazantzis et al, 2000; Thase & Callan, 2006).

Given the importance of homework as an important therapeutic ingredient in CBT and the above mentioned issues that create error variance in the interpretation of CBT research, the authors recommend assessment of therapist completion in assigning homework, i.e., use of the Cognitive Therapy Rating Scale, and the degree of homework completion, both the degree to which they did the homework assignment and the quality of the performance. They advocate specific operationalized criteria that would establish competent performance of both cognitive and behavioral assignments. They advance the concept of an “expert rater” who would judge the quality of the homework performance much like an “expert rater” judges the overall quality of the CBT therapist itself. They also suggest the use of multiple measures of completion such as written logs, therapist interview, and live observation to evaluate homework performance (Dunbar, 1979).

2.11 PSYCHOMETRIC NOMENCLATURE

The American Psychological Association (1985) recommended an alternate approach to determine psychometric properties of tests or assessments. Instead of the traditional delineation of reliability and validity, they advocated validity to be considered a unitary concept. Categories within this unitary concept (Nitko, 1996) provide evidence for validity and include:

1. **Content Representativeness and Relevance**, which determines the degree to which the assessment tasks or items are a representative sample from a larger domain of performance and support the intended use of the assessment.

2. **Thinking Skills and Processes (Substantive evidence)** examines the kinds of thinking processes and skills used to complete the instrument successfully.
3. **Internal Structure Evidence** evaluates the relationship among the assessment tasks or parts of the instrument.
4. **External Structure Evidence** appraises how well the assessment results correlate with other variables or criteria, i.e., how well the SAT predicts scholastic achievement. Within this category are predictive validity evidence (the extent to which the individual's future can be predicted by prior performance on an assessment instrument) and concurrent validity evidence (the extent to which an individual's current status on a criterion can be estimated from current performance on an assessment instrument).
5. **Reliability over Time, Assessors, and Content Domain (Reliability Evidence)** refers to the consistency of the assessment results. Without consistency there is no reliability, which places a limit on validity.
6. **Generalizability over People, Conditions, or Special Instructions and Interventions (Generalizability Evidence)** explores how broadly the assessment results and applications to certain conditions can be validly interpreted.
7. **Intended and Unintended Consequences (Consequential Evidence)** scrutinizes the effects of educational and social values on assessment results, i.e., externally imposed versus classroom-generated assessment of performance.
8. **Cost, Efficiency, Practicality, and Instructional Features (Practicality Evidence)** examine the impediments to the proper use of the assessment such as complexity, training requirements, and cost.

Content, Internal Structure, External Structure, and Reliability Evidence were examined in the psychometric evaluation of the draft and revised instrument “Barriers to CBT Homework Completion Scale.”

2.12 SUMMARY

Depression is a common disorder, having lifetime prevalence from 5 to 17.1%. (National Institute of Mental Health, 2000; Regier et al., 1988; Regier et al., 1993; Kessler et al., 1994; Blazer et al., 1994). This disorder affects greater than nine million Americans each year (National Institute of Mental Health (2000). Greater than 50% of depression treatment occurs in primary care settings (Narrow et al., 1993). The prevalence of depression at primary care settings ranges from 2.8 % to 33 % (Schwenk et al., 1998; Kessler, 1985; Barrett et al., 1998; Kamerow, 1988; Zung, 1983). Unfortunately, Major Depressive Disorder is often misdiagnosed or under-diagnosed in these settings resulting in extensive under-treatment (Katon, 1987). Major Depressive Disorder is frequently co-morbid with other psychiatric and medical disorders (Roder & Voshart, 1986; Stein et al., 1991; Felker et al., 1996; Cassem, 1990). This comorbidity is often associated with poor outcome (Felker et al., 1996). Major Depressive Disorder that is untreated or under-treated leads to poor quality of life on multiple dimensions such as occupational and family functioning (Schonfeld et al., 1997; Pyne et al., 1997; Mintz et al., 1992). The economic impact of Major Depressive Disorder is in the billions of dollars/year, most of the cost due to lost work productivity and work years (Stoudemire et al., 1986; Greenberg et al., 1993, 1996). The worst possible outcome related to Major Depressive Disorder is suicide, which is the 11th leading cause of death in the United States (National Institute of

Mental Health, 2006; Moscicki, 1995). The disorder is described as an episodic and/or chronic illness with high rates of relapse and low rates of remission in a segment of patients afflicted with Major Depressive Disorder (Mueller & Leon, 1976). Yet Major Depressive Disorder is severely under treated with estimates of adequate treatment ranging from only 10 to 33 % (Hirschfeld et al., 1997). Treatment, however, i.e., pharmacotherapy, can, provide improvement in 60 to 80 % of patients with Major Depressive Disorder (Friedman, 1997). Interpersonal Therapy (Klerman et al., 1984) and CBT (Beck et al., 1979) have emerged as therapies shown to be efficacious in the treatment of Major Depressive Disorder. CBT, in particular, has been shown to be efficacious and, often, superior to medication comparisons, waiting list, and placebo (Rush, 1983; Miller & Berman, 1983; Dobson, 1989; Robinson et al., 1990; Butler et al., 2005). In addition, it has been suggested to offer protection from relapse (Thase et al., 1992; Evans et al., 1992; Blackburn et al., 1986; Simons et al., 1986 and Fava et al., 1998). Homework is an important component in CBT (Beck, 1979; Rush, 1983). Several studies have shown completion with CBT homework to be associated with favorable treatment outcome and early treatment response (Fennell & Teasdale, 1987; Zettle & Hayes, 1987; Persons et al., 1988; Neimeyer & Feixas, 1990; Burns & Spangler, 2000). There are, however, manifold identified barriers associated with acceptable homework completion (Detweiler & Whisman, 1999). Barriers to homework adherence may be related to the task itself, therapist behaviors, patient factors, and levels of patient self-efficacy (Detweiler & Whisman, 1999). Unfortunately, there is no systematic method to assess the barriers that may lead to homework non-completion or adequate approach to measure homework completion (Primakoff, 1986). This deficit in CBT may not only hamper individual patient clinical progress but has called into question existing CBT research (Shelton & Levy, 1979; Primakoff, 1986). Without a reliable instrument to assess

barriers to homework completion and acceptable performance of homework, error variance may restrict the interpretation of results. The scale to be developed and psychometrically tested for reliability by this researcher may assist clinicians in consistently measuring barriers to successful CBT homework completion. This is the first step in a multi-stage research process that will eventually include testing of predictive validity of the proposed instrument through measurement of homework completion.

3.0 METHODOLOGY

This non-experimental descriptive study was designed to develop and evaluate the content evidence, internal structure, external structure, and reliability of scores from an instrument “Barriers to CBT Homework Completion Scale.” This instrument was designed to measure barriers a patient may experience in completing CBT homework assignments. The study was conducted in two separate phases. Devellis’ (1991) guidelines on scale development served as the foundation for the study (See Figure 1).

Phase I employed a modified approach to qualitative data collection and analysis to identify the relevant barriers to completion of CBT homework. Barriers were identified through interview of 20 depressed patients currently in CBT as well as 20 therapists considered expert in the field of CBT. These barriers were then developed into items, which were designed into an instrument, through consultation with psychometric experts. Phase II involved piloting the draft instrument in a sample of 56 depressed CBT patients. Internal structure was examined through factor analysis. The instrument was analyzed for reliability as well as external structure evidence, i.e., the instrument’s ability to predict homework completion.

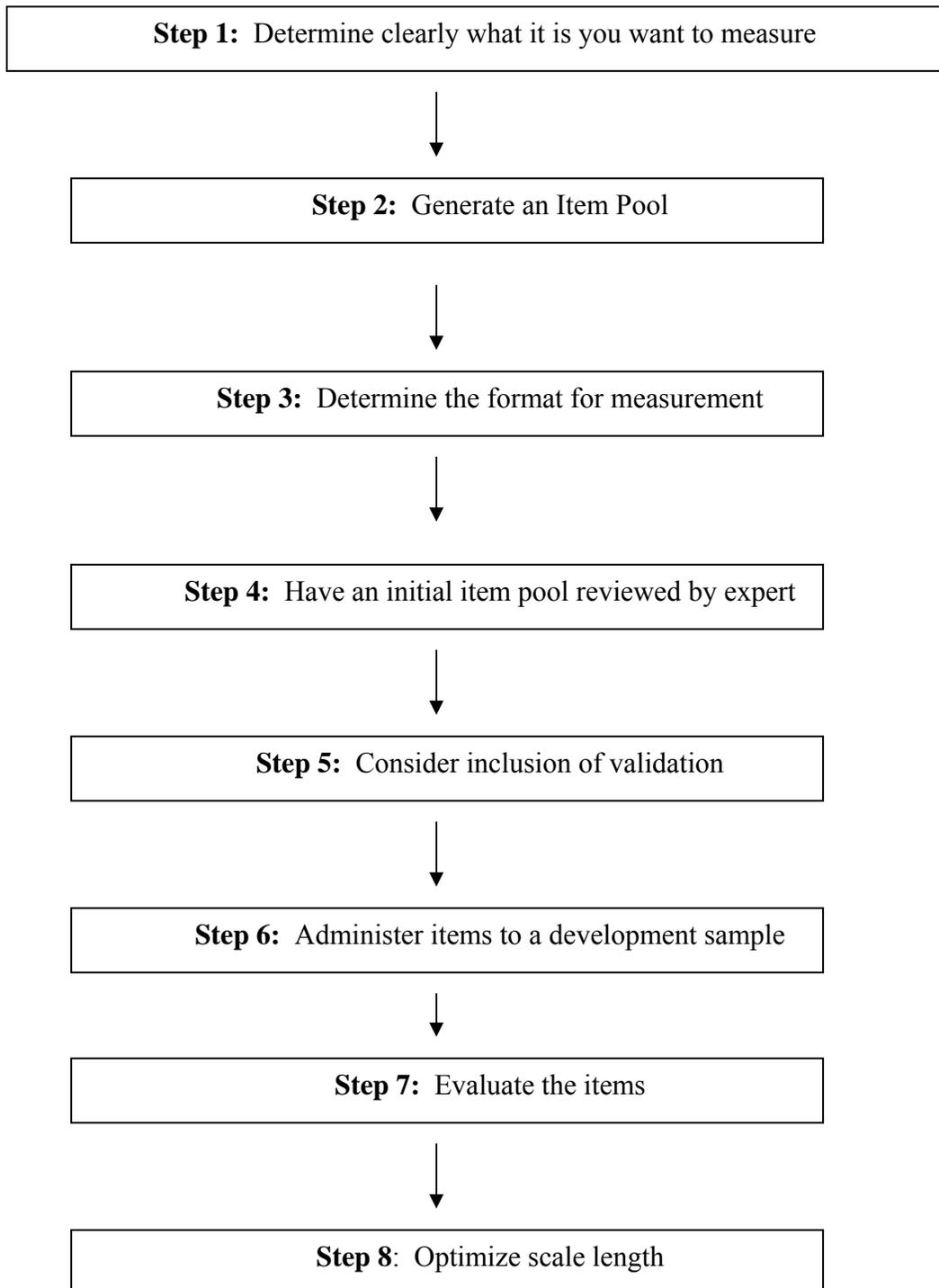


Figure 1 DeVellis Guidelines for Scale Development

3.1 PHASE I

3.1.1 Primary Aim

The primary aim of Phase I of the study was the development of an initial item pool and draft instrument “Barriers to CBT Homework Completion Scale,” through individual interview of depressed patients currently engaged in CBT and therapists expert in the field of CBT.

3.1.2 Setting

The study was carried out in the Mood Disorders Treatment and Research Program at the University of Pittsburgh Medical Center. This large urban clinic, administered by Michael E. Thase, M.D., specializes in depression treatment research, including both National Institute of Mental Health funded and pharmaceutical studies. Written permission was obtained from Dr. Thase to conduct this investigation with all current and future studies involving CBT (See Appendix C for the letter of agreement).

3.1.3 Sample

Twenty patients and 20 therapists met the following inclusion criteria and did not have any of the following exclusionary factors:

3.1.3.1 Patients

Inclusion Criteria

1. Diagnostic and Statistic Manual-IV diagnosis of Major Depressive Disorder (single, recurrent or chronic episode)
2. At the time of entry into CBT, the duration of the Major Depressive Disorder episode was at least four weeks (to ensure stability of Major Depressive Disorder episode)
3. Age at least eighteen years
4. Currently in CBT

Exclusion Criteria

1. Diagnosis of bipolar disorder, schizophrenia, obsessive-compulsive disorder and substance abuse or dependence in the last six months (to ensure diagnostic homogeneity).
2. Inability to read or comprehend at the eighth grade level

3.1.3.2 Therapists

Inclusion Criteria

1. Trained in Beck's version of CBT or a modified CBT that carries the basic theoretical precepts, i.e., Cognitive-Behavioral Analysis System of Psychotherapy (McCullough, 2000).

Exclusion Criteria

1. Therapists who do not routinely assign CBT homework.

3.1.3.3 Sample Size

A sample of both 20 therapists and 20 patients were interviewed for the development of an initial item pool. It was believed that a sample this size provided a reasonable starting point for development of items for the draft instrument.

3.1.4 Recruitment

The sample of patients was primarily obtained through the National Institute of Mental Health funded studies of the Mood Disorder Treatment and Research Program of the University of Pittsburgh Medical Center (Michael E. Thase, M.D., Principal Investigator). These studies made use of advertising in the area's most prominent newspaper, television, and radio stations. Patients were recruited from the CBT studies that were being conducted at the time of Phase I recruitment. Therapists were asked to present the study to their patients and, if the patient expressed interest, an agreed upon time was set up with the patient and the Principal Investigator to review the study, and if agreeable, sign consents and complete the interview. Therapists were recruited from established relationships of those who collaborated in studies at the Mood Disorders Treatment and Research Program, those in Pittsburgh known to practice CBT, and

those who have been known to take CBT training through programs offered at the Mood Disorders Treatment and Research Program.

3.1.5 Ethical Considerations

Approval of the study protocol and consent forms was obtained from the Institutional Review Board of the University of Pittsburgh (See Appendix D). Two separate consents (one for the Cognitive Behavioral therapists and one for the depressed patients in CBT) were approved by the Institutional Review Board for the Phase I development of the item pool (See Appendix E). Eligible subjects (therapists and patients) were informed of the purpose, risks and benefits of the study, which were considered minimal. No study procedures were conducted prior to approval by the Institutional Review Board and documentation of the necessary informed consent.

Strict confidentiality was maintained on all data collected. A unique subject identifier, i.e. 001 and higher was used for the coded results of each interview, i.e., text of their statements. Subjects were asked to sign two originals of the consent document. An original was placed in the subject's onsite research file. The second original was given to the subjects to take home. Subject names were not attached to the data. All data, audiotapes, and subject information were kept in a locked cabinet.

3.1.6 Methods

3.1.6.1 Measures

Perception of Barriers to Completion of CBT Homework

A semi-structured interview guide (used for patients) listed basic open ended questions such as: “If you’ve ever had difficulty completing your assigned homework in CBT, can you tell me what might have made it difficult for you?” Further clarifying questions were asked to elucidate what the specific problem may have been, i.e., “Could you explain further about how you were feeling that made it hard?” “What was it about the task itself that might have made it too hard for you?” “What about the way the task was given by the therapist that may have made it difficult?” See Appendix F for the Patient Interview Guide.

A similar semi-structured interview guide was conducted with the therapists but the questions reflected the therapist’s point of view and experience with patients during therapy (See Appendix F for the Therapist Interview Guide). Examples of some of the open-ended questions included “When you’ve been conducting CBT, what seemed to be some of the barriers to the patient completing CBT homework?” Further clarifying questions, which were asked, included “What were the patient factors that impacted their ability to complete the homework?” “What particular tasks were more difficult than others for some patients?” “What were the therapy elements that served as barriers to the patient getting their homework done?”

Demographic Variables

Two separate questionnaires were used to gather basic demographic information, one for patients and one for therapists. The Patient Demographic Questionnaire surveyed variables including gender, age (in years), educational level (years of education and specific occupation), marital

status as well as details regarding length of time in CBT (in weeks) in a straightforward fill in the blank questionnaire, developed by the researcher. Depressive episode histories were obtained by providing a description of criteria for Major Depressive Disorder and asking the patient to identify time periods when he/she met those criteria (See Appendix F).

The Therapist Demographic Questionnaire surveyed variables such as gender, age (in years), educational level (years of education and specific degree obtained), type of CBT training (introductory, intermediate, advanced, extramural), supervision (yes or no), number of years providing CBT, and number of patients treated using CBT (See Appendix F).

3.1.6.2 Procedures

In Phase I, identified subjects met with the investigator individually to review the purposes and procedures related to the study. Some patients received initial information pertaining to study procedures from the investigator by phone. Following this review, subjects (patients and therapists) if agreeable signed informed consent. For those who were contacted by phone, the consent document was mailed to them along with a self-addressed stamped envelope to mail back to the investigator. An agreed upon time was established for each of the interviews. This interview was semi-structured using general questions that seek to ascertain, from the subject's standpoint, what they view as the most common barriers to the completion of CBT homework. Additional clarifying and elaborating questions were employed to gain maximum information. The investigator conducted and audiotaped each interview. After any further commentary was exhausted and there appeared to be no new information, the interview was terminated. The range for interviews was from thirty to sixty minutes.

3.1.6.3 Data Management

Data were collected for approximately six months. The Principal Investigator screened all data collection sheets for completeness. Every attempt was made to avoid missing data by asking patients to complete any missing items. Prior to recruitment, the subject identification number was placed on the data collection sheets to safeguard the integrity and confidentiality of the data.

A research assistant currently employed at the Mood Disorders Treatment and Research Program entered data. Data were entered on a daily basis in an EXCEL spreadsheet (qualitative data) and/or the ACCESS database.

3.1.6.4 Descriptive Statistics

The following descriptive statistics were used to characterize the sample of patients: Gender, age, educational level, income level, length of time depressed, length of time in treatment, and number of depressive episodes, and marital status. Statistics included frequency counts, minimum and maximum levels, means, medians, and modes, standard deviations, measures of kurtosis and skewness as applicable. Histograms were examined to determine overall empirical distributions.

The descriptive statistics for the therapists were computed on the variables of gender, age (in years), educational level (years of education and specific degree obtained), type of CBT training (introductory, intermediate, advanced, extramural), supervision (yes or no), number of years providing CBT, and number of patients treated using CBT. Statistics included frequency counts, minimum and maximum levels, means, medians, and modes, standard deviations, measures of kurtosis and skewness as applicable. Histograms were examined to determine overall empirical distributions.

3.1.6.5 Data Screening

Data screening primarily focused on assuring that the interviews were accurately transcribed.

Reading and re-reading the content of the interviews accomplished this

3.1.7 Procedure for Development of Item Pool and Scale Development

The following were the steps undertaken (data collection, content analysis, and identification of suitable items) to achieve development of the draft instrument:

3.1.7.1 Interviews and Initial Identification of Barriers

The Principal Investigator conducted interviews on 20 Cognitive Behavioral therapists and 20 depressed patients in CBT to ascertain perceived barriers to the completion of CBT homework. An experienced transcriptionist typed interviews. The investigator reviewed each interview and identified barriers reported by subject. Each barrier was highlighted, numbered and then listed on the “Barriers Worksheet.” (See Appendix G).

Barriers (often identified as a phrase) from the worksheet were converted to a simpler barrier keyword listing and organized with an Excel spreadsheet into “patient,” “therapist/therapy,” and “task” categories. This spreadsheet was referred to as The “Barrier Keyword spreadsheet” (See Appendix H). Each keyword was numbered and sorted alphabetically.

The Research Assistant, who was considered the “non-psychiatric professional representative”, also reviewed each interview, identified barriers and listed them on the “Barriers Worksheet.” The Principal Investigator examined the research assistant’s worksheet, and

converted her listed barriers to the word or phrase most closely representing the barrier from the “Barrier Keyword Spreadsheet.”

3.1.7.2 Additional Transcript Review and Barrier Identification

Eight randomly selected interviews (four patient, four therapist) were given to five psychiatric professionals (one PhD nurse, one MSN nurse, one MA clinician with degree in Psychology Education, one RN who graduated from a three year diploma, and one MSW) to review and identify barriers on the “Barrier Worksheet.” The Principal Investigator converted all of the identified barriers to a corresponding keyword from the “Barrier Keyword spreadsheet.”

3.1.7.3 Identification of Concepts

The entire “Barrier Keyword Spreadsheet” was given to three psychiatric professionals (one MD, one PhD psychologist, and one MSN nurse). They were instructed to group the keywords conceptually, give it a descriptive title that reflects the concept, and to discard keywords that did not fit any other of the concept groupings (See Appendix I for example).

3.1.7.4 Collapsing Initial Item Groupings from Three Raters

The Principal Investigator reviewed all conceptual groupings for similarities.

Each individual keyword was examined in relation to the grouping that the rater placed it, i.e., the name of the conceptual grouping (See Appendix J). For example, the first rater placed the keyword into their conceptual grouping “Major Depressive D/O symptoms; the second rater into a conceptual grouping titled “Patient’s emotional state” and the third rater into a conceptual

grouping titled “Negative Thought Process/Behavior.” The investigator to accommodate these related conceptual themes then generated an overarching conceptual name “Mood States”.

If two or more of the raters discarded a keyword it was removed.

3.1.7.5 Consistency of Concept Identification/Item Selection

The initial raters review was examined for reliability in relation to whether each concept was identified per interview. Each concept was examined in relation to the amount of times it was identified across the three raters (See Appendix K). It was excluded if it was not identified in at least two of the interviews.

Each keyword in the concepts was listed in relation to the amount of times it was identified throughout the 40 interviews (See Appendix L). Each keyword within the conceptual grouping was examined for those that stood out in relation to how often it was identified in a similar fashion as a scree plot, i.e., where there was an obvious cutoff in the frequency. The goal was to have adequate item representation of individual items for each concept. For instance, if a concept contained 12 items, 4 items may have been selected. If a concept had 6 items, 2 may have been selected. Thus, each concept received proportional representation of the most commonly reported barriers.

3.1.7.6 Scale Development

Several iterations of the wording and structure of each instrument item were done (See Appendix N). Scaling, sentence structure, and instrument format were determined. (See final instrument in Appendix O).

3.2 PHASE II

3.2.1 Primary Aims

The primary aims of Phase II were the pilot testing of the draft version of the “Barriers to CBT Homework Completion Scale” and the Assignment Completion Rating Scale (Primakoff, et al., 1986 & Bryant et al., 1999) in a sample of depressed patients. The preliminary psychometric properties, i.e., reliability, internal and external structure (in terms of its ability to predict homework completion) of the instrument “Barriers to CBT Homework Completion Scale” were investigated.

3.2.2 Secondary Aims

The secondary aims of Phase II were the examination of whether subjective level of depression, length of depression, dysfunctional attitudes, length of depression and level of therapist training are related to “Barriers to CBT Homework Completion Scale” scores. Subjective level of depression, length of depression, depression episode subtype, dysfunctional attitudes, time in CBT, level of therapist training, and “Barriers to CBT Homework Completion Scale” scores were examined to determine if a relationship existed in homework assignment completion. Finally, the demographic variables of gender, age, income, educational level, marital status, and ethnic background were examined to see if they predicted the scale and subscale scores of the “Barriers to CBT homework Completion Scale” and final CBT homework completion.

3.2.3 Setting

The study was carried out in four academic treatment and research programs, one in the mid-Atlantic, one in the southwest and two in the Southern part of the United States. Several private practices also served as recruitment sites. Two academic mental health outpatient treatment centers primarily for mood disorders were also utilized. Written permission was obtained from all Principal Investigators/practice partners/heads of clinics to conduct this investigation. (See Appendix P for the letters of agreement).

3.2.4 Sample

3.2.4.1 Patients

In the pilot testing of the draft instrument, patients met the following inclusion and did not possess any of the listed exclusionary criteria:

Inclusion Criteria

1. Diagnostic and Statistic Manual-IV diagnosis of Major Depression (single, recurrent or chronic episode) at the time the patient entered CBT
2. Duration of Major Depressive Disorder episode at least four weeks (to ensure stability) at the time the patient entered CBT
3. Age at least 18 years
4. Currently in CBT

Exclusion Criteria

1. Diagnosis of bipolar disorder, schizophrenia, obsessive-compulsive disorder and substance abuse or dependence in the last six months (to ensure diagnostic homogeneity).
2. Inability to read or comprehend at the eighth grade level.

3.2.4.2 Therapists

Inclusion Criteria

1. Trained in Beck's version of CBT or a modified CBT that carries the basic theoretical precepts, i.e., Cognitive-Behavioral Analysis System of Psychotherapy (McCullough, 2000).

Exclusion Criteria

1. Therapists who do not routinely assign CBT homework.

3.2.4.3 Sample Size

An initial sample of 56 was used for the initial psychometric testing of the instrument. While this is not ideal for psychometric evaluation, it provided initial direction to the adequacy of items. Nunnally (1978, p.276) recommends five to ten subjects for each item. The instrument is seventy items; therefore, the sample size of 56 does not meet this recommendation. Additionally, this does not satisfy Comrey's (1992) sample suggestions to make this a "good" sample size for factor analysis. It should be noted that this is a non-powered sample as the study was exploratory rather than hypothesis driven. Therefore, the smaller sample size of 56 was used in the pilot for preliminary rather than decisive estimation.

3.2.5 Recruitment

This convenience sample was primarily obtained through National Institute of Mental Health funded studies at the academic centers. These studies made use of advertising in the area's most prominent newspaper, television and radio stations. Private practice settings and mental health centers also served as recruitment sites. The investigator gained written permission from the investigators at the participating collaborative sites and private practice CBT therapists to recruit subjects (See Appendix P).

The private practice and the academic treatment clinics requested recruitment procedures that would allow patients to self refer. Large laminated posters (see Appendix Q) were placed in the waiting room of each practice. The poster and accompanying identical fliers, placed in literature holders detailed information regarding the study, time required to volunteer, the voluntary nature of the study, amount of participant payment, and contact information for the Principal Investigator and Research Assistant.

Eligibility was established during the initial subject contact through a phone screening of pertinent demographic material, history of mood symptoms, and general psychiatric profile. Prior to phone screening, the patient was informed of the general purpose of the study, the investigator's background and professional affiliation, desire to ascertain eligibility information, potential risks, as well as their right to refuse to provide this information at any time. Please see Appendix V for script. A waiver (8.3.2) to document written informed consent for the phone screen was obtained as this study involved minimal risk and consent for these phone-screening questions were not normally required outside a research context.

3.2.6 Ethical Considerations

Approval of the study protocol and consent forms was obtained from the Institutional Review Board of the University of Pittsburgh (See Appendix R). The Institutional Review Board approved the consents for depressed CBT patients in the community and their therapists who participated in the psychometric evaluation of the draft instrument. Eligible subjects (patients and therapists) were informed of the purpose of the study and the risks and benefits, which were considered to be minimal to non-existent. No study procedures were conducted prior to approval by the Institutional Review Board and documentation of the necessary informed consent (See Appendix S).

The collaborating research sites folded this research into their existing study procedures. A modification to the Institutional Review Board for the study “Prophylactic Cognitive Therapy in Recurrent Major Depression” (NIMH-58356) added this instrument to the list of assessments. All patients receiving CBT in the acute and continuation phases of the study received the study questionnaires to complete.

Strict confidentiality was maintained on all data collected. A unique subject identifier coded questionnaires. Subject’s names were not attached to the data. All data and subject information was kept in a locked cabinet.

3.2.7 Methods

3.2.7.1 Measurement

Barriers to CBT Homework Completion

The “Barriers to CBT Homework Completion Scale” is a self-report Likert-type instrument of seventy items that lists commonly reported barriers to the completion of CBT Homework, e.g., “The therapist gave too much homework.” The draft instrument can be found in Appendix T. Items were rated on the degree to which each problem (item) may have interfered with the completion of CBT homework assignments. Each item was rated on a zero to four scale, zero representing no interference at all and four representing complete interference. In addition to rating the potential barriers to the completion of homework, the patient was asked to list the actual homework assignment(s) at the end of the instrument and to rate it from one (not difficult at all) to five (extremely difficult) and to rate the percentage of completion. Items were derived from interviews conducted with 20 depressed patients in CBT and 20 Cognitive Behavioral therapists. See Phase I for entire process. This is a draft instrument with no reported psychometric properties and clinical implications in relation to the total scale score.

Homework Completion

Completion of homework assignments was measured through the “Assignment Completion Rating Scale” (See Appendix T) (Primakoff et al., 1986; Bryant et al., 1999). The Assignment Compliance Rating Scale measures the degree to which the patient did the assigned task, i.e., quantity, not the specific quality of the work. Assignment Compliance Rating Scale ratings are an operationalized assessment including six categories that range from one (the patient did not attempt the homework assignment) to six (the patient did more of the homework assignment than was requested). Partial completion of homework was also noted in 25% increments in question

four. For purposes of identifying “good adherence” and “bad adherence” the six-point scale was coded as an eight-point scale. The first five items reflected homework that was not done or was only partially done up to 50% completion. The last three items reflected 75% completion, total completion, or more homework done than required. Scores on the last three items reflected good adherence as it most closely reflects the 80% standard in the field of “good adherence.” The assigned rater assessed the degree of homework completion after information is obtained from the patient regarding completion of the specific homework assignment that was given in the previous week’s session. The CBT therapist rated the Assignment Compliance Rating Scale in this study.

The only available psychometric data of the Assignment Compliance Rating Scale includes correlations between each rater and consensus using the Assignment Compliance Rating Scale made by three raters of 57 taped CBT sessions. Correlations between consensus and each rater ranged from .93 to .99 ($p < .0001$) (Bryant et al., 1999). Percentage agreement (inter-rater reliability) was 97.2% between raters one and two, 91.3% between raters one and three and 88.9% between raters two and three. When criteria for agreement were expanded to include ratings within one point of each other, agreement increased to 100%, 97.8%, and 100% for each of the pairs of raters (Bryant et al., 1999).

Two additional items were incorporated to allow the therapist’s description of the homework assignment and to rate its difficulty from one (not difficult at all) to five (extremely difficult).

Depression Severity

Level of depression was measured with the Beck Depression Inventory (Beck et al., 1961). This self-administered inventory (See Appendix T), originally designed to be clinician administered,

is used to assess the intensity of depression in both depressed and non-psychiatric populations. Twenty-one symptoms and attitudes are rated from zero to three in intensity. They include: mood; pessimism; sense of failure; lack of satisfaction; guilt feelings; sense of punishment; self-dislike; self-accusation; suicidal wishes; crying; irritability; social withdrawal; indecisiveness; distortion of body image; work inhibition; sleep disturbance; fatigueability; loss of appetite; weight loss; somatic preoccupation and loss of libido. The instrument generally takes five to ten minutes to complete. Summing the individual item scores for each of the 21 items derives the score. The cut-off scores are as follows: none or minimal depression is less than 10; mild to moderate depression is 10 to 18; moderate to severe depression is 19 to 29 and severe depression is 30 to 63 (Beck et al., 1988).

The Beck Depression Inventory was chosen as the instrument to measure subjectively reported depression as it appears to be most closely related to Beck's model of depression. Beck et al., (1961; 1988), however, reported that the instrument is not reflective of any particular theory regarding the etiology of the underlying pathological processes in depression. There is, however, a weighting of cognitive elements, as compared to other self-report instruments such as the Zung Depression Rating Scale, which has a greater somatic symptom focus.

The instrument was originally evaluated (Beck et al., 1961) for internal consistency using a split-half approach (N=97) between odd and even items. The resulting reliability coefficient was .86 in this sample of randomly selected, diagnostically diverse clinic and psychiatric patients. This suggests a high level of internal consistency for the Beck Depression Inventory in a wide variety of psychiatric populations.

In a meta-analysis of 25 studies using the Beck Depression Inventory, in both psychiatric and non-psychiatric population, internal consistency was measured. The coefficient alpha ranged

from .76 to .95 with the mean coefficient alpha of .86 (Beck et al., 1988). This indicates a high level of internal consistency for the instrument in diverse psychiatric and non-psychiatric populations.

Concurrent validity was examined in a meta-analysis of reported correlations with the Beck Depression Inventory and a) clinical ratings; b) the Hamilton Psychiatric Rating Scale for Depression (Hamilton, 1960); c) Zung Self-Reported Depression Scale (Zung, 1965); d) MMPI Depression Scale (MMPI-D); and e) the Multiple Affect Adjective Checklist Depression Scale (Zuckerman & Lubin, 1965). The correlation coefficient between the Hamilton Rating Scale for Depression and the Beck Depression Inventory ranged from .61 to .86 with the mean correlation coefficient being .73 in psychiatric patients. The range of correlations with the Zung scale was .57 to .83 in psychiatric patients with a mean of .76. The MMPI-D and Beck Depression Inventory had a range of correlations from .41 to .76 with a mean of .76 for the psychiatric sample. Finally, the correlation between the Beck Depression Inventory and the MAACL-D in two psychiatric studies was .66 and .50 (Beck et al., 1988). Thus, the Beck Depression Inventory has a high level of internal consistency, both in its original testing and in follow-up meta-analyses and moderate concurrent validity with instruments widely used to measure depressive severity suggesting the instrument possesses superior psychometric properties to measure self-reported depressive symptoms.

Dysfunctional Attitudes

The Dysfunctional Attitudes Scale (Weissman & Beck, 1978) was used to examine potential trait influences that may affect the patient's perception of barriers to the completion of homework (Appendix T). The original Dysfunctional Attitudes Scale is a one hundred item self-report questionnaire derived from Beck's cognitive theory of depression. The Dysfunctional Attitudes

Scale -version A (Weissman & Beck, 1978), a subsequently developed forty-item version of this scale, was used for this study. The Dysfunctional Attitudes Scale is purported to measure beliefs that represent predispositions to depression, are considered relatively stable (trait beliefs), and reflect negative schemas (Oliver & Baumgart, 1985). Potential items for the Dysfunctional Attitudes Scale were generated from suggestions by practicing clinicians on the basis of their experience with depressed patients (Weissman, 1979). Maladaptive thinking patterns are reflected in the wording of items using inflexible and absolute language with rigid qualifiers (all, always, never), categorical imperatives (ought to, have to) and pre-emptive class assignments (nothing, but) (Weissman, 1979). Examples include: “If a person asks for help, it is a sign of weakness,” “If someone disagrees with me it probably indicates he doesn’t like me,” and “I should be upset if I make a mistake.”

Respondents rate a modified Likert scale from zero (totally agree) to seven (totally disagree) with scaling ensuring that dysfunctional responses score highest. Items represent seven major value systems: approval, love, achievement, perfectionism, entitlement, omnipotence, and autonomy (Parker et al., 1984). These items are intended to measure those beliefs that might interact with a congruent stressor to produce clinical symptomatology (Beck et al., 1991).

The Dysfunctional Attitudes Scale was further developed to include shortened (forty item) parallel A and B versions. The shortened forms were considered more “user-friendly” for ease of administration in both research and clinical settings. The Dysfunctional Attitudes Scale has been psychometrically tested in non-clinical and clinical samples.

Oliver and Baumgart (1985) tested the Dysfunctional Attitudes Scale in a non-clinical sample of 105 male and 170 female employees of a private hospital in Cleveland and their spouses. The sample was primarily white, middle-class, and married.

The structure of the original one hundred-item Dysfunctional Attitudes Scale as well as the Dysfunctional Attitudes Scale A and B were examined with factor analysis. There was a lack of factorial equivalence between the A and B forms causing the researchers to conclude that the original Dysfunctional Attitudes Scale was more psychometrically sound. Cronbach's Alpha for the Dysfunctional Attitudes Scale-T was .90. Item-total correlations were moderate with 50 % between .30 and .50 and 25 % between .20 and .30, demonstrating some item overlap but overall, a lack of redundancy.

Six-week test-retest results were conducted in a portion of the sample that agreed to complete the Dysfunctional Attitudes Scale-T a second time. The results were .73 ((n=43), $p < .001$), .83 ((n=16), $p < .001$), and .64((n=25, $p < .001$) for the whole sample, males, and females respectively. There was no difference between genders in the mean score of the Dysfunctional Attitudes Scale-T. Males had a mean score of 297.36 (SD = 51.16) and females had a mean score of 294.34 (SD = 47.20).

The discriminant validity between the Dysfunctional Attitudes Scale (full scale) and the Beck Depression Inventory was tested with a Pearson Product Moment correlation. The results were .41((n=273), $p < .001$), .45 ((n=103), $p < .001$), and .38 ((n=168), $p < .001$) for the whole sample, males, and females respectively, demonstrating related but separate constructs.

The authors conclude that the instrument has adequate reliability and validity for assessment of "depressogenic" beliefs in an unselected adult population. They do note, however, that the results may be weakened by the use of a non-random sample and potential systematic bias by the inclusion of spouses as well as possible collaboration of spouses in completing the questionnaire.

Parker et al. (1984) also tested the A and B forms of the Dysfunctional Attitudes Scale in a sample of 251 Australian patients at a general practice office and 43 clinically depressed patients. Factor analysis suggested the A form to be superior in that the four key variables (externalized self-esteem; anaclitic self-esteem, tentativeness; and need for approval) loaded most clearly.

In the sample of depressed patients, the researcher tested the stability of Form A of the Dysfunctional Attitudes Scale and the degree to which dysfunctional attitudes might be antecedent to, or consequences of a depressed mood by comparing the Dysfunctional Attitudes Scale and Zung depression score at baseline and six weeks later. Dysfunctional Attitudes Scale scores decreased slightly (6.8) in the 13 whose depression showed no improvement, decreased more (10.0) in the 16 reporting some improvement, and decreased considerably (28.4) in the 14 reporting moderate improvement, however the difference did not approach significance. The researchers concluded that increased Dysfunctional Attitudes Scale scores are more a consequence of depressed mood rather than an antecedent attributional style placing an individual at risk. A separate study of formerly depressed patients and their first-degree relatives as well as students (Powers et al., 1994) also demonstrated the two shortened forms to have factorial non-equivalent.

The Dysfunctional Attitudes Scale was tested for factor structure in a clinical sample of 2023 outpatients seen for pretreatment diagnostic and psychometric evaluations at the Center for Cognitive Therapy at the University of Pennsylvania by Beck and colleagues (1991). The sample consisted of 1151 women (56.9%) and 872 men (43.1%). The mean age was 36.34 years (SD=12.33). The sample was composed of 93.8% whites, 4.2% Blacks, and 2% Orientals. Fifty-four percent of patients were diagnosed with a primary affective disorder, 28.0% with a primary

anxiety disorder, and 17.2% were diagnosed with a disorder other than affective or anxiety disorder.

From the original 100-item Dysfunctional Attitudes Scale, 12 of the items were dropped for the planned exploratory and confirmatory factor analyses. Two were dropped for redundancy, one was dropped for kurtosis >3 , and nine were deleted for measure of sampling adequacy $< .90$.

In the exploratory factor analysis the sample was divided into three subsamples of 807, 816, and 400. Two were used for model development and one for cross validation. Twelve clusters were identified for the confirmatory factor analysis using the VARCLUS procedure in SAS (SAS Institute, 1988). This procedure reduces the number of variables used to build a segmentation model. VARCLUS clusters variables that are as correlated as possible among themselves and as uncorrelated as possible with variables in other clusters.

Maximum likelihood factor analyses were conducted as the confirmatory approach, based upon the clusters identified during the exploratory procedure. The cutoff of .38 was chosen for ease of interpretability. During the course of the fitting procedure, the items were reduced from 88 to 66 and the number of factors from ten to nine (clusters had been reduced when they were inclusive). The factors that were identified included: vulnerability; need for approval; success-perfectionism; need to please others; imperatives; need to impress; avoidance of appearing weak; control over emotions and disapproval-dependence. All factors had Cronbach Alphas $\geq .70$ except for two (control over emotions and disapproval-dependence).

Thus, it appears that the original Dysfunctional Attitudes Scale has demonstrated reliability (internal consistency and test-retest) in non-clinical and clinical samples. Internal structure (factorial equivalence) of the parallel A and B forms has not been demonstrated across

several studies. On a clinical population the number of items and factors in the original scale was reduced to 66 and nine, respectively, through exploratory and confirmatory factor analysis. Given the lack of factorial equivalence between the A and B forms of the Dysfunctional Attitudes Scale and the use of the Dysfunctional Attitudes Scale-A in most assessments in the study sample, the Dysfunctional Attitudes Scale-A was chosen.

Finally, it is unclear at this time as to the scale's purported ability to measure trait beliefs that reflect underlying negative schemas. At least one study found the scale score to decrease with an improvement in clinical status. Beck et al. (1991) suggest that various factors within the scale may covary with clinical status while some may be expected to be more stable. The scale, then, may measure both trait and state variables.

Demographic/Depression History Variables

The Patient Demographic Questionnaire surveyed variables including gender, age (in years), educational level (years of education and specific degree obtained), marital status as well as details regarding length of time in CBT (in weeks) in a straightforward fill in the blank questionnaire, developed by the researcher. Depressive episode history was obtained by providing a description of criteria for Major Depressive Disorder and asking the patient to identify time periods when he/she met those criteria (See Appendix T). Depression history was obtained from the Structured Clinical Interview for Diagnostic and Statistic Manual-IV (American Psychiatric Association, 2000) for those patients in the academic sample.

The Therapist Demographic Questionnaire surveyed variables such as gender, age (in years), educational level (years of education and specific degree obtained), type of CBT training (introductory, intermediate, advanced, extramural), supervision (yes or no), number of years providing CBT, and cumulative number of patients treated using CBT (See Appendix T).

3.2.7.2 Procedures

In Phase II, identified subjects from the community sample met with the investigator in person or on the phone to review the purposes and procedures as well as potential risks and benefits related to the study. Ample time was allowed to answer all questions thoroughly. Once verbal consent was obtained, the investigator ascertained eligibility. Please note, a specific “Waiver to Document Informed Consent for the Phone Screening Interview” was requested within this Institutional Review Board submission. The script that was used to request verbal consent to proceed with screening for eligibility is included in Appendix V. If agreeable, subjects (patients and therapists) signed two informed consents. Consents were mailed to subjects with a self-addressed stamped envelope to return to investigator. Following receipt of the signed consents, the investigator signed and mailed a completed consent back to the patient. Following receipt of the therapist consent and the questionnaires, specific directions and self-addressed stamped envelopes were sent to the subject. Upon completion, the subject mailed the completed data to the investigator.

There were three separate measurement points at consecutive therapy appointments. At Session A, patients completed the demographic questionnaire, the Beck Depression Inventory and the Dysfunctional Attitudes Inventory. Therapist also completed the demographic questionnaire. At the next session (Session B) this process was repeated with the exception of the demographic questionnaire. Additionally, the patient completed the “Barriers to CBT Homework Completion Scale” and the therapist completed the Assignment Completion Rating Scale. These ratings referenced the homework assigned at Session A. At Session C, the patient completed the “Barriers to CBT Homework Completion Scale” and the therapist completed the Assignment Compliance Rating Scale. Both referenced the homework given in Session B.

There was a minimum of two days between therapy sessions and maximum of three weeks. Below is a schematic representation of the process. The patient completed all questionnaires unless otherwise specified:

Consents

In person or by phone (both patient and therapist)



Session A

Demographic Sheet (both patient and therapist)

Beck Depression Inventory

Dysfunctional Attitudes Scale



Session B

Beck Depression Inventory

Dysfunctional Attitudes Scale

Barriers to Completion of CBT Homework Scale

Assignment Compliance Rating Scale (referencing Session A and completed by therapist)



Session C

Barriers to Completion of CBT Homework Scale

Assignment Compliance Rating Scale (referencing Session B and completed by therapist)

3.2.8 Data Management

Data was collected from the academic, clinical research and all private practice sites at a minimum of twice monthly. The Principal Investigator and Research Assistant screened all questionnaires for completeness. Every attempt was made to avoid missing data by asking patients to complete any missing items. Prior to recruitment of subjects, all questionnaires were labeled with the subject identification number to safeguard the integrity and confidentiality of the data.

A research assistant entered all data. The database of ACCESS was used. A data dictionary was used for coding purposes and range coding for each variable was done so that only a specific range of numbers or values were allowed. All data was reviewed for accuracy prior to entry. Data collected on subjects was analyzed through the SPSS 15.0 database software program.

3.2.9 Data Analysis

3.2.9.1 Descriptive Statistics

The following descriptive statistics were used to characterize the sample in this phase: gender; age; educational level; income level; length of time depressed; length of time in treatment; number of depressive episodes and marital status. Statistics included frequency count, minimum and maximum levels, mean, median, and mode, standard deviation, kurtosis and skewness as applicable. If a continuous type variable, histograms were examined to determine overall empirical distributions; otherwise bar charts were created.. The descriptive statistics for the therapists included variables such as gender; age (in years); educational level (years of education

and specific degree obtained); type of CBT training (introductory, intermediate, advanced, extramural); supervision (yes or no); number of years providing CBT and cumulative number of patients treated using CBT. Statistics included frequency counts, minimum and maximum levels, means, medians, and modes, standard deviations, measures of kurtosis and skewness as applicable. Histograms or barcharts (depending on type of variable) were examined to determine overall empirical distributions.

3.2.9.2 Data Screening Procedures

All data were proofread and examined to identify out of range values or those inconsistent with the coding norms. Graphical presentations of the variables (descriptive statistics) were surveyed with histograms and scatterplots to detect out of range variables. In addition, ranges were verified with contingency checking of related variables.

All outliers were checked for validity. Much of the data was continuous and all of it was ungrouped, therefore, to test for univariate outliers, the graphical methods of histograms, box plots, normal probability plots, and detrended normal probability plots were employed. Multivariate outliers were detected by scatterplots between pairs of the variables and Mahalanobis Distance. Outliers were investigated using Logistic Regression with a dummy variable.

Univariate normality was assessed through examination of the histograms of each variable as well as histograms of each item in the instruments. Skewness and kurtosis were tested at the .01 level, with the desired result a small value close to 0. Normal probability plots and detrended normal probability plots will also be examined for departures from normality. Multivariate normality was examined considering univariate normality, pairwise linearity, and

pairwise homoscedasticity. Appropriate data transformations were considered for departures from normality.

Index plots of the variables determined Independence between subjects. Standardized residuals vs. predicted values were analyzed.

Given the ungrouped data, inspection of bivariate plots was done to assess homoscedasticity. Transformations were considered for data that was particularly heteroscedastic.

Ascertaining the multicollinearity or singularity in these analyses is essential given the desire to avoid item redundancy in the instrument. To evaluate these issues, the variables for each analysis were used to generate the conditioning indices tolerance, variance inflation factor, and BKW diagnostics across variables in the instrument.

Patterns of missing data were examined per patient and per variable (univariate) and the joint distribution of variables (multivariate) for overall quantity as well as patterns of missing data for factor analyses a missing data correlation matrix was employed where all available pairs of values was used to calculate each of the correlations in the correlation matrix.

For cases or variables with large amounts of missing data they will first be evaluated as to whether they correlate to a high degree with another variable and, therefore, can be dropped. Cases with substantial amounts of missing data that will seriously affect any analyses were deleted from the data set (listwise deletion). Missing data was replaced with linear trend at point values.

3.2.9.3 Reliability Assessment

Individual histograms provided information about the distribution of each item as well as the distribution of the entire scale. Skewness and kurtosis statistics were included for each of these distributions. Descriptive statistics related to the reliability analysis included inter-item and item-total correlations and item statistics (mean minimum, maximum, range and variance). Cronbach's alpha was the primary method of estimation of internal consistency. Alpha was estimated on the entire scale as well as any subscales that were revealed through exploratory factor analysis.

Reliability or stability over time (test-retest) was examined through Pearson Product Moment correlations. Time between sessions ranged from a minimum of 2 days and maximum of 3 weeks. Reliability was tested on the entire scale as well as subscales that emerged through factor analysis.

3.2.9.4 Internal Structure Evidence (Factor Analysis)

Prior to performing exploratory factor analyses, the following was examined to determine the adequacy of the correlation matrix: majority of correlations $\geq .30$; Bartlett's Test of Sphericity to determine whether the correlation matrix is an identity (looking for large test statistic with small significance); a small proportion of partial correlation coefficients that are large; a large overall Kaiser-Meyer-Olkin (KMO) statistic as a measure of sampling adequacy; a large Measure of Sampling Adequacy (MSA) for each item; and a large squared multiple correlation coefficient between an item and all other items. Violation of any of these indices resulted in re-evaluating the appropriateness of the correlation matrix of items for the factor analysis.

Following examination of the correlation matrix, a factor extraction was done using the unweighted least squares method which produces a fixed number of factors and minimizes the sum of squared differences between the observed and the reproduced correlation matrices.

An oblique rotation (Promax) was chosen as factors were assumed to be correlated. Promax is designed to give an oblique solution that represents a modification of an orthogonal solution toward a better oblique simple structure (Comrey & Lee, 1992).

Factor loadings were examined for confirmation of the structure related to the proposed theoretical division of the concept “barriers to CBT homework completion.” Only factor loadings of .40 or more were considered. To obtain parsimony the least amount of factors to explain the concept was considered, making use of the scree plot while also maximizing explained variance. Comrey's (1988) criterion that items must be specifically written to measure the same construct and that they satisfy a statistical criterion of relatedness by correlating with each other sufficiently to define an item factor was the overall guiding principal for determination of item adequacy.

Due to instability of the initial factor analysis, an altered strategy was employed to utilize the concepts, derived from the Phase I process that were used to develop the item pool, as an alternative to the instrument items. Scores from each item within a concept were added together to become the concept as an item, i.e., if a concept had 5 items all 5 items were added together to serve as a composite. This simplified (24 items as opposed to 70 item correlation matrix) the structure for conducting the factor analysis.

3.2.9.5 External Structure Evidence

Each separate validity analysis (correlations and multiple linear regression) had descriptive information including means, minimums, maximums, standard deviations, frequencies (valid and

missing), variance, modes, medians, indicators of skewness and kurtosis, histograms of each item and variable, frequencies and percentages of each item and variable, as well as extreme values. All correlation matrices of these procedures were included as descriptive statistics to examine the relationships between the items.

Number of homework assignments (1 and greater than 1 assignment) and time (early, middle, and late) were tested with an ANOVA relative to their differences in completing homework (Assignment Compliance Rating Scale scores). The ANOVA was tested at a .05 significance level.

Therapist and Patient ratings of assignment difficulty and the association with homework completion (measured by the Assignment Compliance Rating Scale and the patient's rating of homework compliance) were examined through separate Pearson Product Moment correlations performed at a .05 significance level.

The primary measures of predictive validity were obtained with a series of regression equations tested at the .05 (two-tailed) significance level. A series of Multiple Linear Regression equations explored independent variables predicting "Barriers to CBT Homework Completion Scale" scores and homework completion. The following models were tested initially to examine controlling variables:

Gender + age+ educational level+ income level + marital status+ ethnicity □ Barrier to CBT Homework Completion (total and separate subscale scores) (Dependent variables).

Gender + age+ educational level+ income level+ marital status +ethnicity□ Homework Completion (Dependent variable)

After these controlling variables are examined in relation to scale and subscale scores and the prediction of homework completion, as measured by the Assignment Compliance Rating

Scale, the other variables of interest were added in a series of regression equations until the following models are tested:

Level Severity of Subjective Depression (Beck Depression Inventory score) + Length of Time in Treatment + Length of Depression + number of depressive episodes + dysfunctional attitudes (Dysfunctional Attitudes Scale) + therapist level of training (IV's) + Gender + age + educational level + income level + marital status + ethnicity □ Barrier to CBT Homework Completion (total and separate subscale scores) (Dependent variables).

Level of Subjective Depression + Length of Time in Treatment + Length of Depression + Barriers to CBT Homework Completion total Scale score + Barriers to CBT Homework Subscale Scores + number of depressive episodes + dysfunctional attitudes (Dysfunctional Attitudes Scale) + therapist training level (Independent variables) + Gender + age + educational level + income level + marital status + ethnicity □ Homework Completion (Dependent variable).

The multiple linear regressions were completed with all routine descriptives, partial plots, standardized predicted values, Cook's distance, leverage values, studentized deleted residuals, standardized DfBetas, and DfFits.

The following concurrent data screening occurred with the multiple linear regressions: examination of residual plots for normality, linearity, homoscedasticity, and outliers. Outliers of X were examined with leverage of $> 4/N$. Independence was examined with plots of the residuals as a function of time and the Durbin Watson test. To further examine normality, N-P plots of the studentized residuals as well as scatterplots was done. Residual against predictor plots was used to detect non-linearity. Partial Regression Plots examined undue influence of every predictor variable. DfFits, DfBetas, Cook's D, and Covratio were examined for undue influence or fit in the values. Data screening determined the need to transform or use an alternate method of

regression. R squared, s squared, and adjusted R squared was examined to determine the best model. Positively skewed variables were made more normal with a square root transformation. Negatively skewed variables were reflected and made more normal with square root transformation. The relative importance was examined through the magnitude of beta for each predictor. Press statistics and Mallows' C were also examined for prediction errors and under/over fitting of the model.

Concurrent validity was examined through 2 separate Pearson Product Moment correlations of the “Barriers to the Completion of CBT homework Scale” and the Beck Depression Inventory and Dysfunctional Attitudes Scale, both tested at the .05 significance level.

Finally, the contrasting groups of patients with “low adherence” and “high adherence” were tested through a binary logistic regression analysis in relation to scale and subscale score as the independent variables at a .05 significance level. High adherence was defined by an adherence rating of 75% or higher on the Assignment Compliance Rating Scale for each individual assignment (a score of 5 or above on the recoded Assignment Compliance Rating Scale). Low adherence was defined as lower than 75% on the Assignment Compliance Rating Scale for each individual assignment.

3.2.10 Summary

This chapter described the descriptive psychometric study of the development of the instrument “Barriers to CBT Homework Completion Scale.” The study was done in two phases. They included the development of the item pool through interview of 20 depressed patients currently in CBT and 20 CBT therapists and administration of the draft instrument to a sample of 56 depressed patients currently in CBT. The initial psychometric testing included evaluation of

reliability, internal structure, and external structure. In particular, the instrument's ability to predict CBT homework completion was examined.

4.0 RESULTS

The purpose of this descriptive study was to develop and psychometrically evaluate the draft instrument “Barriers to CBT Homework Completion Scale.” The study was conducted in two separate phases. An item pool for the draft instrument was developed in Phase I through interviews of 20 Cognitive Behavioral therapists and 20 depressed patients who had been receiving CBT. The draft instrument was piloted in Phase II. Fifty-six depressed patients, who had been in CBT, completed the draft instrument prior to successive therapy appointments on two occasions. Initial psychometric properties were assessed. The results of each phase are presented separately.

4.1 PHASE I

4.1.1 Characteristics of the Patient Sample

Table 2 displays the categorical demographic characteristics of the 20 patients who participated in Phase I. It should be noted that all of the subjects were recruited from an ongoing National Institute of Mental Health study of CBT in patients with recurrent major depression. The study was conducted at a large academic center in a mid-size Mid-Atlantic state.

Table 2 Phase I Categorical Patient Demographic Statistics (N=20)

Variable	N	%
<hr/>		
Gender		
Male	4	20
Female	16	80
Race		
Caucasian	19	95
African-American	1	5
Marital Status		
Married	7	35
Separated/Divorced	9	45
Never married	4	20
Highest Degree		
High School	6	30
Associates/Tech	6	30
College	4	20
Master's	4	20
Income		
Less than \$29,999	8	40
\$30,000 - \$49,999	8	40
\$50,000 - \$99,999	3	15
Greater than \$100,000	1	5

Table 3 displays non-categorical demographic information for the Phase I patient sample.

Table 3 Phase I Continuous Patient Demographic Statistics (N=20)

Variable	Mean \pm SD	Median	Range
Age (years)	49.95 \pm 11.78	48	23-63
Years of Education	15.50 \pm 2.48	15	12-20

The sample is largely female (80%) and middle-aged (M 50 years \pm 12 years). It was primarily a Caucasian sample (95%). The group was by and large married (35%) or divorced (45%). Seventy percent of the sample had an educational level greater than high school with mean years of education being 15.5 \pm 2.48 years. Eighty percent of the sample earned less than fifty thousand dollars.

Table 4 provides information about characteristics of the patient sample's Major Depressive history and details regarding the current episode.

Table 4 Phase I Patient Major Depressive Episode Characteristics (N=20)

Variable	Mean/SD	Median	Range
MDD Age of Onset (years)	21.73 ± 13.71	17.5	8 – 57
Time in Current Episode Of MDD in weeks	26.60 ± 42.16	12	5- 190
Time in CBT in weeks	13.65 ± 10.74	11.5	3-40

The mean age of onset for major depressive disorder was approximately 22 years of age ± 14 years with a wide range of 8 to 57 years. The majority (68%) of patients had greater than four lifetime depressive episodes. The mean of the present episode was approximately 27 weeks ± 42 weeks. Mean time spent in CBT was approximately 14 weeks ± 11 weeks. The range of time in CBT was wide from 3 to 40 weeks. Table 5 provides information about the total number of episodes of MDD for this sample.

Table 5 Phase I Patient Sample Number of Depressive Episodes (N=19)

Number of Episodes	N	%
One	1	5.5
Two to Three	5	26
Greater Than Four	13	68

The majority (68%) of the patients had greater than four episodes of MDD.

4.1.2 Characteristics of the Therapist Sample

Therapists were recruited from a mid-size Mid-Atlantic city. They had been identified as primarily Cognitive Behavioral therapists. Therapists were recruited from established relationships of those who collaborated in studies at the Mood Disorders Treatment and Research Program, those in Pittsburgh known to practice CBT, and those who have been known to take CBT training through programs offered at the Mood Disorders Treatment and Research Program. Table 6 illustrates the characteristics of the therapist sample.

Table 6 Phase I Therapist Categorical Demographic Statistics (N=20)

Variable	N	%
Gender		
Male	8	40
Female	12	60
Race		
Caucasian	20	100
Highest Degree		
Master's	8	40
Doctorate	11	55
Medical	1	5
Professional Discipline		
Psychiatrist	1	5
Psychologist	11	55
Social Work	8	40

Table 7 displays continuous Phase I Therapist Demographic statistics.

Table 7 Phase I Continuous Therapist Demographic Statistics (N=20)

Variable	Mean \pm SD	Median	Range
Age years)	47.35 \pm 9.34	51.5	33-61
Years of Education	21.20 \pm 2.48	21	18-26

The therapist sample was nearly evenly divided between the male and female gender. The mean age was approximately 48 years \pm 9 years. The range of therapist age was 33 to 61 years. All of the therapists were Caucasian. All of the therapists had an educational level of master's degree or higher with the mean education being 21 years \pm 2.5 years and a range of 18 to 26 years. Table 8 provides information about the therapist's professional background and training.

Table 8 Phase I Therapist Professional Background and Training (N=20)

Variable	Mean \pm SD	Median	Range
Hours of CBT Supervision	294.10 \pm 652.44	123	0–3000
Years Doing CBT Full-time	5.75 \pm 7.27	2.5	0 – 24
Years Doing CBT Part-time	20.00 \pm 6.42	5	0 – 24

The majority of the therapists (75%) had advanced training in CBT. Nearly all of the therapists participated in supervision. Mean hours of supervision received were 294 hours/lifetime \pm 652 hours. The sample reported doing CBT fulltime with a mean of nearly 6 years \pm 7 years and part-time for 20 years \pm 6 years. Half of the therapists had treated greater than 200 patients using CBT. The majority (75%) treated at least 60 patients with CBT. Therapist professional discipline was nearly evenly divided between PhD level (55%) and MSW level (40%). Table 9 details categorical statistics concerning professional background and training.

Table 9 Phase I Therapist Professional Background (Categorical Variables)

Variable	N	%
<hr/>		
Type of CBT Training		
Intermediate	5	25
Advanced	15	75
Received CBT Supervision		
Yes	19	95
No	1	5
Number of Patients Treated With CBT		
21-60	5	25
61-100	3	15
101-150	2	10
151-200	0	0
201+	10	50

4.1.3 Subject Interviews

The Principal Investigator conducted interviews on 20 Cognitive Behavioral therapists and 20 depressed patients in CBT to ascertain perceived barriers to the completion of CBT homework. An experienced transcriptionist typed all of the interviews. By repeatedly reviewing the text of each interview, sentence by sentence, barriers reported by each subject were identified. Each

barrier was highlighted, numbered and then listed on the “Barriers Worksheet.” (See Appendix G).

Barriers (often identified as a phrase) from the worksheet were converted to a simpler barrier keyword listing and organized with an Excel spreadsheet into “patient,” “therapist/therapy,” and “task” categories. This spreadsheet was referred to as The “Barrier Keyword spreadsheet” (See Appendix H). Each keyword was numbered and sorted alphabetically. There were 283 barrier keywords.

The Research Assistant, who was considered the “non-psychiatric professional representative,” (to represent a patient’s perspective) also reviewed each interview, identified barriers and listed them on the “Barriers Worksheet.” The Principal Investigator examined the research assistant’s worksheets, and converted her listed barriers to the word or phrase most closely representing the barrier from the “Barrier Keyword Spreadsheet.”

Eight randomly selected interviews (four patient, four therapist) were given to five non-subject psychiatric professionals (one PhD nurse, one MSN nurse, one MA Counselor Ed clinician, one RN who graduated from a three year diploma, and one MSW) to review and identify barriers on the “Barrier Worksheet.” The Principal Investigator converted all of the identified barriers to a corresponding keyword from the “Barrier Keyword spreadsheet.”

Examples of patient barriers are abilities/deficits (inability to monitor moods, avoidance); fears (to be judged); constitutional factors (age, personality disorders, obsessive compulsive disorder); mood states (anger, anxiety, frustration, being overwhelmed); cognitive states (boredom, concreteness, forgetful) and situational issues (chaotic life or coerced into treatment). Therapist/Therapy Barriers include examples of therapist activities (alliance, collaboration, therapist does not address barriers or homework not placed on the agenda) and characteristics of

the therapy itself (patient designs their own homework, the phase of the therapy, and too short of a time between sessions). Examples of task barriers included the quality of the assignments (changing core beliefs, homework connecting emotions and thoughts and length of the assignment) and the types of assignments (thought records or writing assignments).

Appendix M illustrates the number of barriers identified in each patient interview by each of the raters (Principal Investigator, non-psychiatric professional, and psychiatric professional). Each of the sampled patient interviews had three separate raters identifying reported barriers.

The total number of distinct patient barriers identified by raters was from 238 to 426. Total patient barriers identified were 1020 across the three raters and 20 interviews with a mean of 340 total per rater category. The average number of identified barriers per patient interview was 17.

The total number of distinct therapist barriers identified by raters ranged from 460 to 656. Total therapist barriers were 1738 across the three raters and 20 interviews with a mean of 579 per rater. The average number of identified barriers per interview in the therapist group was 29. Regardless of nearly identical interview formats, the quantity of reported barriers was significantly different between the therapist and patient interviews. T tests were conducted for each of the 3 raters at the .05 significance level to determine if there was a significant difference between the amount of perceived barriers reported by the patients and the therapists. Table 10 displays the statistics regarding this comparison.

Table 10 T Test of Reported Barriers between Patient and Therapist Interviews (Phase I)

Rater	Patient		Therapist		Group T test
	N	Mean/SD	N	Mean /SD	p-value
PI	356	17.8/5.9	656	32.8/6.2	.0001
RA	426	21.3/9.0	622	31.1/7.2	.0001
Psych Pro	238	11.9/5.8	460	23.0/7.5	.0001

Thus, the therapists reported many more barriers than the patients in the interviews. Additionally, there was a significant difference between the psychiatric professionals and the Principal Investigator/ Non-psychiatric professional ratings. The identified barriers in the psychiatric professional group ranged from 59 to 74% of the quantity of barriers identified by the Principal Investigator and non-psychiatric professionals.

The mean differences of identified barriers between the principal investigator and the research assistant were 2.3 identified barriers. There was a mean difference of 5.90 identified barriers between the PI and Psychiatric Professional. There was a mean difference of 8.2 identified barriers between the research assistant and the psychiatric professionals. Thus, the psychiatric professionals identified fewer barriers in the patient sample than the principal investigator or the research assistant.

The mean differences between the principal investigator and the research assistant showed a mean difference of 1.95 identified barriers. The mean difference between the principal investigator and the psychiatric professional was 9.70 identified barriers and the research assistant and the psychiatric professionals was a mean difference of 7.75 identified barriers.

Thus, the psychiatric professionals identified significantly fewer barriers in the therapist sample than the principal investigator or the research assistant.

4.1.4 Concept Identification

The entire “Barrier Keyword Spreadsheet” was given to three psychiatric professionals (one MD, one PhD psychologist, and one MSN nurse). They were instructed to group the keywords conceptually, give it a descriptive title that reflects the concept, and to discard keywords that did not fit any other of the concept groupings (See Appendix I for example).

The MD rater identified the following concepts: CBT-Homework issues; Co-morbid conditions; Depression features; External factors; Patient Behaviors/Actions; Patient Beliefs; Patient’s Knowledge; Patient’s Cognitive Abilities; Patient’s Emotional State; Patient’s Personality Characteristics; Patient’s Self-Esteem; Therapist Behaviors/Actions; Therapist Experience; Therapist Personality Characteristics and Therapist-Patient relationship. Seven items were discarded.

The PhD rater identified the following concepts: Causes Emotional Distress-Would Rather Avoid; Clinical Availability; Clinical Expertise; Clinician Characteristics; Clinician Management of Sessions; Difficulties with Specific CBT Components; Difficulty Understanding CBT Model; Dislike/Cynicism Re: CBT Model; Doesn’t Discuss/Explain HW Sufficiently; Entitlement/Lack of Taking Responsibility for Recovery; Explain Concepts Clearly; External Life Factors; Fear of Changing/Recovering; Lack of Belief in Utility of Homework; Lack of Psychological Mindedness; Major Depressive Disorder: Cognitive Symptoms; Major Depressive Disorder: Mood Symptoms; Major Depressive Disorder: Physical Symptoms; Organizational Difficulties; Patient Inconvenience; Patient Noncompliance/Oppositionality; Patient Pathology;

Patient's Background/Biographical Data; Procrastination; and Self-Efficacy/Lack of Confidence. This rater discarded 25 items.

The Master's prepared nurse identified the following concepts; CBT Task Behaviors; Depressive Symptoms; Dual Diagnosis; Indicator of CBT Working/Patient Engaged in Treatment; Lack of Insight; Motivating Factors by Therapist; Negative Thought Process/Behavior; Not Engaged in Treatment; Personality Traits; Practical Patient Barriers to Treatment; Prediction of Good Response; Prediction of Poor Response; Resistance; Therapist Factors That Would Have Positive Impact; Therapist Factors/Behaviors That Would Have Negative Impact; Therapist: Good Skill Level; Therapist: Inadequate Skill Level. This rater discarded 22 items.

4.1.5 Final Concept Identification

The Principal Investigator reviewed all conceptual groupings for similarities and clustering of items. Each individual keyword was examined in relation to the grouping that the rater placed it, i.e., the name of the conceptual grouping (See Appendix J). For example, the first rater placed the keyword into their conceptual grouping "Major Depressive D/O symptoms; the second rater into a conceptual grouping titled "Patient's emotional state" and the third rater into a conceptual grouping titled "Negative Thought Process/Behavior." The investigator, to accommodate these related conceptual themes, then generated an overarching conceptual name "Mood States". If two or more of the raters discarded a keyword it was removed.

Through this "item X rater X concept" review, the Investigator identified the following concepts based upon the thematic clustering: Dislike/Cynicism Re. CBT Model; Psychological Readiness; Oppositionality; Therapist Skill; Therapist Qualities; Avoidant Beliefs; Self

Efficacy/Self-Esteem; Patient-Therapist Relationship; Patient Background/Demographics; Noncompliance; Mood State; Cognitive Ability/Features; CBT Task Behaviors; Co-morbid; Depression Features; External Features; Knowledge CBT Model; Personality Characteristics; Therapist Actions; Procrastination; Nature of Assignment; Positive CBT Tools; Prediction of Good Response; and Patient Beliefs. Fifty-three items were discarded.

4.1.6 Item Selection

The initial raters review was examined for consistency in relation to whether each concept was identified per interview (See Appendix K). Each concept was examined separately in the therapist interviews and the patient interviews as to whether it was identified in an interview by the raters. Twenty four one-way ANOVAs were conducted to examine the 24 concepts in the patient interviews and then the 24 concepts for the therapist interviews in relation to differences in the raters' abilities to identify it as a reported barrier within the interview. There was only one concept on the patient interviews that had a significant result. The concept "therapist actions" was significantly different ($F= 5.01, p= .01$). Within the therapist interviews, there were 3 ANOVA's that were significant, indicating a difference between the raters' identification of the particular concept in the therapist interview. They included "therapist skill" ($F =4.32, p= .02$); "external factors" ($F= 3.17, p=.05$) and "prediction of good response" ($F=5.5, p=.01$). Therefore, in the patient interviews, there was no difference in the raters' identification of the concepts in 95% of the patient interviews and in 85% of the therapist interviews.

Each item keyword in the concepts was listed in relation to the amount of times it was identified throughout the forty interviews (See Appendix L). This frequency count was

examined in a similar method to a scree plot i.e., where there was an obvious cutoff in the frequency. The goal was to have sufficient item representation for each concept.

Each concept had between 1 and 5 items that were selected to be included in the final item pool. Two things determined which items were selected: 1) quantity of items per concept and 2) a clear numerical cutoff in the amount of interviews in which the barrier was identified. For instance, the concept CBT Task Behaviors had eighteen items. Three items were included in the item pool with frequencies of 41 (writing assignments), 37 (Thought records), and 25 (Homework Connecting Emotions and Thoughts). The next closest frequency was 8 (alternative beliefs). Thus, these three items clearly were foremost in this concept grouping in relation to how often they were mentioned as barriers by patient and therapists.

The following items were selected from each of the concepts: Avoidant Beliefs (avoid feelings, don't want to acknowledge depression); Cognitive Ability/Features (concentration, disorganized, forgetfulness, personality disorder); Co-Morbid (co-morbid diagnosis, obsessive compulsive disorder); Depression Features (depression length, depression severity, low energy); Dislike/Cynicism Re: CBT Model (short time between sessions, mechanistic tasks); External Factors (chaotic life, excessive responsibilities, imposition, means to do the assignment); Knowledge of CBT Model (Homework is new); Mood State (frustration, helplessness, hopelessness, motivation, overwhelmed); Nature of the Assignment (homework shows results, tailored homework assignments, complicated, how involved is assignment, confusing assignments); Non-compliance (unwilling to do homework, inconsistent pattern of doing homework); Oppositionality (negative connotations with homework, passive); Patient Background/Demographics (success level in life); Patient Beliefs (belief homework valuable, don't believe in therapy, Doctor will fix them); Patient-Therapist Relationship (collaboration,

power struggle patient/therapist, patient/therapist relationship, trust); Personality Characteristics (dependence; passive-aggressive, perfectionism); Positive CBT Tools (prioritization; time-management, patient designing their own homework); Prediction of Good Response (support level, willingness to change, initial success with homework); Procrastination (procrastination); Psychological Readiness (psychologically minded, therapy expectations); Self Efficacy/Self-Esteem (fear of failing, low self-esteem, will disappoint therapist, success with homework); Therapist actions (designing do-able homework, homework importance not stressed, not adequately explained, not checking homework, overload with homework); Therapist Qualities (flexibility, therapist patience) and Therapist Skill (socialization to the CBT Model, therapist moving patient too quickly, therapist skill, therapy too structured). See Appendix V for the specific questions associated with each concept.

4.1.7 Construction of the Scale

There were five iterations of the wording and structure of the draft instrument. The initial version (7/24/05) contained 85 items (See Appendix N). The scaling of this Likert-type instrument allowed for six choices including: not at all; slightly; somewhat; moderately; quite a bit and extremely. Informants are instructed to examine each potential barrier and mark the degree to which each item may have interfered with the homework assignment that was given in the most recent session. A stem sentence began each item with “When I didn’t complete my CBT homework (or completed it in a lesser degree than was expected) the following factors contribute.” Each item was simply stated as a word, i.e., assertiveness, anxiety, or a phrase, i.e., therapist is too technical, haven’t had positive results from doing homework. At the end of the instrument there was a section that asked the patient to list their homework assignment(s) and to

rate from one to ten (one being not difficult at all and ten being extremely difficult) the difficulty of the assignment.

Version Two (7/29/05) had a reduction from 85 items to 70 items (See Appendix N). This change of item amount allowed for proportional representation of each concept while reducing burden on the person completing the scale. The initial number of items was changed for ease of administration while allowing for adequate coverage of each concept in the draft instrument. Additionally, the directions were amended to include two introductory sentences: “Everyone misses all or part of a homework assignment during CBT sometimes during treatment. This questionnaire lists some of the barriers that might get in the way of completing CBT homework assignments.” These introductory sentences normalize the experience of having difficulty with homework. Normalizing difficulty in completing homework assignments may decrease defensiveness in rating the barriers that may have contributed to non-completion.

Several of the items were re-worded and an additional question was added to determine (on a scale of one to ten (none to all) how much of the homework assignment was completed. See Appendix N. Determining quantity of homework completion is a more complete measurement of adherence to the assignment.

Re-wording of items for greater clarity continued in version three (7/30/05). The rating of completion of homework was changed from a scale of one to ten to rating the completion of homework on a percentage basis for a more specific range. See Appendix N.

The fourth iteration of the questionnaire (8/10/05) reduced the amount of scaling by re-wording the range from: not at all; slightly; somewhat; moderately; quite a bit and extremely to: not at all; somewhat; moderately; very much and completely. This reduction in scale allowed for greater distinction in categories.

Barriers were also organized into Patient, Task, and Therapy/Therapist with specific directions for each of the categories. Space was provided for a second and third assignment rating of difficulty and the percentage of completion as there is often more than one homework assignment per therapy session. See Appendix N.

The fifth and final version of the draft instrument (8/11/05) allowed for modification of the general directions of rating the barriers from the most recent previous session to “since you began CBT therapy.” It was believed that information about barriers would be missed if the framework was restricted to the most recent session and homework assignment. The formatting clearly distinguished the labeling of Patient, Task, and Therapy/Therapist barrier categories.

Each item was also re-worded to state the item in a personalized past-tense manner, i.e., “I was afraid of failing” or “I was frustrated.” Finally, shading was introduced in every other row for ease of reading. See Appendix O.

4.2 PHASE II

4.2.1 Characteristics of the Sample

The majority (86%) of the subjects were recruited from an ongoing National Institute of Mental Health study of CBT in patients with recurrent major depression. This multi-site study was conducted at large academic centers in a mid-size Mid-Atlantic state and a large state in the South. Additional patients were recruited from community centers (see Methodology section) in the mid-Atlantic city as well as two mid-size cities in the South. Table 11 displays the

recruitment flow from the community sample. Only 19.23% of those eligible provided a complete dataset and 11.54% provided a partial dataset.

Table 11 Recruitment Flow from the Community

Responded to Flier	42
Eligibility	26 eligible/16 ineligible 13 diagnosis other than MDD 2 not currently in CBT 1 unknown
Entered study (signed consents)	15
Dropped out of study (did not return study forms)	7
Completed Study	5 returned full data 3 returned partial data

Table 12 displays the demographic characteristics of the total sample of 56 patients who participated in Phase II. Information for income is incomplete with 28.6% missing data.

Table 12 Phase II Categorical Demographic Statistics (N=56)

Variable	n	%
Gender (n= 56)		
Male	19	33.9
Female	37	66.1
Race (n= 56)		
Caucasian	56	88.9
African-American	4	6.3
Other	3	4.8
Marital Status (n= 56)		
Married/Cohab	19	33.9
Sep/Div/Widow	16	28.6
Never married	21	37.5
Highest Degree (n= 56)		
High School	20	35.7
Associates/Tech	8	14.3
College	19	33.9
Master's/PhD/MD	9	16.1
Income (n= 40)		
Less than \$29,999	19	33.9
\$30,000 - \$49,999	12	21.4
Greater than \$50,000	9	16.1

The sample is largely female (66%) and middle-aged (M 46 years \pm 12.5 years). It was primarily a Caucasian sample (88.9%). The group was nearly evenly divided between the married (34%), divorced/separated/widowed (29%), and the never married groups (38%). Sixty-four percent of the sample had an educational level greater than high school with mean years of education being 15.6 ± 2.71 years. Fifty-five percent of the sample earned less than fifty thousand dollars (28.6% missing data on this variable). Descriptive statistics on continuous descriptors are provided in Table 13.

Table 13 Phase II Continuous Patient Demographic Statistics (N=56)

Variable	Mean/SD	Median	Range
Age (years)	45.84 + 12.49	49	19-67
Years of Education	15.64 \pm 2.71	15.50	10-24

Table 14 provides information about characteristics of the patient sample's Major Depressive history and details regarding the current episode.

Table 14 Phase II Patient Major Depressive Episode Characteristics (N=56)

Variable	Mean/SD	Median	Range
MDD Age of Onset	24.88 ± 12.35	20.0	9-60
Time in Current Episode Of MDD in weeks	20.26 ± 26.57	12	1-120
Time in CBT in weeks	8.11 ± 19.29	3	<1-130

The mean age of onset for major depressive disorder was approximately 25 years of age ± 12 years with a wide range of 9 to 60 years. Approximately half (53.6%) of the patients had greater than four lifetime depressive episodes. The mean of the present episode was approximately 20.26 weeks ± 26.57 weeks. Mean time spent in CBT was approximately 8 weeks ± 19 weeks. The range of time in CBT was wide from <1 to 130 weeks. Number of episodes of MDD is detailed in Table 15.

Table 15 Phase II Patient Number of Episodes of MDD (N=56)

Number of Episodes	n	%
One	3	5.4
Two to Three	21	37.5
Greater Than Four	31	53.6

4.2.2 Characteristics of the Therapist Sample

Therapists were recruited from a mid-size Mid-Atlantic city, a large Southern city, and 2 mid-size Southern cities. They had been identified as primarily Cognitive Behavioral therapists. Therapists were recruited from established relationships of those who collaborated in studies at the Mood Disorders Treatment and Research Program, those in Pittsburgh known to practice CBT, and those who have been known to take CBT training through programs offered at the Mood Disorders Treatment and Research Program. Table 16 illustrates the characteristics of the therapist sample.

Table 16 Phase II Therapist Categorical Demographic Statistics (N=13)

Variable	n	%
Gender		
Male	3	23.1
Female	10	76.9
Race		
Caucasian	13	100
Highest Degree		
Master's	6	46.2
Doctorate	7	53.8
Professional Discipline		
Psychologist	7	53.8
Social Work	6	46.2

About three fourths of the therapists were females (77%). The mean age was approximately 48.5 years \pm 9 years. The range of therapist age was 33 to 68 years. All of the therapists were Caucasian. All of the therapists had an educational level of master's degree or higher (evenly divided between PhD psychologists and Masters prepared social workers) with the mean education being 21 years \pm 2.0 years (the range was 18 to 25 years). Table 17 reports descriptive statistics for continuous therapist demographics.

Table 17 Phase II Continuous Therapist Demographic Statistics (N=13)

Variable	Mean/SD	Median	Range
Age (years)	48.54 ± 8.67	53.0	33-68
Years of Education	21.08 ± 2.29	20	18-25

Table 18 and 19 provides information about the therapist's professional background and training.

Table 18 Phase II Therapist Professional Background and Training (N=13)

	%	n
Training		
Intermediate	15.4	2
Advanced	84.6	11
Received CBT Supervision		
Yes	100	13
No. of Patients Treated with CBT		
21-60	15.4	2
61-100	15.4	2
101-200	15.4	2
201+	53.8	7
Professional Discipline		
PhD Psychologist	53.8	7
MSW	46.2	6

The majority of the sample (85%) had advanced training in CBT. All of the therapists had received clinical supervision in CBT. Mean hours of supervision received were 263 hours/lifetime \pm 276 hours. The sample reported doing CBT fulltime with a mean of nearly 6 years \pm 7 years (missing 7.7% data) and part-time for 5 years \pm 3 years (missing 38.5% data). Approximately half of the therapists had treated greater than 200 patients using CBT. The

majority (85%) treated at least 60 patients with CBT. Therapist professional discipline was nearly evenly divided between PhD level (54%) and MSW level (46%).

Table 19 Phase II Therapist Professional Background and Training (N=13)

Variable	Mean/SD	Median	Range
Hours of CBT Supervision	262.43 ± 275.93	180	1-1000
Years Doing CBT Full-time	7.75 ± 7.07	7.5	0 – 24
Years Doing CBT Part-time	20.00 ± 6.42	5	0 – 20

4.2.3 Summary of Internal Structure

An unweighted least squares factor analysis with oblimin rotation (initial rotation) was conducted on subjects completing the Barriers to CBT Homework Completion Scale (n=54) at measurement B. Missing items were replaced with linear trend at point values. There was a small amount of missing data. Examination of the correlation matrix indicated an ill conditioned matrix with many negative, low, or excessively high (indicative of redundancy) correlations. Determinant =.000. Communalities ranged from .486 to .893. The analysis failed to rotate after 25 iterations with missing items replaced, so a listwise deletion was employed, further reducing

the sample to 46. The factor analysis was repeated, and again, the rotation failed after 25 iterations.

Issues with sample size in relation to the amount of items, was considered the primary area of concern. An attempt to reduce the amount of items, while maintaining the conceptual underpinnings of the item pool, was attempted. Given the strict methodology of concept identification in Phase I, the resulting concepts derived from that process were considered a logical approach to examine the factor structure (See Appendix I for concept groups).

An unweighted least squares factor analysis was performed with a Promax (for a simpler structure) rotation on the 24 concepts identified in the Barriers to CBT Homework Completion Scale. The concepts that were analyzed as “items” were computed by adding together all individual items within the concept. A 2 factor solution was forced as each scree plot (see figure 2) in previous factor analyses indicated the solution had 2 factors. Each of the concepts comprises between 1 and 5 of the items. The instrument administered at measurement B was conducted with a sample of 54 subjects. Missing data was replaced with linear trend of point values.

The correlation matrix was found to be well conditioned with 83% of the correlations being $> .30$. The Determinant was $2.15E-012$ and not zero. The Kaiser-Meyer-Olkin value was $.83$ indicating excellent sampling adequacy. Bartlett’s test of sphericity was 1179.7 and was significant at the $.001$ level suggesting $R \neq I$. There were very few non-significant pairwise correlations. Item MSA values ranged from $.71$ to $.90$, with 75% of the values being above $.80$. This also provides an excellent indication of sampling adequacy. The majority of the partial correlations were extremely small in the Anti-Image Matrix. Communalities ranged from $.75$ to $.91$ indicating a high degree of correlation between the items. The rotation succeeded after 3

iterations.

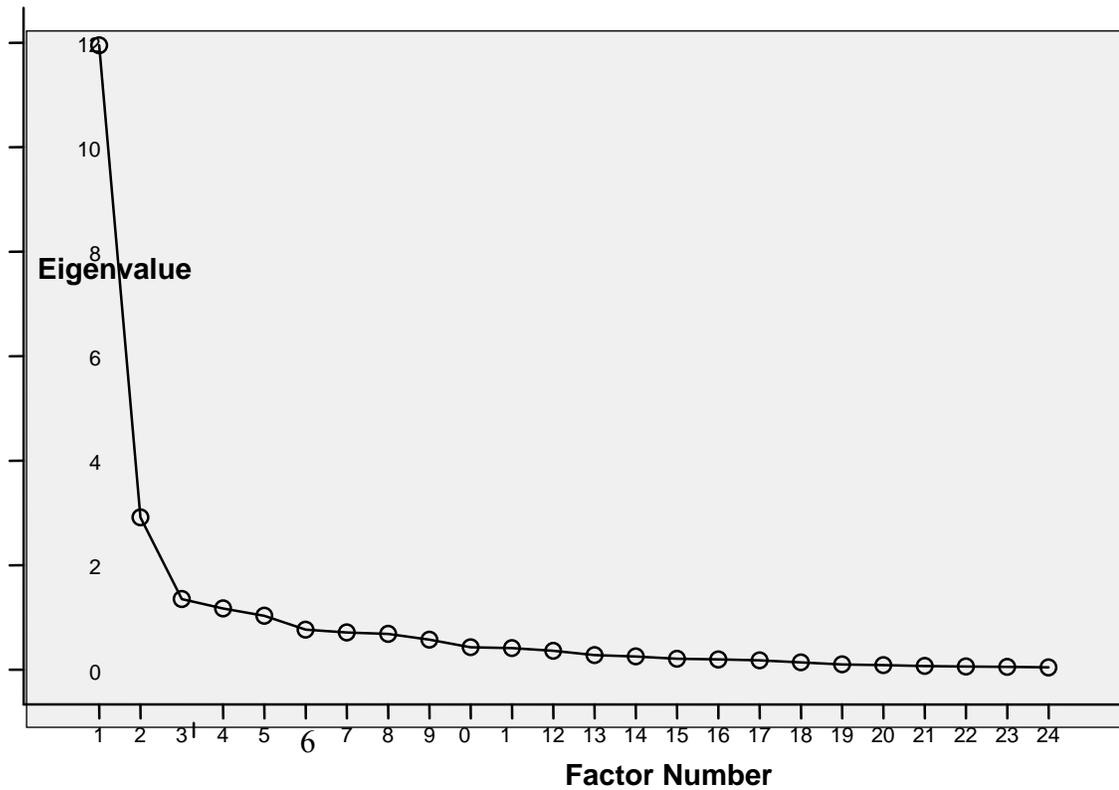


Figure 2 Scree Plot

The scree plot also revealed a clear 2 factor cutoff (see Figure 2). The eigenvalues that were extracted had values of 11.61 and 2.7. They explained 48.39% and 11.24% of the variance. Total variance explained by the two factors was 59.6%. Factor 1 explaining the greatest amount of variance was titled “Patient Factors” and Factor 1 was titled “Therapist/Task Factor.” The Patient Factor loaded heavily ($> .4$) on the following concept items: opposition; patient beliefs;

mood state; prediction of good response; self efficacy/self-esteem; non-compliance; depression features; CBT task behaviors; procrastination; psychological readiness; positive CBT tools; patient background; co- morbidity; cognitive abilities; knowledge of CBT model; external factors; and avoidant beliefs. The Therapist/Task Factor loaded on the following concept items: patient/therapist relationship; therapist skill; therapist qualities; therapist actions; nature of the assignment, personal characteristics; and dislike/cynicism of the CBT model (See Appendix W). It should be noted that the final concept loaded at .35, which was slightly lower than the cutoff. It was considered reasonable to include it, given the proximity and conceptual meaningfulness.

Table 20 provides information on the rotated factor loadings for each of the concepts in the Patient and Therapist/Task Factors.

Table 20 Barriers to CBT Homework Completion Scale Factor Loadings for Concept Subscales

<i>Factor 1</i>		<i>Factor 2</i>	
<i>Concept No./Name.</i>	<i>Loading</i>	<i>Concept No./Name.</i>	<i>Loading</i>
3 Opposition	.96	8 Pt/Therapist Relation	.98
24 Patient Beliefs	.85	4 Therapist Skill	.98
11 Mood State	.83	5 Therapist Qualities	.95
23 Predict Good Response	.81	19 Therapist Actions	.75
7 Self Efficacy/Self-esteem	.80	21 Nature of Assignment	.60
10 Non-compliance	.77	18 Personality Charac.	.51
15 Depression Features	.72	1 Dislike/Cynicism Model	.35
13 CBT Task Behaviors	.72		
20 Procrastination	.71		
2 Psychological Readiness	.71		
22 Positive CBT Tools	.71		
9 Pat. Background/Demos	.69		
14 Co-morbidity	.63		
12 Cognitive Abilities	.62		
17 Knowledge CBT Model	.62		
16 External Factors	.58		
6 Avoidant Beliefs	.54		

4.2.4 Summary of Reliability (Internal Consistency and Item Analysis)

Cronbach's Alpha was the primary measure on internal consistency for the Barriers to CBT Homework Completion Scale. Reliability was examined for the entire 70-item scale as well as the 65-item scale after 5 items had been deleted following the initial item analysis (due to very low item-total correlations). Additionally, reliability was examined on the aggregated concept items (see summary of internal structure). The instruments had been administered at Measurement B, the first administration of the Barriers to CBT Homework Completion Scale. Table 21 displays relevant psychometric statistics in this analysis.

Table 21 Barriers to CBT Homework Completion Scale (Measurement B) Internal Consistency

Statistic	Total (70 items)	(65Item) Scale
Cronbach's Alpha	.97	.97
Item Mean/SD	.65 ± .49	.70±.48
Item Mean Range	.02 -1.57	.04±1.57
Inter-item Correlation Mean/SD	.29 ± .21	.3±.18
Inter-item Correlation Range	-.24 -.89	.24±.89
Corrected Item Total Correlation Range	-.08 -.78	.25- .78
Items Below .2	51, 52, 53, 55, 56	none
Cronbach's Alpha if Item Deleted Range	.97-.97	.97-.97
Scale Mean/SD	45.78 ± 37.09	45.03±36.93

The possible range for the 70 item scale was 0 to 280 points. The possible range for the 65 item scale was 0 to 260 points. The scale mean for the 70 item scale was 45.78 ± 37.09. The scale mean for the 65 item scale was 45.02 ± 36.93. The total scores, then, are highly positively skewed. The item means for the 70 item scale were .65 ± .49. The item mean for the 65 item scale was .70 ± .48. Examinations of the distributions reveal a J curve on the item and scale level (See Figures 3, 4, and 5).

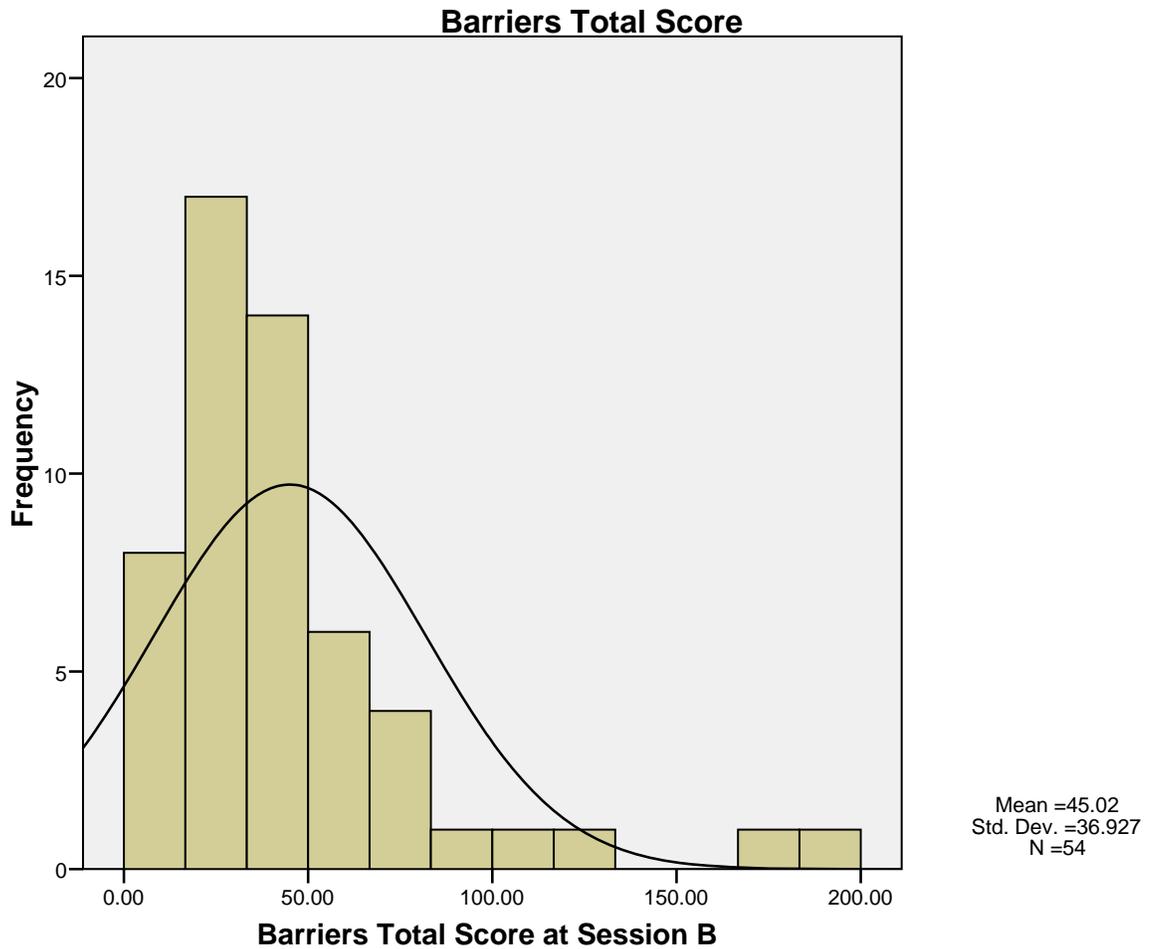


Figure 3 Distribution of Barriers to CBT Homework Completion Scale (65 items)

The correlation matrix of the 70 and the 65 item scale satisfied Kerlinger’s (1973) criteria that at least half of the correlations were $\geq .30$. Cronbach’s alpha for the 70 item scale was .97. Mean inter-item correlations ranged from -.24 to .89. Mean inter-item correlations were $.29 \pm .21$, demonstrating the items are from the same domain. Some redundancy exists as the mean inter-item correlation should not be greater than .20 (Nunnally, 1978). The range of the item-total correlations was -.08 to .78 indicating some items that had little relationship with the total score. On inspection these items were found to be numbers 51, 52, 53, 55, and 59. They were deleted from the instrument and the reliability analysis was repeated without them.

Cronbach's alpha for the revised 65 item scale was also .97. The mean inter-item correlation was $.34 \pm .18$ demonstrating again, the items are from the same domain yet some redundancy exists. The corrected item-total correlation range was from .25 to .78, indicating satisfactory relationship between individual items and the total score.

Given the instability of the initial Factor Analyses of the Item Scale and a satisfactory solution with the underlying concepts as the items, internal consistency will be examined on the concepts in the entire scale as well as the subscales that emerged from the final factor analysis. Henceforth, all examinations of the Barriers to CBT Homework Completion Scale will be with the 5 items deleted (from the initial item analysis) and at the concept as items level. Table 22 provides relevant statistics as to the internal consistency of the concept as items scale at measurement B.

Table 22 Barriers to CBT Homework Completion Scale (Measurement B) Internal Consistency for Concepts

Statistic	Total Scale	Pt. Subscale	Ther/TaskSub
# of Items	24	17	7
Cronbach's Alpha	.94	.94	.86
Item Mean/SD	1.90 ± 1.55	2.36 ± 1.57	.70 ± .58
Item Mean Range	.06- 5.90	.50- 5.89	.0-1.50
Inter-item Correlation Mean/SD	.47 ± .17	.53 ± .12	.6-.14
Inter-item Correlation Range	-.07 -.83	-.29 -.79	.24 -.83
Corrected Item Total Correlation	.41-.84	.56-.83	.52 -.84
Items Below .2	none	none	none
Alpha if Item Deleted Range	.94-.94	.93-.94	.81-.86
Scale Mean/SD	45.02 ± 36.93	40.13 ± 31.09	4.90 ± 7.87

The possible range for the 24 concept item scale was 0 to 260 points. The possible range for the Patient Subscale was 0 to 180. The possible range for the therapist/task subscale was 0 to 80. The scale mean for the 24 concept item scale was 45.02 ± 36.93. The scale mean for the 17 item Patient Subscale was 40.13 ± 31.09. The Scale mean for the Therapist/Task 7 item subscale was 4.90 ± 7.87. The total scores, then, are highly positively skewed. The item means for the 24 item scale were 1.90 ± 1.55. The item mean for the 17 item Patient subscale was 2.36 ± 1.57.

The item mean for the 7 item therapist/task subscale was $.70 \pm .58$. Examinations of the distributions reveal a J-shaped curve on the scale and subscale level. Figures 4 and 5 illustrate the J-shaped curves of the subscales.

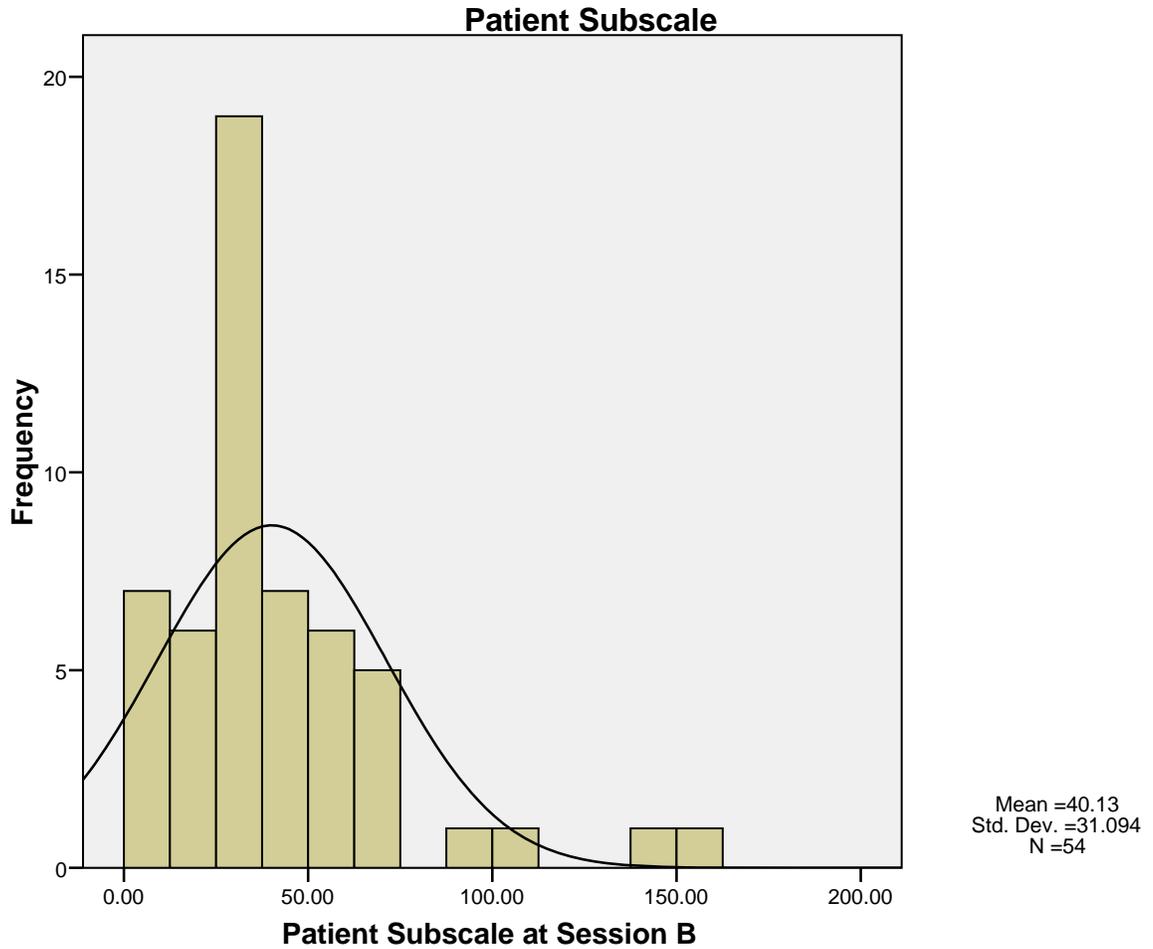


Figure 4 Patient Subscale Distribution

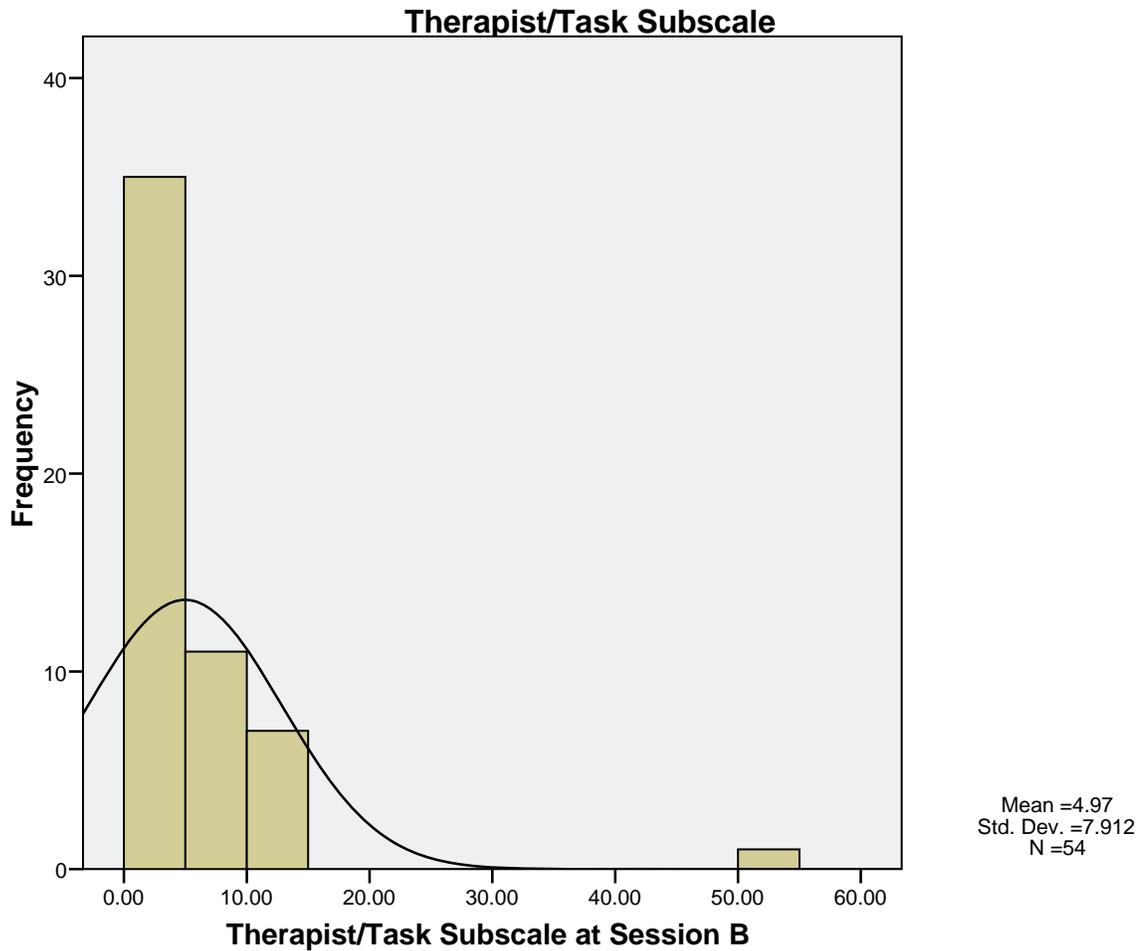


Figure 5 Therapist/Task Subscale Distribution

The correlation matrix of the whole scale and the subscales satisfied Kerlinger's (1973) criteria that at least half of the correlations were $\geq .30$. Cronbach's alpha for the 24 concept as item scale was .94; for the patient subscale .94; and the therapist/task subscale .86. Mean inter-item correlations ranged from .47 to .61 among the 3 scales. Mean inter-item correlations were $.47 \pm .17$; $.53 \pm .12$; and $.61 \pm .14$ respectively for the 3 scales, demonstrating the items are from the same domain. Some redundancy exists as the mean inter-item correlation should not be greater than .20 (Nunnally, 1978). The range of the item-total correlations were -.41 to .84; .56-

.83; and .52-.84 respectively for the Scale and subscales, indicating all items that had a moderate to high relationship with the total score. Alpha of item deleted remained nearly the same for the whole scale and the Patient subscale. There was some spread in the effect of items on Alpha with a range of .81 to .86.

Table 23 illustrates the internal consistency statistics for the concept as items entire scale and the Patient and Therapist/Task subscales at Measurement C.

Table 23 Barriers to CBT Homework Completion Scale (Measurement C) Internal Consistency for Concepts

Statistic	Total Scale	Pt. Subscale	Ther/Task Sub
Cronbach's Alpha	.94	.93	.80
Item Mean/SD	1.62 ± 1.38	1.99 ± 1.43	62 ± .59
Item Mean Range	.08- 5.10	.18- 5.10	.08 ± .56
Inter-item Correlation Mean/SD	.47 ± .18	.50 ± .16	.45 ± .27
Inter-item Correlation Range	-.18-.93	-.18 -.84	.93
Corrected Item Total Correlation	.39-.86	.41-.86	.80
Items Below .2	none	none	none
Cronbach's Alpha if Item Deleted	.94-.94	.92-.93	.73-.81
Scale Mean/SD	38.78 ± 34.22	33.90 ± 27.67	4.35 ± 7.20

The ranges, of course, remain the same as previously reported. The scale mean for the 24 concept item scale was 38.78 ± 34.22. The scale mean for the 17 item Patient Subscale was 33.90 ± 27.67. The Scale mean for the Therapist/Task 7 item subscale was 4.35 ± 7.20. The total scores continue to be highly positively skewed. The item means for the 24 item scale were 1.62 ± 1.38. The item mean for the 17 item Patient subscale was 1.99 ± 1.43. The item mean for

the 7-item therapist/task subscale was $.62 \pm .59$. Examinations of the distributions reveal a J curve on the scale and subscale level.

The correlation matrix of the whole scale and the subscales satisfied Kerlinger's (1973) criteria that at least half of the correlations were $\geq .30$. Cronbach's alpha for the 24 concept as item scale was .94; for the patient subscale .93; and the therapist/task subscale .80. Mean inter-item correlations ranged from .45 to .50 among the 3 scales. Mean inter-item correlations were $.47 \pm .19$; $.50 \pm .16$; and $.45 \pm .27$ respectively for the 3 scales, demonstrating the items are from the same domain. Some redundancy exists as the mean inter-item correlation should not be greater than .20 (Nunnally, 1978). The range of the item-total correlations were .39-.86 ; .41-.86; and .20-.80 respectively for the Scale and subscales, indicating most items that had a moderate to high relationship with the total score. At least one of the items in the Therapist/Task subscale had a low item-total correlation that was on the border of being unacceptable. Alpha of item deleted remained nearly the same for the whole scale and the Patient subscale. Again, there was some spread in the effect of items on Alpha with a range of .73 to .81. Alpha for the therapist/task factors subscale is significantly lower than the entire scale and the patient subscale.

4.2.5 Reliability over Time

Reliability over time was examined through Pearson Product Moment Correlation from scores of the whole scale, the Patient subscale, and the Therapist/Task subscale from measurement B to measurement C. The minimum period of time between administrations of the instrument was two days and the maximum was three weeks. Table 24 displays the Pearson's correlation and associated significance level.

Table 24 Barriers to CBT Homework Completion Scale Test-Retest Reliability (N=48)

Scale	Pearson's Correlation	p
Entire Scale	.95	.01
Patient Subscale	.94	.01
Therapist/Task Subscale	.72	.01

While all correlations were significant, the entire scale and the Patient subscale had a much more robust association, indicating greater stability over time as compared to the therapist/task subscale.

4.2.6 Summary of Demographic Prediction

The following are a series of regression analyses to examine demographic predictors of Barriers to CBT Homework Completion Scale scores and Assignment Compliance Rating Scale scores as well as a larger prediction model that includes the demographic predictors and the variables of patient depression severity and characteristics, dysfunctional attitudes, therapist training and background, and time in therapy. It should be noted that due to the positively skewed distributions of the Barriers Scale and Subscales and the negatively skewed distribution of the Assignment Compliance Rating Scale (both having J-shaped curves); transformations were required to induce normality. See Figure 6 for the original ACRS distribution. A square root transformation was performed on the Barriers Scale and subscale scores which did bring the

distribution further towards a normal distribution. A reflect and square root transformation was performed on the Assignment Compliance Rating Scale. While it improved the distribution, it did not achieve the level of normality that was desired.

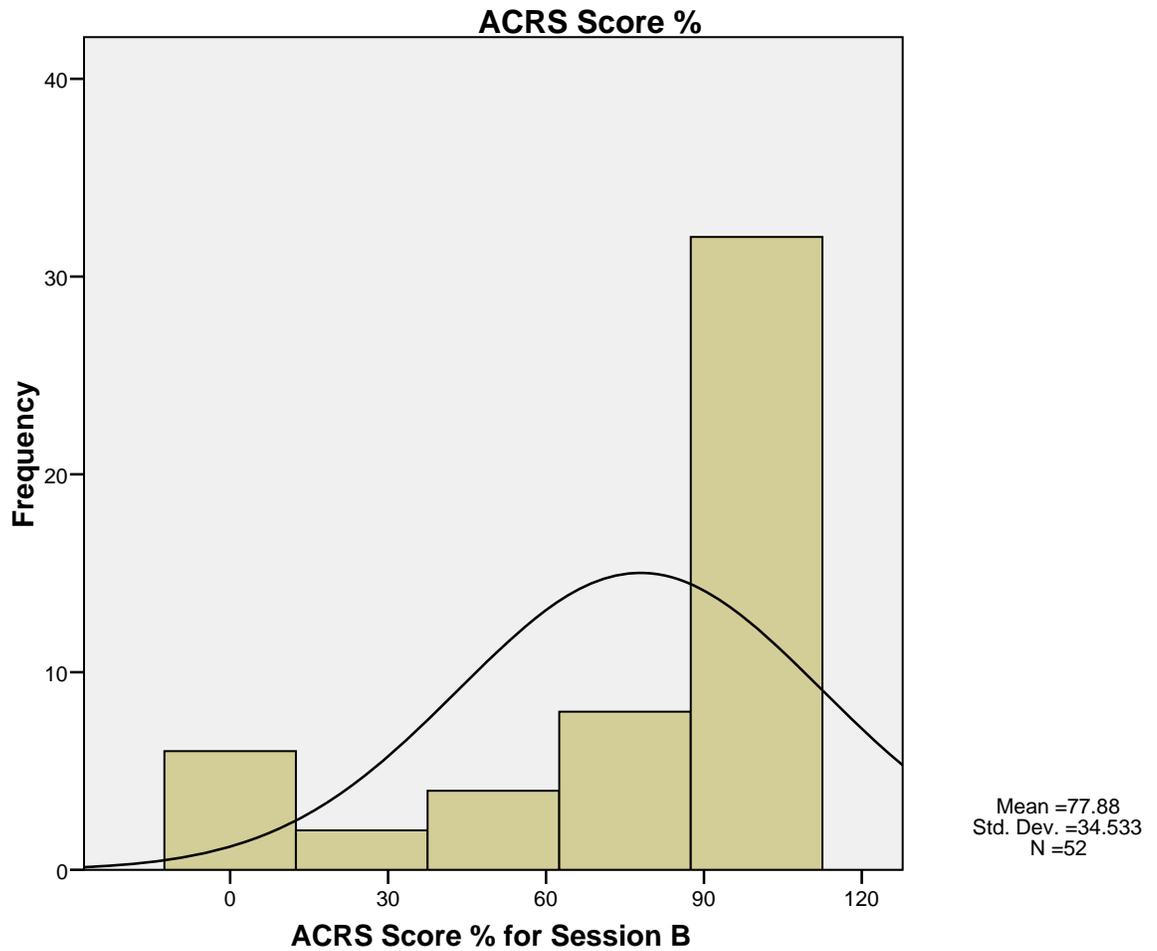


Figure 6 ACRS Distribution

Table 25 lists the coding related to all of the following regression analyses.

Table 25 Coding Guidelines

Variable	Coding
BDI	total Score
Time in Treatment	weeks
Length of Depression	weeks
Barriers Scores	summed score for scale or subscale
Number of Depressive episodes	0-3 episodes = 0; 4+ episodes = 1
DAS	total score
Therapist Education	years of education
Therapist Supervision	hours of supervision
Therapist Number of Patients	≤ 150 patients = 0; ≥ 151 patients = 1
Patient Marital Status	married/cohabitating = 1; other = 0
Patient Gender	male = 1; female = 0
Patient Age	years
Patient Race	White = 1; Other = 0
Patient Education	years of education

4.2.6.1 Demographic Predictors of Barriers to CBT Homework Completion Scale Scores

In an attempt to determine if there were demographic predictors of the Barriers Scores, a series of multiple regression equations were completed. The total scale as well as the Patient and Therapist/Task Subscales were examined. Table 26 presents the multiple regression results of the demographic variables of marital status, race, gender, age, and educational level and their ability to predict Barriers to CBT Homework Completion Scale scores at Measurement B.

Table 26 Multiple Regression of Demographic Predictors on Barrier to CBT Homework Completion Scores at Measurement B (65 Item Scale, N=54)

Adjusted R ²	b (SE)	F(df)	β	p-value
.21		3.73 (5,48)		.01
	Constant: 10.48 (2.2)			
	Gender: -.37 (.65)		-.07	.57
	Age: -.002 (.03)		-.01	.92
	Marital: 1.88 (.65)		.36	.01
	Education: -.12 (.11)		-.13	.31
	Race: -3.02 (1.10)		-.35	.01

This model was significant at the .01 level, showing the predictors of marital status (being married or cohabitating) and race (non-white) predicting higher Barriers to CBT Homework Completion Scale scores. Table 27 illustrates the same analysis on the Patient Subscale.

Table 27 Multiple Regression of Demographic Predictors on Barriers to CBT Homework Scores at Measurement B (Patient Subscale, N=54)

Adjusted R ²	b (SE)	F (df)	β	p-value
.18		3.35 (5, 48)		.01
	Constant: 9.55 (2.06)			
	Gender: -.25 (.60)		-.05	.69
	Age: -.001 (.02)		-.01	.98
	Marital: 1.74 (.61)		.37	.01
	Education: -.12 (.11)		-.14	.28
	Race: -2.49 (1.00)		-.32	.02

Again, marital status (being married or cohabitating) and race (non-white) were significant predictors of higher Barriers to CBT Homework Completion Patient Subscale scores. Table 28 illustrates the findings for the regression of demographic predictors on the Therapist/task subscale.

Table 28 Multiple Regression of Demographic Predictors on Barriers to CBT Homework Completion Scores at Measurement B (Therapist/Task Subscale, N=54)

Adjusted R ²	b (SE)	F(df)	β	p-value
.13		2.54 (5,48)		.04
	Constant: 3.94 (1.28)			
	Gender: -.41 (.38)		-.14	.28
	Age: -.007 (.02)		-.06	.64
	Marital: .69 (.38)		.24	.07
	Education: -.12 (.07)		-.04	.79
	Race: -1.70 (.62)		-.36	.01

Once again, race (non-white) was a significant predictor of higher barriers scores. Marital status demonstrated a trend toward prediction. The preceding regression analyses were also done for the entire scale, and the Patient and Therapist/Task subscales at Measurement C. Table 29 illustrates the regression analysis for demographic predictors on the entire Barriers scale.

Table 29 Multiple Regression of Demographic Predictors on Barriers to CBT Homework Completion Scores at Measurement C

Adjusted R ²	b (SE)	F (df)	β	p-value
.21		3.53 (5,43)		.009
	Constant: 10.82 (2.28)			
	Gender: -.02 (.70)		-.004	.97
	Age: -.005 (.03)		-.02	.85
	Marital: 1.88 (.71)		.35	.01
	Education: -.16 (.12)		-.18	.18
	Race: -3.18 (1.21)		-.35	.01

Marital status (being married or cohabitating) and race (non-whites) continue to serve as predictors of higher Barriers to CBT Homework Completion Scores at the .01 significance level. Table 30 illustrates the demographic regression analysis for the Patient Subscale at measurement C.

Table 30 Multiple Regression of Demographic Predictors on Barriers to CBT Homework Scores at Measurement C (Patient Subscale, N=49)

Adjusted R ²	b (SE)	F (df)	β	p-value
.16		2.82 (5,43)		.03
	Constant: 9.54 (2.11)			
	Gender: -.07 (.64)		-.01	.92
	Age: -.006 (.02)		-.03	.81
	Marital: 1.64 (.65)		.34	.02
	Education: -.15 (.11)		-.18	.18
	Race: -2.39 (1.12)		-.29	.04

The regression of demographic predictors continues to show that race (non-whites) and marital status (married or cohabitating) are significant predictors of higher Patient subscale scores. Table 31 illustrates the demographic predictor regression on the Therapist/Task Subscale.

Table 31 Multiple Regression of Demographic Predictors on Barriers to CBT Homework Completion Scores at Measurement C (Therapist/Task Subscale, N=49)

Adjusted R ²	b (SE)	F (df)	β	p-value
.25		4.12 (5, 43)		.004
	Constant: 4.14 (1.27)			
	Gender: -.19 (.39)		-.06	.63
	Age: -.007 (.01)		-.06	.64
	Marital: .90 (.39)		.28	.04
	Education: -.04 (.07)		-.08	.52
	Race: -2.46 (.67)		-.47	.001

In summary, race (non-whites) and marital status (married or cohabitating) were significant in nearly all of the regression analyses done to determine if demographic variables may have predicted higher Barriers to CBT Homework Completion Scale and Subscale scores. The non-significant analysis on the Therapist/Task subscale at measurement B was, nonetheless, at the trend level of .07.

4.2.6.2 Demographic Predictors of the Assignment Compliance Rating Scale

The demographic variables of marital status, race, gender, age, and educational level were examined in multiple regression analyses with the Assignment Compliance Rating Scale, the primary outcome measure for compliance. They were done at measurement points B and C. Table 32 illustrates these findings for measurement B.

Table 32 Multiple Regression of Demographic Predictors on Assignment Compliance Rating Scale Scores at Measurement B (N=52)

Adjusted R ²	b (SE)	F (df)	β	p-value
.10		2.12 (5, 46)		.08
	Constant: 10.00 (3.24)			
	Gender: -.78 (.96)		.109	.42
	Age: -.009 (.04)		.03	.82
	Marital: 1.11 (.96)		.16	.25
	Education: -.36 (.16)		-.30	.03
	Race: -2.44 (1.55)		-.47	.12

The omnibus F test was non-significant but showed a trend toward significance, i.e., .10 or lower. Nonetheless, the individual predictor of education (fewer years of education) was significant at the .03 level, indicating less education predicts higher levels of homework completion. Table 33 provides the statistics for the regression of demographic variables on Assignment Compliance Rating Scale scores at measurement C.

Table 33 Multiple Regression of Demographic Predictors on Assignment Compliance Rating Scale Scores at Measurement C (N=50)

Adjusted R ²	b	F (df)	β	p-value
-.01	.90 (5,44)			.49
	Constant: 8.84 (3.60)			
	Gender: -.03 (1.07)		.004	.98
	Age: -.03 (.04)		.09	.53
	Marital: -.58 (1.12)		-.08	.60
	Education: -.36		-.30	.03
	Race: -.19 (.19)		-.15	.32

Education (less education) continued to be a significant predictor of higher levels of homework completion as measured by the Assignment compliance rating scale at measurement C.

4.2.7 Prediction of Barriers to CBT Homework Completion Scale Scores

Additional potential predictors of Barriers to CBT Homework Completion Scale scores were included in the multiple regression models. They included: severity of depression as measured by the Beck Depression Inventory; length of time in CBT therapy (in weeks); length of current Major Depressive episode in weeks; number of depressive episodes; dysfunctional attitudes as

measured by the Dysfunctional Attitudes Scale and therapist training. These predictors were added to the demographic variables already included. These regression analyses were done on the entire 65 item scale Patient subscale, and Therapist/Task subscales at measurements B and C. Table 34 displays the multiple regressions for the predictors detailed above on the entire Barriers to CBT Homework Completion Scale at Measurement B.

Table 34 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale Scores at Measurement B (65 Item Scale)

Adjusted R ²	b (SE)	F (df)	β	p-value
.29		2.30 (13, 29)		.03
	Constant: 4.15 (6.26)			
	Gender: -1.05 (.77)		-1.36	.18
	Age: -.02 (.03)		-.62	.60
	Marital: 1.95 (.80)		2.46	.02
	Education: -.004 (.14)		-.03	.98
	Race: -2.33 (1.26)		-1.84	.08
	Time in CBT: -.004 (.04)		-.12	.91
	Duration episode: .01 (.01)		.81	.42
	Number episodes: 1.51 (.72)		2.10	.05
	Therapist educ: .13 (.24)		.53	.60
	Hours supervision .001(.002)		.66	.51
	Patients treated .31 (1.20)		.26	.80
	DAS .01 (.01)		.71	.48
	BDI .03 (.05)		.70	.49

The model was significant but the only significant predictors in the model were number of episodes of depression and marital status. More depressive episodes and being married or cohabitating predicted higher barriers to homework completion. Table 35 tests this regression model on the Patient subscale.

Table 35 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale Scores at Measurement B (Patient Subscale, N=43)

Adjusted R ²	b	F (df)	β	p-value
.29		2.32 (13,29)		.03
	Constant: 3.44 (5.63)			.55
	Gender: -.78 (.69)		-.18	.27
	Age: -.02 (.03)		-.09	.58
	Marital: 1.89 (.72)		.45	.01
	Education: -.006 (.13)		-.007	.97
	Race: -1.57 (1.14)		-.20	.18
	Time in CBT: -.01 (.03)		.006	.97
	Duration episode: .01 (.01)		.12	.50
	Number episodes: 1.46 (.65)		2.10	.05
	Therapist educ: .13 (.22)		.11	.64
	Hours supervision: .001 (.001)		.17	.41
	Patients treated: .22 (1.08)		.05	.84
	DAS: .01 (.01)		.09	.56
	BDI: .03 (.04)		.13	.46

Marital status (being married or cohabitating) and number of depressed episodes (higher number of episodes) remained the significant predictors in the model for higher patient subscale scores. Table 36 displays the results on the Therapist/Task Subscale.

Table 36 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale Scores at Measurement B (Therapist/Task Subscale, N=43)

Adjusted R ²	b (SE)	F (df)	β	p-value
.16		1.63 (13, 29)		.13
	Constant: 2.84 (4.25)			.51
	Gender: -1.07 (.52)		-.35	.05
	Age: -.01 (.02)		-.12	.49
	Marital: .42 (.54)		.14	.45
	Education: -.001 (.10)		-.008	.97
	Race: -1.99 (.86)		-.36	.03
	Time in CBT: -.02 (.03)		-.132	.47
	Duration episode: .01 (.01)		.12	.50
	Number episodes: .52 (.49)		.18	.30
	Therapist educ: .05 (.16)		.08	.75
	Hours supervision: .001 (.001)		-.10	.65
	Patients treated: .69 (.81)		.23	.42
	DAS: .01 (.01)		.20	.23
	BDI: .001 (.03)		.01	.97

The predictor model for the Therapist/Task Subscale was not significant even though 2 of the predictors, race (non-white) and gender (female), were significant for predicting higher Therapist/Task Subscale scores. The preceding models are tested on the measurement C evaluations. Table 37 displays the predicted model for the entire scale.

Table 37 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale at Measurement C (65 item scale, N=42)

Adjusted R ²	b (SE)	F (df)	β	p-value
.20		1.76 (13, 28)		.10
	Constant: 13.17 (7.61)			.09
	Gender: .08 (.83)		.02	.92
	Age: -.02 (.03)		-.11	.53
	Marital: 1.73 (.92)		.35	.07
	Education: -.16 (.14)		-.19	.26
	Race: -.3.12 (1.51)		-.34	.05
	Time in CBT: -.04 (.04)		-.19	.28
	Duration episode: .01 (.02)		.06	.74
	Number episodes: 1.44 (.78)		.30	.08
	Therapist educ: -.19 (.32)		-.17	.55
	Hours supervision: .001 (.002)		-.05	.81
	Patients treated: .72 (1.27)		.15	.58
	DAS: .01 (.01)		.10	.60
	BDI: .000 (.05)		-.002	.99

Again, the model was not significant but race (non-white), as an individual predictor was, and number of episodes (higher number of episodes) and marital status (married or cohabiting)

showed a trend towards significance. Table 38 displays the predictors in the regression for the Patient Subscale.

Table 38 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale at Measurement C (Patient Subscale, N=42)

Adjusted R ²	b (SE)	F (df)	β	p-value
.15		1.56 (13, 28)		.16
	Constant: 11.37 (6.89)			.11
	Gender: .15 (.75)		.03	.84
	Age: -.02 (.03)		-.13	.47
	Marital: 1.62 (.84)		.37	.06
	Education: -.14 (.12)		-.20	.26
	Race: -2.09 (1.37)		-.26	.14
	Time in CBT: -.04 (.04)		-.17	.33
	Duration episode: .01 (.02)		.07	.70
	Number episodes: 1.35 (.71)		.32	.07
	Therapist educ: -.16 (.29)		-.16	.59
	Hours supervision: .001 (.001)		-.04	.85
	Patients treated: .50 (1.15)		.12	.67
	DAS: .004 (.01)		.06	.77
	BDI: .002 (.04)		.01	.97

The model for the predictors with the Patient Subscale was also non-significant. Only number of episodes (higher number of episodes) and marital status (married or cohabiting) had a trend towards prediction. Table 39 displays the Therapist/Task Regression of the selected predictors at measurement C.

Table 39 Multiple Regression Model for Prediction of Barriers to CBT Homework Completion Scale at Measurement C (Therapist/Task Subscale, N=42)

Adjusted R ²	b (SE)	F (df)	β	p-value
.22		1.87 (13, 28)		.08
	Constant: 5.38 (4.48)			.24
	Gender: -.31 (.49)		-.10	.37
	Age: -.001 (.02)		.01	.94
	Marital: .35 (.54)		.12	.53
	Education: -.05 (.08)		-.11	.53
	Race: -2.86 (.89)		-.5	.003
	Time in CBT: -.03 (.02)		-.19	.26
	Duration episode: .001(.01)		.03	.88
	Number episodes: .47 (.46)		.17	.31
	Therapist educ: -.09 (.19)		-.13	.64
	Hours supervision: .001(.001)		-.11	.61
	Patients treated: .71 (.75)		.25	.35
	DAS: .01(.01)		.31	.11
	BDI: -.02 (.03)		-.11	.50

Again, the model did not predict the Therapist/Task Subscale scores at the .05 significance level. There was a trend, however, at .08, and a significant predictor in the race (non-white) variable in predicting barriers to homework completion.

4.2.8 Summary of External Structure Evidence

4.2.8.1 Prediction of Assignment Compliance Rating Scale Scores

A model was tested to predict the above variables with the Barriers to CBT Homework Completion Scale scores (Total scale, Patient and Therapist/Task Subscales) as additional predictors. This model is tested at Measurement points B and C. Table 40 and 41 displays the results for the multiple regression analyses at measurements B and C.

Table 40 Multiple Regression Model for Prediction of Assignment Compliance Rating Scale Scores at Measurement B (N=41)

Adjusted R ²	b (SE)	F (df)	β	p-value
-0.08		.81 (16, 24)		.67
	Constant: 9.41 (12.27)			.24
	Gender: -.30 (1.60)		.04	.85
	Age: -.006 (.06)		.02	.91
	Marital: 1.25 (1.70)		.18	.47
	Education: -.32 (.27)		-1.20	.24
	Race: -7.35 (3.43)		-.56	.04
	Time in CBT: -.04 (.08)		-.11	.61
	Duration episode: .01(.03)		.08	.71
	Number episodes: .59 (1.51)		.09	.70
	Therapist educ: -.15 (.47)		-.10	.76
	Hours supervision: .001(.003)		.07	.80
	Patients treated: .92 (2.36)		.13	.70
	DAS: .01(.02)		.09	.65
	BDI:-.04 (.09)		.08	.71
	Barriers-Total: -6.39 (7.80)		-4.26	.42
	Patient Sub: 6.35 (7.59)		3.80	.41
	Ther/Task Sub: 1.20 (2.16)		.51	.58

Table 41 Multiple Regression Model for Prediction of Assignment Compliance Rating Scale Scores at Measurement C (N=41)

Adjusted R ²	b (SE)	F (df)	β	p-value
.10		1.28 (16, 24)		.28
	Constant: -17.15 (14.11)			.24
	Gender: -.98 (1.38)		.13	.48
	Age: -.05 (.05)		.19	.31
	Marital: -1.64 (1.70)		-.22	.34
	Education: .21 (.23)		-.17	.38
	Race: -.65 (3.40)		-.05	.85
	Time in CBT: -.06 (.07)		.17	.38
	Duration episode: -.001 (.03)		-.01	.97
	Number episodes: 1.56 (1.34)		.22	.26
	Hours supervision: .001(.003)		.08	.73
	Patients treated: -4.53 (2.25)		-.64	.06
	DAS: -.01(.02)		-.06	.80
	BDI: .07 (.08)		.18	.38
	Barriers-Total: -4.54 (6.70)		-2.93	.51
	Patient Sub: 5.04(6.43)		2.84	.44
	Ther/Task Sub: 1.86 (2.13)		.74	.39

Neither of these models was significant in predicting Assignment Compliance Rating Scale Scores. Only race (non-whites) at measurement B was a significant individual predictor of homework compliance. At measurement C, the number of patients treated was significant at trend level (fewer patients treated predicted homework compliance).

4.2.8.2 Logistic Regression of Barriers Subscales to the Assignment Compliance Rating Scale

A series of logistic regression analyses were completed to examine the subscales ability to identify those in the adherent group and those who were non-adherent. Adherence was defined as 75 % or greater homework completion on the Assignment Compliance Rating Scale. The initial models included both the Patient Subscale and the Therapist/Task Subscales. Table 42 displays this model at measurement B.

Table 42 Measurement B Logistic Regression of Patient and Therapist/Task Subscales to Identify Membership in Adherence Group

Variable	β (SE)	Wald	Odds Ratio	CI		Overall
				Lower/Upper		
Patient Sub	-.472 (.24)	3.86*	.62	.39/1.00		
Ther/Task Sub	.32 (.35)	.86	1.38	.70/2.71		
-2 Log Likelihood						50.74
Omnibus X^2						5.44
Classification						75%
Hosmer & Lemeshow						6.87
Sensitivity						8.3%
Specificity						95%

* $p < .05$, *** $p < .001$

The omnibus analysis was not significant but demonstrated a trend at .07. Within the model the patient subscale was significant in predicting high adherence. Lower patient subscale scores predicted high adherence.

Table 43 illustrates the logistic regression for measurement C.

Table 43 Measurement C Logistic Regressions of Patient and Therapist/Task Subscales (N=47) to Identify Membership in Adherence Group

Variable	β (SE)	Wald	Odds Ratio	CI Lower/Upper	Overall
Patient Sub	-.36 (.25)	2.05	.70	.42/1.14	
Ther/Task Sub	-.13 (.36)	.13	.88	.44/1.77	
-2 Log Likelihood					46.75
Omnibus X^2					6.65*
Classification					76%
Hosmer & Lemeshow					5.68
Sensitivity					16.7 %
Specificity					97.1 %

*P< .05, ***p< .001

While the Omnibus F test was significant in this analysis, neither of the subscales had a significant Wald statistic. The logistic regression done at measurement B had a significant Wald statistic for the Patient Subscale. Given this, and the significant Omnibus F test for measurement B, a model with only the Patient subscale was explored in 2 additional logistic regression analyses to identify its value in identifying high or low adherence. Table 44 displays this altered model at measurement B.

Table 44 Measurement B Logistic Regression of Patient Subscale (N=52) to Identify Membership in Adherence Group

Variable	β (SE)	Wald	Odds Ratio	CI Lower/Upper	Overall
Patient Sub	-.32 (.16)	4.03*	.73	.54/.99	
-2 Log Likelihood					51.63
Omnibus X^2					4.56*
Classification					78.8%
Hosmer & Lemeshow					4.09
Sensitivity					16.7%
Specificity					97.5%

*P< .05, ***p< .001

The model of predicting group membership with the Patient subscale at measurement B was significant at the Omnibus F level and correctly identified nearly 80% of the cases. Low patient subscale scores predicted high adherence. Table 45 illustrates this analysis at measurement C.

Table 45 Measurement C Logistic Regression of Patient Subscale (N=47) to Identify Membership in Adherence Group

Variable	β (SE)	Wald	Odds Ratio	CI Lower/Upper	Overall
Patient Sub	-.43 (.19)	5.10*	.65	.45/.95	
-2 Log Likelihood					46.88
Omnibus X^2					6.52**
Classification					76.6%
Hosmer & Lemeshow					1.00
Sensitivity					16.7%
Specificity					97.1%

* $p \leq .05$, ** $p \leq .01$, *** $p \leq .001$

The Patient Subscale alone (low scores), again, was a significant predictor of high adherence group at measurement B. Membership was identified correctly in 77% of the cases.

4.2.8.3 Correlations of Barriers to CBT Homework Completion Scale scores and Assignment Compliance Rating Scale Scores

In Pearson Product Moment correlations of the Barriers to CBT Homework Completion Scale scores (total and subscales) the following correlations were evidenced at measurement B and C in Table 46.

Table 46 Pearson Product Moment Correlations of Barriers to CBT Homework Completion Scale Scores and Assignment Compliance Rating Scale Scores

Variable	Total Scale	Patient Subscale	Ther/Task Subscale
Correlation at B	.32*	.33*	.18
Correlation at C	.46*	.46*	.34*

* $p \leq .05$

Thus, the Barriers to CBT Homework Completion Scale had significant moderate correlations with the Assignment Compliance Rating Scale scores for the total and patient subscale at both measurement points and at measurement C for the Therapist/Task subscale.

4.2.8.4 Relationship of Homework Difficulty to Homework Adherence

Homework difficulty was rated by the patients and the therapists on separate scales. The patient estimate of difficulty of each assignment was rated on the Barriers to CBT Homework Completion Scale on a likert-type scale from one, not difficult at all, to five, extremely difficult. The therapist rating of difficulty was on a 6-point scale, from one, not difficult at all, to six, extremely difficult. Patient's rated completion of each assignment with a percentage completed indicated. Therapists rated completion on the Assignment Compliance Rating Scale (ACRS) which allowed for percentage completed in 25 % increments. Table 47 lists the related means and standard deviations for all of these correlations.

Table 47 Descriptives for Correlation Analyses of Difficulty and Completion

Variable	Correlation	Measurement B	Measurement C
		Mean/SD (N)	Mean/SD (C)
HW 1	Pt Diff	2.0 ± 1.1 (52)	2.2 ± 1.3 (47)
	Pt Comp	73.0 ± 35.7 (51)	80.5 ± 31.6 (47)
HW 2	Pt Diff	1.9 ± 1.1 (39)	2.2 ± 1.1 (32)
	Pt Comp	81.9 ± 31.1 (36)	68.9 ± 39.7 (31)
HW 3	Pt Diff	2.0 ± 1.3 (23)	2.3 ± 1.3 (15)
	Pt Comp	76.1 ± 38.3 (21)	55.3 ± 46.5 (16)
HW1	Pt Diff	2.0 ± 1.1 (52)	2.17 ± 1.3 (47)
	ACRS	3.3 ± 3.4 (52)	4.1 ± 3.6 (50)
HW 2	Pt Diff	1.9 ± 1.1 (39)	2.2 ± 1.1 (32)
	ACRS	3.3 ± 3.4 (52)	4.1 ± 3.6 (50)
HW 3	Pt Diff	2.0 ± 1.3 (23)	2.3 ± 1.3 (15)
	ACRS	3.3 ± 3.4 (52)	4.1 ± 3.6 (50)
HW 1	Ther Diff	2.9 ± 1.0 (52)	3.3 ± 1.1 (50)
	Pt Comp	73.0 ± 35.7 (51)	80.5 ± 31.6 (47)
HW 2	Ther Diff	2.9 ± 1.0 (52)	3.3 ± 1.1 (50)
	Pt Comp	81.9 ± 31.1 (36)	68.9 ± 39.7 (31)
HW 3	Ther Diff	2.9 ± 1.0 (52)	3.3 ± 1.1 (50)
	Pt Comp	76.1 ± 38.3 (21)	55.3 ± 46.5 (16)
Overall	Ther Diff	2.9 ± 1.0 (52)	3.3 ± 1.1 (50)
	Ther Comp	3.4 ± 3.4 (52)	4.1 ± 3.6 (50)

Table 48 lists the Pearson Product Moment correlations of the individual pairings at measurement B and C. Comparisons are made on a possibility of three assignments recorded per therapy session.

Table 48 Patient and Therapist Ratings of Homework Difficulty Correlated with Assignment Completion

Variable	Correlation	Pearson's (B)	Pearson's(C)
HW 1	Pt Diff vs. Pt Comp	-.37** (n=50)	.47***(n=46)
HW 2	Pt Diff vs. Pt Comp	-.58** (n=36)	.45**(n=30)
HW 3	Pt Diff vs. Pt Comp	-.74** (n=21)	-.45 (n=15)
HW 1	Pt Diff vs. ACRS	-.07 (n=50)	.11 (n=45)
HW 2	Pt Diff vs. ACRS	-.01 (n=38)	.21 (n=30)
HW 3	Pt Diff vs. ACRS	.23 (n=23)	.07 (n=14)
HW 1	Ther Diff vs. Pt Comp	-.187 (n=34)	.01 (n=47)
HW 2	Ther Diff vs. Pt Comp	.02 (n=34)	-.04 (n=29)
HW 3	Ther Diff vs. Pt Comp	-.02 (n=21)	-.15 (n=16)
Overall	Ther Diff vs. Ther Comp	.308 (n=48)*	-.08 (n=50)

** $p \leq .01$ *** $p \leq .001$

Patients own rating of assignment difficulty correlated with their own record of assignment completion had the most consistent relationship with moderate to strong correlations in 5 out of the 6 correlations. The therapist's rating of assignment difficulty and completion was significant in only the B measurement.

4.2.8.5 Relationship between Number of Assignments and Completion in Phase of Therapy

The question of whether adherence to homework is different in relation to period of therapy, i.e., early, mid, or later in therapy, and number of assignments was tested with separate one-way ANOVA tests at the .05 significance levels for measurement B and C. Neither ANOVA was significant, indicating neither number of assignments, period of therapy, nor period X number of assignments, effected homework adherence.

4.2.8.6 Discriminant Evidence

While the Barriers to CBT Homework Completion Scale and the BDI and DAS measure separate constructs, they are overlapping and related in the sense that the constructs within the BDI and DAS interrelate with some concepts in the Barriers scale. Given this, examining the correlations of these gold standards with the Barriers to CBT Homework Completion offers some support for discriminant evidence. Table 48 provides information about the correlations with the total scale and the 2 subscales.

Table 49 BDI and DAS Correlations with the Barriers to CBT Homework Completion Scale

Correlation	Pearson's (B)	Pearson's (C)
BDI vs. Total Scale	.40** (n=49)	.23 (n=48)
BDI vs. Patient Sub	.41** (n=49)	.24 (n=48)
BDI vs. Ther/Task Sub	.25 (n=49)	.11 (n=48)
DAS vs. Total Scale	.26 (n=50)	.32*(n=47)
DAS vs. Patient Sub	.25 (n=50)	.31* (n=47)
DAS vs. Ther/Task Sub	.26 (n=50)	.34* (n=14)

* $p \leq .05$, ** $p \leq .01$ *** $p \leq .001$

Pearson Product Moment correlations examining the relationship between the BDI and DAS instruments to the Barriers to CBT Homework Completion Scale were primarily significant for the BDI at measurement B and the DAS for measurement C. The correlations are low to moderate. It should be noted that of the 7 non-significant correlations, 5 of them were at the trend level of a significance level of .10 or under.

4.2.9 Summary

This chapter described results for the descriptive psychometric study of the development of the instrument “Barriers to CBT Homework Completion Scale.” The study was done in two phases.

Results from the development of the item pool through interview of 20 depressed patients currently in CBT and 20 CBT therapists was presented. The draft instrument was administered to a sample of 56 depressed patients currently in CBT. The initial psychometric testing included evaluation of reliability (internal consistency and test-re-test), internal structure (factor analysis), and external structure (concurrent and predictive validity). In particular, the instrument's ability to predict CBT homework completion was examined.

Factor Analysis revealed a 2-factor solution of "Patient Factors" and "Therapist/Task Factors." Internal Consistency demonstrated Alpha Coefficients of the Subscale and Entire scales that ranged from .80 to .95. Test-Re-Test correlations demonstrated Pearson correlations of .72 to .95. The only consistent demographic predictors of levels of Barriers to CBT Homework Completion Scale scores were race and marital status. The Patient subscale (the lower the scores, the higher the adherence) was able to satisfactorily classify patients (75-79 %) with low and high adherence to homework assignments. There were no consistent predictors of assignment compliance. The Barriers to CBT Homework Completion Scale scores did correlate significantly with Assignment Compliance (.32-.46). Ratings of assignment difficulty and reports of completion demonstrated patient-rated assignment difficulty and patient reports of completion had significantly moderate correlations (-.37 to .46) while therapists' reports of difficulty correlated with patient's reports of completion were non-significant (-.19 to .02). Therapists' rating of assignment difficulty correlated with therapist rating of completion was only significant at measure B (.31).

5.0 SUMMARY AND CONCLUSIONS

The purpose of this study was to develop and psychometrically evaluate an instrument to measure barriers that may deter adherence to CBT homework. The instrument, to be administered after an assignment of homework in each therapy session, was designed to assist therapists to identify and clinically intervene with patient's barriers to homework at that session.

Phase I of the study involved development of an item pool for the Barriers to CBT Homework Completion Scale through the interview of 20 depressed CBT patients and 20 CBT therapists. Phase II included administration of the draft instrument to 56 depressed patients in CBT and psychometric evaluation. This included evaluation of internal structure, reliability (both internal consistency and reliability over time), and external structure, particularly the instrument's ability to predict homework completion. The summary and conclusions for each phase will be presented separately.

5.1 PHASE I

The primary aim of Phase I of the study was the development of an item pool and draft instrument "Barriers to CBT Homework Completion Scale through the interview of depressed patients currently in CBT and therapists, expert in the field of CBT.

5.1.1 Sample Characteristics

Patient Sample

This convenience sample of patients was primarily female, Caucasian, and middle-aged. The majority were separated, divorced or never married. Most had a higher education and an income greater than \$30,000. All patients were recruited from an ongoing study of CBT in Recurrent Major Depression. The mean length of depression was 27 weeks \pm 42 weeks.

To obtain content validity, representative sampling from the subset of the universe of appropriate items representing the latent variable must be achieved (Anastasi & Urbina, 1997). Content validity, then, concerns item sampling adequacy, the extent to which a specific set of items reflects a content domain (DeVellis, 1991). To achieve a representative sample of items, in this study, a representative sample of depressed patients in CBT and a representative sample of Cognitive therapists were required.

The sample of patients, who volunteered to do this study, may be a somewhat non-representative sample. Ratio of female to male (4:1) was somewhat higher than the two to one ratio seen by the National Comorbidity Study or even the 59/41% ratio of the Epidemiological Catchment Area study (See Literature Review). This may reflect women's willingness to seek treatment to a greater degree than men. Patients recruited for Phase I took part in an ongoing study of CBT in recurrent Major Depression. The larger ratio of women may, not only reflect a greater likelihood that women seek treatment more than men, but also that they may seek treatment at academic treatment research centers more often than men.

The sample was primarily Caucasian, which reflects the findings of the two major epidemiological studies regarding Major Depression being a disorder that is seen more often in Whites than non-whites. However, the NCS, the most recent of the epidemiological studies,

found the racial proportion of Major Depression in non-blacks to be 69%. This sample (95 % Caucasian) does not reflect this racial proportion and may reflect a racial bias for not seeking CBT or receiving therapy at this academic center.

Age was a point of disagreement in the 2 studies with the ECA identifying higher ages and younger ages for depression and the NCS, younger, despite its methodology of an upper age range of 54 years. The middle-aged sample in Phase I was most likely reflective of the fact that the sample includes all patients with recurrent depression, and, therefore, would be more likely to be in this age range.

The NCS described patients with depression as having less than a high school education. The Phase I sample varies considerably from this demographic. The mean years of education were 15.5 ± 2.5 years with 70% having a greater than high school education. Mean household income in the US is \$42,409 (DeNavas et al., 2003). Forty percent of the sample fall below \$30,000/year in income and 20 % fall above \$50,000. It appears, then, that the sample approximated this average or falls somewhat below it.

Implications for this non-representative sample relate to content validity. All of the subjects have recurrent Major Depression. Their perceptions regarding barriers to CBT homework may be different than a person who is in their first episode of depression. They are likely to be different from someone with chronic depression, i.e., greater than two years in length. They may view barriers from a more hopeless and helpless standpoint, given the cyclical nature of their disorder. They are likely to have tried many treatments with limited success and may view barriers in a more pessimistic manner. Sixty five percent of the sample had greater than 4 episodes. The mean age of onset was 21.73, so given the middle age mean, most had a history of depressive episodes for greater than 20 years. Most had been in the present episode

for 6 months. This long history may reflect a different barrier report than individuals with a short-term, acute profile. It should be noted, nonetheless, that depression is more likely a chronic and recurring disorder so having a sample with recurrent depression may be more representative than not.

The extent of advanced education in the sample is also non-representative. A different point of view based on different thinking processes may occur. Cognitive processes such as opinion, judgment, belief, etc. may be different due to advanced education and could be reflected in the barriers that were reported. It can be argued that advanced education may assist them to communicate their perceptions more clearly and to have greater discernment.

The sample is not representative of the cultural profile in America or the demographic profile of depressed individuals. This may skew the report of barriers as strictly those of a Caucasian person.

Therapist Sample

The therapist sample was middle aged and nearly evenly divided between male and females. All were Caucasian. The majority had an advanced degree (mean years of education was 21 years \pm 2.5 years) and advanced CBT training, extensive experience, and supervision.

There is little data in the research literature to ascertain if the therapist sample is representative of CBT practitioners in the country. Judith Beck PhD, director of the Cognitive Therapy Institute (personal communication, 2007) states “Many graduate students in the mental health disciplines are at least exposed to cognitive therapy in their training, with some getting robust training. A smaller percentage receives supervision. Although increasing numbers of mental health professionals say they use cognitive behavioral techniques in their work, we do not

know precisely how many actually work from a cognitive conceptualization.” She denied knowledge of existing demographic statistics for cognitive therapists in the country.

Some information can be gleaned from a recent survey of the APA by Kazantzis and colleagues (2005) regarding practicing psychologists’ use and attitudes towards homework in psychotherapy. Thirty nine percent of the sample (>800) who returned the questionnaire identified themselves as cognitive therapists. The survey reported 48% were male and 51% females. Ninety three percent were Caucasian. Eighty three percent were PhD psychologists, but this is not surprising, given the survey was of APA members. The mean age was 52.43 ± 9.63 years. The mean years in clinical practice were 20.65 ± 9.09 .

If this survey is used as an approximation, it appears that the age, training, and gender of this sample are representative of the general CBT practitioner population. While there is no specific data to substantiate this supposition, the CBT therapist sample appears to have a greater degree of individual supervision and training in CBT than most community practitioners are likely to have. Fehm and Kazantzis (2004) indicate that therapists trained in university settings are much more likely to apply CBT in a more motivated and creative manner than those in the community. This, they state, leads to a difference in the way in which these empirically supported processes are practiced. Close to half of the therapist sample was university trained.

In summary, both the patient and therapist sample for Phase I met the inclusion and exclusion criteria for the study. They were clearly depressed CBT patients and cognitive therapists. There are aspects of their demographic and training profile that do make them non-representative. These aspects are, however, not likely to reduce information to any great extent for an adequate item pool, but may make it skewed according to those areas of non-representation.

5.1.2 Scale Development

Clark and Watson (2003) discuss Loevinger's classic articulation regarding scale development "the items of the pool should be chosen so as to sample all possible contents which might comprise the putative trait according to all known alternative theories of the trait." The initial item pool should be large and may include tangential items as the subsequent psychometric evaluation will determine which items are weak and unrelated to the putative trait."

Devellis (1991) asserts that validity is inferred from the manner in which the scale was constructed. To evaluate the effectiveness of the Phase I process in producing a representative item pool the following areas are examined:

1. Was the process a systematic examination and analysis of the behavioral content domain to be tested (Anastasi & Urbina, 1997)?
2. Do the items reflect what has been written in the literature (Fishman & Galguera, 2003)
3. Is there scale specificity in relation to content domain, setting, and population (DeVellis, 1991)?
4. Is there sampling adequacy and does the test reflect the latent variable (DeVellis, 1991)?

The process of developing an item pool for the psychological construct "barriers to CBT homework" was systematic in the sense that the procedure was clear, the intent clear, and the outcome based on extensive investigation into this latent variable. Following an extensive review of the literature, which was primarily anecdotal in nature, 40 interviews were conducted. Utilizing a semi-phenomenological approach, patient's and therapist's perceptions were painstakingly elicited in a relatively non-directive manner. A semi-structured interview guide

was used with a broad patient/therapist/task theoretical framework provided by Detweiler & Whisman (1999). Only question asking for expanded explanations were used. The steps reported in the methodology were developed to systematically investigate the content domain from not only the patient's perspective but also the therapist's. Identification of reported barriers was made from not only the one person's view but 3 people's, one of them representing a non-psychiatric professional (the patient surrogate). The same is true for the identification of concepts. There were 3 people's inspections, so as not to bias the identification. To the extent possible, quantitative procedures were brought into play.

The items do reflect what has been written in the literature. The items are, to some extent, reflective of those barriers reported anecdotally in the literature (See Appendix A). Additionally, items gleaned correspond to related literature in this population and other populations regarding: health beliefs expectations producing variance in outcome (Kelly et al., 1987); barriers in CBT of chronic pain such as motivation, beliefs about pain, and readiness to change (Johnson & Kazantzis, 2004); Adherence to medication in psychiatric treatment related to minimization of need for care and perceived stigma (Sirey, 2001); patient beliefs associated with adherence to medication (Aikens et al., 2005); negative expectations about treatment outcome associated with reduced benefit (Westra et al., 2002); regimen complexity and duration, provider skill and aptitude, and process variables and their association with barriers (Burke & Dunbar-Jacob, 1995); detailed profile of non-adherer reflects some of the items in the Barriers scale (Meichenbaum & Turk, 1987); reasons for non-compliance elucidated by Shelton & Levy overlap with some of the barriers reported (1981); patient-provider relationship a predictor of non-adherence in treatment of Diabetes Mellitus (Ciechowski et al., 2001); results of survey for non-adherence to medications demonstrating forgetfulness, other priorities, lack of info and

emotional factors as barriers (Osterberg & Blaschke, 2005); patient barriers in affective disorder (Frank et al., 1997); patient beliefs and expectations, therapist factors, and the possibility that CBT may not be for everyone as being barriers (Davis & Hollon, 1999); incomplete adherence related to patient and provider factors (Burke & Dunbar-Jacob, 1995); and patient variables seen as most crucial for homework compliance (Helbig & Fehm, 2004).

The procedures to gather an item pool were specific to depressed patients in CBT in outpatient treatment. The specific domain related to the barriers this population may experience in the completion of homework assignments. Careful eligibility assessment was done to achieve the appropriate target sample to gather this item pool.

Sampling adequacy can be reflected in the nearly 300 reported barriers identified. While labeling of the barriers may have resulted in overlap and redundancy, this amount of items, as well as identification of 24 concepts, gives some indication of sampling adequacy. Specific measures of sampling adequacy will be discussed in the Factor Analysis section.

Some areas of note is the clear difference in the amount of barriers identified by the principal investigator, research assistant, and the psychiatric professionals. In the therapist and patient interviews there was no difference between the principal investigator and research assistant but differences between these 2 raters and the psychiatric professionals in the identification of barriers. This may be partially explained by the day to day sharing of information about the study, its procedures, goals, etc. There appears to have been a clear understanding between these raters as to the extraction of barriers. Possible reasons for the differences between the first 2 raters and the psychiatric professionals may have been a lack of clarity regarding procedure or a “pre-emptive” collapsing of individual barriers into general conceptual themes. Regardless of this lack of agreement, there was agreement in identified

concepts within the interviews in 85% of the therapist and 95% of the patient interviews between the 3 interviewers.

Of interest is the statistically different quantity of reported barriers between the therapists and the patients. This was consistent across all three raters in separate t tests. The greater number reported by the therapists may have related to the experience, training, and sophistication of the therapist sample. Patients most likely presented those barriers of most weight to them and may not have been as globally reflective as the therapist sample. It is also possible, that patient's may have a clearer understanding of the latent variable and were able to communicate it clearly and concisely.

It should be noted that the grouping of items into concepts by the second set of 3 raters was, perhaps, the most subjective, of the steps in the development of the scale. Given the differences in labeling and an inability to “quantify” the process, there may be some bias in the final conceptual groupings. Quantification did assist in deciding the proportion of items to select to represent a given concept. How many times the barrier was mentioned determined the proportion of items per concept and which carried greater weight.

At the present time the scale is longer than might be considered practical for its intended use. This is acceptable, as the draft instrument should be longer to have a larger pool of items to select those that are most reliable. It should be noted that all of the items are negatively phrased given that it is a scale specifically focused on barriers. This is not recommended in the literature (DeVellis, 1991) due to concerns about response bias. This concern was not borne out in the data with a clearly positively skewed distribution of most individual items and low item means.

Several iterations of the instrument were done to improve wording and design. Nonetheless, in the initial item analysis, five items were deleted for poor performance. This may have been due to poor wording.

In summary, the patient and therapist sample may not be fully representative of the target population. This may affect content validity as the pool of items that represent the latent variable “barriers to CBT homework” may be represented in a manner based on these sample differences. The process of gathering an item pool and developing the instrument were painstaking and systematic. The results reflect much of what has been reported in the literature.

5.2 PHASE II

The primary aims of Phase II were the pilot of the draft version of the “Barriers to CBT Homework Completion Scale” and the Assignment Completion Rating Scale (Primakoff, et al., 1986 & Bryant et al., 1999) in a sample of depressed patients. The preliminary psychometric properties, i.e., reliability, internal and external structure (in terms of its ability to predict homework completion) of the instrument “Barriers to CBT Homework Completion Scale” were investigated.

The secondary aims of Phase II were the examination of whether subjective level of depression, length of depression, depression episode subtype (single, recurrent, or chronic), dysfunctional attitudes, length of depression and level of therapist training are related to “Barriers to CBT Homework Completion Scale” scores. Subjective level of depression, length of depression, dysfunctional attitudes, time in CBT, level of therapist training, and “Barriers to CBT Homework Completion Scale” scores were examined to determine if a relationship existed

in homework assignment completion. Finally, the demographic variables of gender, age, income, educational level, marital status, and ethnic background were examined to see if they predicted the scale and subscale scores of the “Barriers to CBT homework Completion Scale” and final CBT homework completion.

5.2.1 Phase II Sample Characteristics

The goal for recruitment into the pilot of the draft instrument was to have a balanced sample in which close to 50 % were from the community and 50% were from the academic recruitment sites. Unfortunately, 86% of the sample ended up being recruited from the academic sites. Despite the addition of sites, both in the city and across the country, the study was unable to recruit enough patients receiving CBT in non-study settings.

Potential reasons for not volunteering for this study may relate to the reasons they are receiving treatment in non-study settings in the first place. For example, it involves time and effort and they may not have the time and motivation to participate. Evaluation of the recruitment process may reveal hazards to the ultimate goal of balanced recruitment. Having sites that are remote with little access to the study staff heightens the possibility that flow will be slow. Private and community mental health practitioners had little motivation and time to focus on assisting the recruitment effort. Processes to motivate them and potential subjects were inadequate. It may have been more fruitful to have fewer sites, but greater presence in those that provided subjects. A participant payment of \$20 may have been inadequate to motivate most busy people.

Despite this, numerous efforts were made to have a balanced sample. Nevertheless, the sample was not representative of CBT on the whole. The sample and related issues are similar to

that of Phase I. They are primarily female, Caucasian, and middle-aged. Two-thirds have greater than a high school education. Marital status, however, is more evenly represented in the Phase II sample. MDD history continues to be comparable to the literature and statistics. Again, all subjects have recurrent major depression, so any analyses involving comparisons with depression subtype with outcome and barrier level was not possible. Conclusions that are drawn are based on a primarily Caucasian, middle-aged, educated sample with recurrent episodes of MDD.

The therapist sample is also similar to that of Phase II but for a greater proportion of academic therapists and greater proportion of women. Their training level, amount of supervision continues to indicate a conclusion that is based on a skill level that is most likely more advanced than their community counterparts. Barriers, for example, may have been reduced or managed in such a way as to allow the patient to not experience them as barriers at all. Providing CBT in a prototypical manner may have reduced the scores on the Barriers scale and altered the outcome measure of homework completion. The positive skewing in the scale scores and negative skewing in the ACRS may have related to the advanced therapist sample.

Additionally, despite aggressive recruitment efforts, the targeted sample size of 100 was not achieved. A sample of 100 was already considered insufficient for many of the tests, i.e., factor analysis. A final sample of 56, then, makes most of the results preliminary and conclusions drawn tentative.

5.2.2 Evaluation of Internal Structure

Previous comments regarding the sample are most applicable to the evaluation of the Factor analysis conducted in this study. Comrey (1988) has stated 200 subjects might be acceptable for

an instrument having no more than 40 items. Comrey and Lee (1992) recommend up to 1000 subjects to conduct a factor analysis but when this is not possible to have very conservative interpretation of the results. Given the 70 item scale and the sample of 56, the conclusions drawn from the factor analysis done in this study should be tentative.

Initial difficulties in the completion of a stable factor structure were most likely due to the small sample size and issues of multicollinearity. Adjusting the process to have previously designated concepts (that comprise specific items) serve as the items greatly improved the process of the factor analysis, satisfying most of the requirements of the correlation matrix, sampling adequacy, etc. The factor analysis demonstrated the scale does have very good sampling adequacy as demonstrated by the KMO and diagonal measures of individual sampling adequacy. This provides validity for the process that was conducted in Phase I to gather an acceptable item pool.

The two-factor solution of Patient Factors and Therapist/Task Factors corresponds to some degree to the initial Detweiler & Whisman model of three separate and equal factors of Patient, Task, and Therapist affecting Homework adherence. The two factor solution differs in its preponderance and weight given to Patient Factors. This differs as well to a 3 factor model described by Burke and Dunbar-Jacob (1995) identifying patient, regimen, and provider factors in incomplete adherence. Helbig & Fehm (2004), in contrast, identify patient factors as being paramount in homework adherence.

In a self-report identifying barriers related to homework completion, it is conceivable that patients did not score items related to, what may have been perceived as, therapist deficiencies. Patients were reassured of strict confidentiality, i.e., their therapists would not see their responses. Nevertheless, this may provide some guidance that, self-report, as a vehicle to report

issues regarding their therapist, as they relate to barriers to homework completion, may not be useful. The therapeutic relationship is considered very valuable to most patients. There may have been hesitation to report any deficiencies on the part of the therapist, both in the nature of the relationship, and in the manner of task assignment.

It is also quite possible, that the patient factor is the most important in understanding barriers to CBT homework and resulting completion. In subsequent analyses, it can be seen that the Patient subscale performs the best in relation to prediction and relationship to specific variables. The preponderance of patient variables reported in the patient interviews validates the latter position.

In summary, using the concepts as items allowed a satisfactory two-factor solution comprising the Patient Factor and Therapist/Task Factor. This model corresponds to some degree to three-factor models of nonadherence but demonstrates a much greater weight on patient factors. This model, while corresponding to the conceptual literature and findings from Phase I, must be viewed with caution due to the extremely small sample size.

5.2.3 Evaluation of Reliability

Cronbach's Alpha was consistently high with the majority of the Alpha coefficients for total scale and subscale being greater than .90. Internal consistency was high for both the item scales and the concepts as items scales. Subscales demonstrated high internal consistency as well although the Therapist/Task scale was somewhat lower (but still highly adequate). Five items were deleted for inter-item correlations below .20.

In commenting on adequacy of the internal consistency, the relationship to the amount of items must be recognized. Cortina (1995) and Cronbach (1951) identify coefficient Alpha as an

imperfect measure of internal consistency because it is a function of two parameters: the number of test items and the average intercorrelations among the items. Given the fact that this instrument has a large number of items, it is possible that the Coefficient Alpha reported may be an overestimate of internal consistency. They recommend a target mean inter-item correlation in the range of .15 to .50. For broad higher order constructs such as extraversion, a mean inter-item correlation as low as .15 to .20 is desirable and for a narrower construct such as talkativeness, a higher mean correlation is needed, i.e. .40 to .50. The mean inter-item correlations for the whole item scales (65 and 70 item) was in the range of .30 whereas the subscales and whole scale inter-item correlations of the concepts was .47 to .61. It is likely there is redundancy with the inter-item correlations being somewhat high for a construct that is not narrow or totally broad. A mean correlation in the range of .35 to .45 may be more appropriate.

Evaluation of potential items to cut that may reduce excessive redundancy and maintain an acceptable Cronbach's Alpha should be undertaken in future revisions of the instrument. Regardless of the above cautionary note regarding high amounts of items, the instrument and its subscale has highly acceptable internal consistency

Evaluation of reliability over time was accomplished with a Pearson's Product Moment Correlation of the Barriers to CBT Homework Completion Scale from measurement point B to C. The entire scale and subscales were analyzed. Both the entire scale and the Patient Subscale had very high correlations of .94 and .95, indicating it was stable in its measurement over time. The Therapist/Task subscale was significantly lower with a correlation of .72. All, nonetheless, were significantly high correlations. The difference between the Therapist/Task Subscale compared to the others highlights concerns that it performs at a different level than the other two. Subsequent analyses demonstrate this difference as well. For this analysis, an explanation may

be that patient factors are slower to change and may be more “trait-like” than more variable measurements of Therapist/Task factors.

5.2.4 Evaluation of Demographic Prediction

A series of multiple linear regression equations were conducted to determine if there were demographic predictors of both Barriers to CBT Homework Completion Scale Scores and Homework Completion (measured by the Assignment Compliance Rating Scale). Regressions done at Measurement B and C on the entire scale and the subscales revealed a stable set of predictors for the Barriers scores. They included race and marital status. White race predicted lower Barrier Scores. Being married predicted higher barrier scores. Variance accounted for by this model only ranged from .13 to .25, did not account for a large amount of variance.

Regression models examining demographic prediction of homework completion did yield one consistent predictor of education. Lower education predicted lower compliance. But again, only small amounts of variance are accounted for by this model (.09-.19).

Numerous researchers have indicated that there is no consistent demographic predictor of adherence in various clinical populations (Gorkin et al., 1990; Lingham & Scott, 2002; Stilley et al., 2002, Vermeire et al., 2001; and Dunbar-Jacob, 2000). Age has in some studies been identified as a predictor of compliance with persons who are older, i.e. > 60 being more likely to be compliant with treatment regimes (Sirey, 2001; Frank et al., 1985; DeGeest et al., 1990, Dunbar-Jacob, 1998; and Dunbar-Jacob & Mortimer-Stephens, 2001). Bryant et al., (1999) found education was unrelated to adherence in CBT Homework. Race has been identified as being a risk factor for recurrence due to noncompliance with antidepressant regime (Melfi et al., 1998) while race (black race) has been reported to be associated with increased compliance. Social

isolation was a risk factor for non-adherence to transplant regime (Degeest, 1999). Social support was identified as a predictor of adherence (Dunbar-Jacob, 1998).

These inconsistencies indicate that race may be an inconsistent predictor and marital status, approximated by related variables such as social support or isolation may be a positive predictor. Thus, the findings regarding marital status are supported by the available literature and race remains unclear. Marital status, as a predictor of higher Barrier scores may be explained by the emotional and environment support that may be available to married persons. Race and often, associated lower income, education, etc may also result in added social pressures that may result in additional perceived barriers beyond those with a more stable social environment.

Bryant's finding regarding education being unrelated to homework adherence refutes these findings. Regardless, a possible reason for its significance as a predictor in this study is the possible assistance it may provide patients in problem solving barriers in order to complete homework.

5.2.5 Evaluation of Prediction model of Barriers Scores and Homework Completion

Those demographic variables already used in the prediction model were added to various patient variables and therapist variables. In analyses of both measurement points and using entire scale and subscales, significant models and predictors were insignificant.

On only 2 occasions were the models to predict barriers scores significant. In addition to marital status and race, the only recurring significant predictor was for greater number of episodes predicting higher barriers scores. This concurs with the data presented in the literature review regarding the recurring nature of major depression. Recurrent depression increases the

risk of relapse into depression and is a risk factor for a poor prognosis. Given this, it is likely that it is associated with greater reported barriers to complete assignments.

In the analyses to use the model to predict actual homework completion, both models were non-significant. None of the therapist variables demonstrated any prediction power, while the only patient variable demonstrating some prediction was race on one of the measurement occasions.

The variable, of most note, is depression severity. This result does concur with Bryant et al., 1999; Patten et al., 2002; Nelson & Borkovec, 1989; Burns & Nolen-Hoeksema, 1991 that depression severity does not correlate with compliance. On the other hand, it does not concur with the following research which does report a relationship between depression presence and severity with nonadherence in a wide variety of disorders: Gorkin et al., 1990; Stilley et al., 2004; Catz et al., 2000; Brown et al., 2005; Bosley et al., 1995; Zeigelstein et al., 2000; Startup & Edwards, 1994; and DiMatteo et al., 2000. DiMatteo states that depression increases the odds of non-adherence by 3 times.

It should be noted that the sample size might have resulted in a lack of statistical power to test this model. It does appear, though, that factors related to the therapist have limited predictive power in relation to barriers scores and noncompliance to homework.

5.2.6 Barriers Scores Prediction of Compliance

The Pearson correlations demonstrated a relationship between the Patient Subscale, the Entire Scale, and the therapist/task subscale on one occasion. The relationship can be described as a moderate correlation. The logistic regressions completed, indicate that the Patient subscale is able to identify those that are likely to be good adherers (> 75% adherence). The Therapist/Task

Subscale did not evidence this capability. This finding, again, provides some light, to the weakness of the therapist/task factor in comparison to the patient subscale. Not only was it weak in the logistic regression, but also weaker in the correlational analysis.

In a clinical sense, therapist and task issues may be pertinent in relation to adherence. But it may be that when measuring patient perceived barriers, only they end up being more powerful in relation to prediction of outcome. In other words, they are their domain and they have greater access to patient information than the other variables.

It should be noted that both the ACRS distributions and most of the Barriers scores (concept and individual item) distributions were J-shaped. This J shaped distribution (Allport, 1934; Dunbar-Jacob, et al., 1998) reflects a population pattern in relation to adherence behaviors. So the majority of the population will adhere, while a smaller proportion will not. Allport (1934) describes this in a theory of conforming behavior, i.e., there will be a field of conforming behavior in which more than half adhere or conform to the prescribed or proper behavior. This produces a standard J curve as seen in his study.

The critical question is, if there is a standard of conforming behavior in homework compliance, which the distributions tend to indicate, can the instrument adequately (reliably) assist with the identification of barriers in the smaller proportion of non-conforming patients. seventy-five percent was defined as the standard of good adherence for this study. Given this standard, and using the ACRS, 74.1 % of the subjects met the criteria for good adherence. This is on the higher range of the average across populations of an average of 50 % compliance (Dunbar-Jacob, 2000). The above analyses indicate the instruments ability to identify good adherer's even when there are so few poor adherers and to demonstrate a significant moderate relationship between the instrument and the outcome measure.

5.2.7 Homework Difficulty and Reports of Homework Completion

In pairings of reports of perceived homework difficulty and patient or therapist report of homework compliance, it was found that the only significant ratings or positive correlation between rating of difficulty and percent completion was when the patient rated the difficulty and rated the percent completion (third homework assignment was at a trend level). The correlations were moderately high $-.47$ and $-.45$, indicating higher ratings of difficulty led to less homework completion.

This corresponds to Sennott-Miller & Miller's (1987) finding that difficulty was the most consistently strongest predictor of likelihood of treatment adoption, i.e., likelihood of adoption decreased substantially when difficulty moved from low to moderate. Conoley et al., (1994) also noted that difficulty was negatively associated with adherence, $r = -.63$. The less complex and time consuming, the more likely it is that the assignment will be carried out.

When method is considered i.e., patient self-report of adherence, there is some controversy as to the validity of this significant relationship. For instance, self-report has been identified as an unreliable measure of compliance. Patient reports are often higher than objective comparative measures bare out (Burke & Dunbar-Jacob, 1995; Dunbar-Jacob et al., 1998. Berg et al., 1998 found that self-reported compliance was higher than a chronologic measure. So the patient's report did not match the objective measure. Kazantzis et al., 2000, found that both the therapist and the patient's rating of homework compliance over-estimated what was actually done.

This calls into question, the self-report correlations above. It is possible that the patient has more information to provide than the therapist. But those psychological processes that lead to over-estimation such as wanting to please the therapist and embarrassment as well as cognitive

processes such as forgetting and poor recall may result in self-report as the least valid measure of compliance.

Rand (1990) and Vermeire (2002) recommend multiple measures to assess adherence to treatment. For homework completion, perhaps a joint estimation can be made as well as information from significant others, depending upon the assignment. Reduction of over-estimation bias may be assisted by multiple reporters of adherence and reliance on objective information.

5.2.8 Adherence Related to Number of Assignments and Time in Treatment

The literature has shown that non-adherence increased with the complexity of the treatment regime and as time goes on in treatment, especially in the maintenance phase. To test this issue related to homework assignments (number given) compared to period in treatment (early, mid, late) a one-way ANOVA was completed. The result was non-significant, indicating there was no difference in the completion of HW assignment regardless of whether the person had one assignment or greater than one assignment or if they were early, middle, or late in their treatment.

Gaynor et al., 2006, suggest that there is significant within subject instability and session-to-session variability. This may make it difficult to note a time effect when sessions are aggregated. Sample size, again, may have been the critical effect for this lack of finding.

Regardless, issues of quality vs. quantity may be the most significant factor of homework completion. Rees et al., 2005 indicate that homework quality may be the better predictor of outcome than quantity. In a group of 48 patients treated for panic disorder with or without agoraphobia, estimates of quality of homework were the best predictor of outcome.

5.2.9 Summary

The findings for a two-phase study to develop, pilot, and psychometrically evaluate the instrument Barriers to CBT Homework Completion Scale have been presented. A systematic and painstaking process was conducted to develop an exhaustive item pool. The sample, both therapist and sample, in Phase I may have been non-representative, which may have affected the results.

The initial pilot, done with less than the desired sample, yielded the following results: the measure has demonstrated internal consistency and test-re-test reliability; a two factor structure which yielded the Patient and Therapist/Task Subscales; the Patient Subscale appears to be the most robust in prediction of good adherence; and a model of prediction of factors demonstrated only 1 set of consistent predictors of Barriers scores, race and marital status. Level of depression severity, and all of the therapist factors did not add to the regression model.

5.2.10 Implications for Future Research

Additional testing is required with a large sample to test this factor structure and examine the regression model with greater power to detect an effect. The sample should be more representative of the demographics of major depression in the United States as well as those of therapists in the community. Alternate recruitment strategies should be employed to promote larger samples to conduct the type of psychometric testing that might validate this instrument more fully. A larger sample may add power to the regression models and strengthen the findings of the 2-factor model.

Changes for consideration in the scale include adding a measure to assess the quality of the homework assignment as well as quantity. In the ACRS and the Barriers scale there should be measures for quantity and quality completed for each homework assignment and rated by both the therapist and the patient.

The length of the scale must be reduced while still maintaining the reliability. Each concept can still have proportional item representation but to a smaller degree. The instrument must be useful for patients, clinicians, and researchers.

A measure of adherence for homework must be included in all CBT studies. This instrument serves this function as well as assisting the clinician to improve homework adherence. Focus on the issue of assignment difficulty must be a consistent agenda item. Examining homework and its relevance, in proportion to difficulty, is essential.

Examination of this scale in other populations, i.e., anxiety disorders, phobia, etc. may be indicated. While it was developed for a depressed population in CBT, it may serve a similar function in a broader group of patients. Barriers to doing homework in other fields, i.e., behavioral management, exercise, home health tasks, may benefit from an instrument focusing on barriers to successful completion. With this future research in mind, it is logical that the title of the scale be changed to “Barriers to Homework Completion Scale.” This allows for a generically titled instrument to measure homework adherence and barriers to the completion of homework in diverse populations.

Finally, newer technology can be explored to reduce barriers to homework completion. Knowledge of the barriers gleaned from this research may serve as a platform for the development of computer-assisted homework tools. Regardless, of the research direction, it is

important that researchers keep adherence to CBT homework on the table, as it is likely to improve patient outcome.

APPENDIX A: Patient Factors Associated with Homework Noncompliance

Patient Factors Related to Homework Nonadherence

Emotional

1. Discomfort anxiety (Broder, 2000)
2. Fear of Failure (Persons et al., 1988)
3. Increased levels of depressive symptoms (Edelman & Chambless, 1995)
4. Fear and uncertainty at the start of treatment; fear of change (Newman, 1995)
5. Unexpressed anger towards therapist (Burns & Auerbach, 1992)
6. Hopelessness (Beck, 1995)
7. Being overwhelmed (Beck, 1995)

Maladaptive Cognitions

1. homework a test of personal worth (Beck, 1979)
2. Faulty cognitions elicit denial anger, i.e. belief about the future (Russo, 1987)
3. Negative predictions about homework (Beck, 1995)
4. Belief in medical model, i.e. therapist should fix me (Detweiler & Whisman, 1999)
5. Overestimate the time and effort it will take to complete homework (Beck, 1995)
6. Poor self-evaluation, i.e. "I'm ineffectual (Beck, 1995)

Patient Characteristics

1. Dependency (Burns & Auerbach, 1992)
2. Perfectionist (Persons et al., 1988; Beck, 1979; and Beck, 1995)
3. Need to please others (Persons et al., 1989)
4. Difficulties in organization (Beck, 1995)
5. Deficits in Functioning (Newman, 1994)
6. Co-morbid personality disorders (Edelman & Chambless, 1995)
7. Coercion sensitivity (Burns & Auerbach, 1992)

Lack of Understanding

1. The benefits of homework (Broder, 2000)

2. The specific rationale of a homework assignment (Beck, 1995)

Resistant Behavior

1. Providing edited/intellectual versions i.e. thought records (Otto et al., 1995)

2. Lack of commitment (Shelton & Levy, 1981)

Environmental

1. Devoid of positive reinforcement (Shelton & Levy, 1981)

2. Unsupportive home environment (DiMatteo & DiNicola, 1982)

3. Lack of time and opportunity (Beck, 1995)

APPENDIX B: Types of Homework Assignments

Types of Cognitive Behavioral therapy Homework

1. Taping and listening to therapy sessions
2. Self-monitoring through mood assessments such as the Beck Depression Inventory
3. Cognitive assignments to record automatic negative thoughts and test dysfunctional beliefs
4. Behavioral assignments such as exposure, flooding, and response prevention
5. Bibliotherapy such as self-help books on depression and interpersonal relationships
6. Interpersonal assignments
7. Goal setting and prioritizing
8. Mood management techniques such as the emotional fire drill
9. Affirmations
10. Mood Diary
11. List Making
12. Guided Imagery
13. Relaxation and Meditation
14. Thought stopping techniques
15. Constructing activity schedules
16. Scheduling activities to increase pleasure
17. Scheduling activities to provide a sense of mastery
18. Identifying distortions
19. Graded task assignments
20. Cognitive Rehearsal
21. Role Playing
22. Examining advantages/disadvantages
23. Insomnia activities
24. Exercise
25. Time management

26. Coping cards

27. Assertiveness and other skills training

APPENDIX C: Phase I Letter Agreement



Western Psychiatric Institute and Clinic

of UPMC Presbyterian

Depression Treatment and Research Program

*Part of
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Bellefield Towers, Eighth Floor
3811 O'Hara Street
Pittsburgh, PA 15213-2593
412-624-5110
Toll Free: 1-888-427-1532

April 17, 2003

Judith A. Callan, RN, MSN
Senior Program Coordinator
Western Psychiatric Institute and Clinic
3811 O'Hara St.
Pittsburgh, PA 15213

Dear Judy,

I believe your investigation of factors that may effect compliance with Cognitive Behavioral Therapy Homework assignments is both a needed area in CBT research and may ultimately be a useful clinical tool. You have my permission to conduct your doctoral research with existing and future research subjects at the Mood Disorders Treatment and Research Program.

Sincerely,

A handwritten signature in black ink that reads "Michael E. Thase M.D." with a stylized flourish at the end.

Michael E. Thase, M.D.
Professor of Psychiatry

MET:jac



Western Psychiatric Institute and Clinic

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Judith A. Lis RN, MSN
Senior Program Coordinator
Mood Disorders Treatment Research Program
Western Psychiatric Institute and Clinic
3811 O'Hara St.
Pgh, PA. 15213

Dear Judy,

I am interested in participating in your doctoral research "Development of a Scale: Barriers to Cognitive Behavioral Research Homework Compliance." I understand that this participation will involve one taped interview of my opinions regarding barriers to the completion of Cognitive Behavioral therapy homework assignments. I understand that this interview will take approximately 30 minutes and will be scheduled at a time that is convenient to my schedule. I believe homework to be an integral part of CBT and this research to be worthwhile. Thank You.

Sincerely,

A handwritten signature in black ink, appearing to read "G. R. Z. A." with a stylized flourish at the end.



Western Psychiatric Institute and Clinic

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Mood Disorders Treatment Research Program
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Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Straforn".



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Sincerely,

A handwritten signature in black ink that reads "Tiffany L. Pate".



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Sincerely,

Claudia A. Zucko, MEd.

AMHA Allegheny Mental Health Associates, P.C.

Lee Reichbaum Ph.D.

Christopher Coburn, Ph.D.

Michael Greenwald, Ph.D.

Sander Komblith, Ph.D.

Donna Goberish, M.S.W.

Pam Hoopes, L.S.W.

Thomas McHugh, L.S.W.

Shanthi Pathniak, L.S.W.

Joanne Tyzenhouse, L.S.W.

June 6, 2003

Judith A. Lis RN, MSN
Senior Program Coordinator
Mood Disorders Treatment Research Program
Western Psychiatric Institute and Clinic
3811 O'Hara St.
Pittsburgh, PA. 15213

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Sincerely,



Michael Greenwald, Ph.D.

Licensed Psychologist PS-2970 PA

Vice-President, AMHA

Founding Fellow, Academy of Cognitive Therapy



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Sincerely,

Karen L. Woodall, Ph.D.



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Sincerely,

ELIZABETH M. PACOE, PH.D.
(412) 624-3293



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Mood Disorders Treatment Research Program
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Sincerely,

A handwritten signature in black ink that reads "Sandra J. Kornblith, PhD". The signature is fluid and cursive.



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Sincerely,

A handwritten signature in black ink, appearing to read 'Longman' followed by a flourish.



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Sincerely,

A handwritten signature in black ink, appearing to read "Angela Bridgeman". The signature is written in a cursive style with a large initial letter.

APPENDIX D: Phase I IRB Approval



University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 578-3424
(412) 578-8553 (fax)

MEMORANDUM:

TO: Judith Lis, R.N., M.S.N.

FROM: Christopher Ryan, Ph.D., Vice Chair 

DATE: September 26, 2003

SUBJECT: IRB# 0307128: Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (5,7).

Please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: 9/26/2003
Renewal Date: 9/25/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 578-8569 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by Assurance No. M-1259, given to DHHS by the University of Pittsburgh.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR/ky



University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Judith A. Lis, RN., MSN

FROM: Christopher Ryan, Ph.D., Vice Chair 

DATE: February 26, 2004

SUBJECT: IRB #0307128: Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale

The Institutional Review Board reviewed the recent modifications to your protocol and consent form(s) and find them acceptable for expedited review. These changes, noted in your submission of 2/23/04, are approved.

Please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: February 26, 2004
Renewal Date: September 25, 2004
University of Pittsburgh
Institutional Review Board
IRB #0307128

The protocol and consent form(s) together with a brief progress report must be resubmitted at least **one month** prior to the date of renewal listed above for annual review as required by the General Assurance No. M-1259 given to DHHS by the University of Pittsburgh.

If your research proposal involves an investigational drug, please forward a copy of this approval letter along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:cc



University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM:

TO: Judith Callan, RN, MSN

FROM: Christopher Ryan, Ph.D., Vice Chair 

DATE: September 20, 2004

SUBJECT: IRB #0307128: Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale

Your renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board. **This approval is for analysis of data only.**

Approval Date: September 17, 2004

Expiration Date: September 16, 2005

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00006600 (Children's Hospital of Pittsburgh).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:dj



University of Pittsburgh

School of Nursing

Office of the Dean
350 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401

Jacqueline Dunbar-Jacob
PhD, RN, FAAN
Dean
412-624-2400
E-mail: dunbar@pitt.edu

March 18, 2003

Susan A. Albrecht, PhD, RN
Associate Dean for Student/Alumni
Services and Development
412-624-2403
E-mail: saa01@pitt.edu

TO: IRB Committee

RE: Judith Lis, RN, MS
Doctoral Candidate, School of Nursing

Patricia A. Bohachick, PhD, RN
Interim Associate Dean for Clinical
Education
412-624-6616
E-mail: pab@pitt.edu

FROM: Jacqueline Dunbar-Jacob, PhD, RN, FAAN
Professor and Dean, School of Nursing

Cynthia E. Allhouse, MBA, CPA
Assistant Dean for Administration
412-624-6905
E-mail: cea32@pitt.edu

As Ms. Lis' dissertation advisor I am writing in support of the proposed study submitted to the IRB for review by Judith Lis. Ms Lis has completed her required course work for her doctoral degree. During her course of study she completed supervised training in Cognitive Behavioral Therapy, a component of which forms the core of her dissertation research. Ms Lis has successfully passed her qualifying examination and dissertation proposal approval. She is ready to begin her dissertation research.

Ms. Lis' dissertation committee, which will supervise her research, consists of:

Jacqueline Dunbar-Jacob, PhD, RN, FAAN; Professor of Nursing, Epidemiology, and Occupational Therapy. In addition to being a registered nurse I am a licensed (inactive) psychologist in the state of Pennsylvania

Mary Kerr, PhD, RN, FAAN; Professor of Nursing and Director, Center for Nursing Research in the School of Nursing

Susan Sereika, PhD; Associate Professor of Nursing, Epidemiology, and Biostatistics, Associate Director, Center for Nursing Research

Clement Stone, PhD; Professor and Director, Psychology in Education Program

Michael Thase, MD; Professor of Psychiatry



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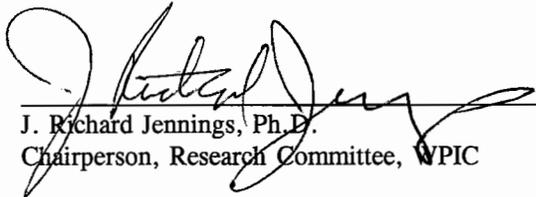
3811 O'Hara Street
Pittsburgh, PA 15213-2593

MEMORANDUM

TO: Judith A. Lis, R.N., M.S.N.

RE: Development of a Scale: Barriers to CBT Homework Compliance Scale

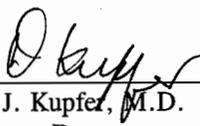
Since your Thesis Committee has reviewed and approved your proposal referenced above, the WPIC Research Review Committee does not need to undertake a second review, but accepts the Thesis Committee's recommendation for approval.



J. Richard Jennings, Ph.D.
Chairperson, Research Committee, WPIC

4/23/03

Date



David J. Kupfer, M.D.
Chairman, Department of Psychiatry

4/23/03

Date



University of Pittsburgh

School of Nursing

Office of the Dean
350 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401
www.nursing.pitt.edu

Jacqueline Dunbar-Jacob
PhD, RN, FAAN
Dean
412-624-7838
E-mail: dunbar@pitt.edu

August 19, 2003

Susan A. Albrecht
PhD, RN, FAAN
*Associate Dean for Student/Alumni
Services and Development*
412-624-2403
E-mail: saa01@pitt.edu

MHIRC for the Study of Mood and Anxiety Disorders
Western Psychiatric Institute and Clinic
3811 O'Hara Street, Suite 279
Pittsburgh, PA 15213

Helen K. Burns, PhD, RN
*Associate Dean for Clinical
Education*
412-624-6616
E-mail: burnsh@pitt.edu

Dear MHIRC Review Committee:

Cynthia E. Allshouse, MBA, CPA
Assistant Dean for Administration
412-624-6905
E-mail: cea32@pitt.edu

I am the primary mentor for Judith A. Lis, doctoral student in the University of Pittsburgh School of Nursing. This letter serves as the written assurance that I have reviewed the final version of Ms. Lis's proposal, "Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale."
I have judged her proposal ready for peer review by the MHIRC Review Committee.

Thank you very much for your consideration to this important research.

Sincerely,

Jacqueline Dunbar-Jacob, PhD, RN, FAAN
Dean, School of Nursing
Professor, Nursing, Epidemiology, and Occupational Therapy
University of Pittsburgh School of Nursing



University of Pittsburgh

School of Nursing

Office of the Dean
350 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401
www.nursing.pitt.edu

Jacqueline Dunbar-Jacob
PhD, RN, FAAN
Dean
412-624-7838
E-mail: dunbar@pitt.edu

November 22, 2004

Susan A. Albrecht
PhD, RN, FAAN
Associate Dean for Student/Alumni
Services and Development
412-624-2403
E-mail: saa01@pitt.edu

TO: IRB Committee
RE: Judith Callan, RN, MS
Doctoral Candidate, School of Nursing

Helen K. Burns, PhD, RN
Associate Dean for Clinical
Education
412-624-6616
E-mail: burnsh@pitt.edu

FROM: Jacqueline Dunbar-Jacob, PhD, RN, FAAN
Professor and Dean, School of Nursing

Janice S. Dorman, PhD
Associate Dean for Scientific
and International Affairs
412-624-8392
E-mail: jsd@pitt.edu

As Ms. Callan's dissertation advisor, I am writing in support of the proposed study submitted to the IRB for review by Judith Callan. Ms. Callan has completed her required course work for her doctoral degree. During her course of study she completed supervised training in Cognitive Behavioral Therapy, a component of which forms the core of her dissertation research. Ms. Callan has successfully passed her qualifying examination and dissertation proposal approval. She is ready to continue her dissertation research (Phase I of her dissertation research is completed).

Cynthia E. Allshouse, MBA, CPA
Assistant Dean for Administration
412-624-6905
E-mail: cea32@pitt.edu

Ms. Callan's dissertation committee, which will supervise her research, consists of:

Jacqueline Dunbar-Jacob, PhD, RN, FAAN; Professor of Nursing, Epidemiology, and Occupational Therapy at the School of Nursing. In addition to being a registered nurse I am a licensed (inactive) psychologist in the state of Pennsylvania

Mary Kerr, PhD, RN, FAAN; Professor of Nursing at the School of Nursing

Susan Sereika, PhD; Associate Professor of Nursing, Epidemiology, and Biostatistics, Director, Center for Research and Evaluation, at the School of Nursing

Ellen Olshansky, PhD, RN, Professor and Chair, Health and Community Systems Department at the School of Nursing

Clement Stone, PhD; Professor and Director, Psychology in Education Program, at the School of Education

Michael Thase, MD; Professor of Psychiatry at the School of Medicine



Western Psychiatric Institute and Clinic

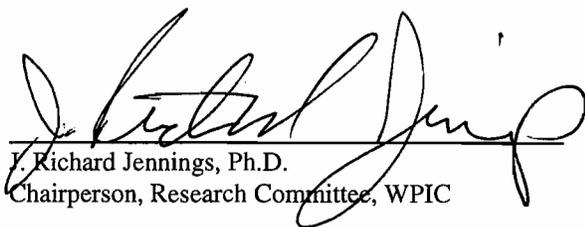
3811 O'Hara Street
Pittsburgh, PA 15213-2593

MEMORANDUM

TO: Judy Callan, R.N., M.S.N.

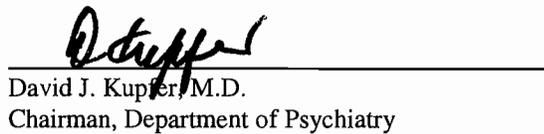
RE: Development of a Scale: Barriers to Cognitive Behavioral Homework Scale

Since your Dissertation Committee has reviewed and approved your proposal referenced above, the WPIC Research Review Committee does not need to undertake a second review, but accepts the Dissertation Committee's recommendation for approval.



J. Richard Jennings, Ph.D.
Chairperson, Research Committee, WPIC

5/6/04
Date



David J. Kupfer, M.D.
Chairman, Department of Psychiatry

5/6/04
Date



Western Psychiatric Institute and Clinic
of UPMC Presbyterian

Part of
UPMC Health System

3811 O'Hara Street
Pittsburgh, PA 15213-2593

September 12, 2003

Judith Lis, R.N., M.S.N.
Bellefield Towers, Rm. 849
100 N. Bellefield Avenue
Pittsburgh, PA 15213

Dear Ms. Lis:

The Seed Money Review Committee reviewed your proposal, "Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale," on September 8, 2003.

Please be advised that the Committee:

Approved your proposal. Please contact Susan Dachille regarding your budget. You will also need to obtain IRB approval.

Approved your proposal, contingent on your written responses to the issues raised in the individual reviews and the Committee discussion.

Did not approve your proposal.

The Committee discussion focused on the following issues:

- The representativeness of the items you will generate with only 10 patients and therapists in phase 1.
- Concerns regarding recruitment. Can you document support for including your measure at this site and the multiple other sites proposed?
- The potential complexity of a measure that includes barriers from task, patient, and therapist perspectives.

Please see the comments of the individual reviewers, which are attached. If you have any questions, feel free to contact me at 412-624-5591.

Sincerely,

Paul A. Pilkonis, Ph.D.

Paul A. Pilkonis, Ph.D.
Chair, Seed Money Review Committee

CC: David J. Kupfer, M.D.
Susan V. Dachille, R.N., M.B.A.



Western Psychiatric Institute and Clinic
of UPMC Presbyterian

Part of
UPMC Health System

3811 O'Hara Street
Pittsburgh, PA 15213-2593

September 12, 2003

Judith Lis, R.N., M.S.N.
Bellefield Towers, Rm. 849
100 N. Bellefield Avenue
Pittsburgh, PA 15213

Dear Ms. Lis:

The Seed Money Review Committee reviewed your proposal, "Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale," on September 8, 2003.

Please be advised that the Committee:

Approved your proposal. Please contact Susan Dachille regarding your budget. You will also need to obtain IRB approval.

Approved your proposal, contingent on your written responses to the issues raised in the individual reviews and the Committee discussion.

Did not approve your proposal.

The Committee discussion focused on the following issues:

- The representativeness of the items you will generate with only 10 patients and therapists in phase 1.
- Concerns regarding recruitment. Can you document support for including your measure at this site and the multiple other sites proposed?
- The potential complexity of a measure that includes barriers from task, patient, and therapist perspectives.

Please see the comments of the individual reviewers, which are attached. If you have any questions, feel free to contact me at 412-624-5591.

Sincerely,

Paul A. Pilkonis, Ph.D.

Paul A. Pilkonis, Ph.D.
Chair, Seed Money Review Committee

CC: David J. Kupfer, M.D.
Susan V. Dachille, R.N., M.B.A.

APPENDIX E: Phase I Consents

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

**CONSENT TO PARTICIPATE AS A SUBJECT
(PATIENT VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT)
Homework Compliance Scale

PRINCIPAL INVESTIGATOR: Judith A.Lis, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Senior Program Coordinator
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24-hour number

STUDY SPONSOR: None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you are currently depressed and in CBT. Your participation in this study will last from 30 to 60 minutes. Twenty male and female patients ages 18 and older will be participating in the study.

This study is supported by a seed money grant from the MHIRC for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of a doctoral dissertation in the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

Subject Initials _____

Purpose of the Study

The purposes of the Study are to:

- Develop a list of items that represent commonly experienced obstacles to the completion of CBT homework for depressed patients
- From this list of items, develop a draft assessment tool that may be used to help therapists and patients identify factors that might prevent patients from completing CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

Your therapist has introduced the study to you and provided some general background. You have also been provided a copy of this consent prior to contacting the investigator to participate.

Study Procedures

If you are interested in participating, your therapist will give you the name and phone number of the investigator. An agreed upon time will be set up between you and the investigator. You will meet with the investigator or speak on the phone to review the purposes and procedures related to the study. If you are agreeable you will either sign the consent document now or you have provided verbal consent on the phone and will send the signed consent that will be mailed to you along with a self-addressed stamped envelope for its' return to the investigator. Ample time will be allowed to answer all questions thoroughly. If you are agreeable, you will then sign informed consent.

An agreed upon time will be established with you for each of the interviews. This interview will be semi-structured using general questions that seek to determine, from the your standpoint, what you view as the most common barriers to the completion of CBT homework. The investigator will conduct (in person or on the phone) and audiotape each interview. Additional clarifying and elaborating questions will be used to gain maximum information. After you have no new comments, the interview will terminate. It is estimated that each interview will take 30 to 60 minutes.

After all of the interviews have taken place, a research assistant will transcribe the audiotapes and the investigator will organize the material into tables. From these tables, the most frequently determined factors that may prevent a patient from completing their CBT homework will be organized into a draft assessment tool.

The information you provide, along with a similar interview with ten CBT therapists, and review of the CBT published literature, will assist in developing these items.

Subject Initials _____

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

Risks and Benefits

It is estimated that there will be minimal risks associated with your participation. Some risks that may be associated with your participation relate to confidentiality and privacy. All interviews, which will contain personal opinions and information related to your CBT involvement, will be audiotaped which carries a risk related to inappropriate use and disclosure of confidential material. Your name will not be attached to the tapes or the transcribed interview. Results of each interview and tapes will be coded by a unique subject identifier, i.e. 001 and higher that cannot be connected back to your name. There will be a research list that does connect the unique subject identifier to your name that will be kept in a locked file in the principal investigator's office. Only the principal investigator, research assistant, and data manager will have access to this list. All data, audiotapes, and subject information will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. Other risks may include embarrassment or psychological disturbance related to discussing your difficulties in therapy. The investigator has 23 years in the psychiatric nursing and will be prepared to help with any of your concerns. The interviews will take some time out of your schedule. The investigator will make effort to set up a time for the interview that is convenient for you.

There are no direct benefits for your participation in the study. Long-term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of MDD. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

COSTS AND PAYMENT:

You will not be paid for your participation in this study. You will not be charged for the study interview. Neither will your insurance be billed for any aspect of this study.

CONFIDENTIALITY:

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh

Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in

Subject Initials _____

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW:

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future medical care. Please be informed that you can be withdrawn from this study without your consent if your therapist feels it is in your best interest, or if you fail to follow the study procedures. You are under no obligation to participate in any research study offered by your therapist.

VOLUNTARY CONSENT:

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Participant's Signature

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Subject Initials _____

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

**CONSENT TO PARTICIPATE AS A SUBJECT
(THERAPIST VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT)
Homework Compliance Scale

PRINCIPAL INVESTIGATOR: Judith A. Lis, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Senior Program Coordinator
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24-hour number

STUDY SPONSOR: None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you have received specific training in CBT and are primarily identified as being a CBT therapist. Your participation in this study will last from 30 to 60 minutes. Twenty male and female therapists ages 18 and older will be participating in the study.

This study is supported by a seed money grant from the MHIRC Study for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of the doctoral program at the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

Subject Initials _____

Purpose of the Study

The purposes of the Study are to:

- Develop a list of items that represent commonly experienced obstacles to the completion of CBT homework for depressed patients
- From this list of items, develop a draft assessment tool that may be used to help therapists and patients identify factors that might prevent patients from completing CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

Study Procedures

You are being asked to participate in the study because you have conducted CBT in one of the associated studies at the Depression Treatment and Research Program or in the UPMC Bellefield clinic. An agreed upon time will be set up between you and the investigator. You will meet with the investigator to review the purposes and procedures related to the study. If you are agreeable you will either sign the consent now or you have provided verbal consent on the phone and will send the signed consent that will be mailed to you along with a self-addressed stamped envelope for its return to the investigator. Ample time will be allowed to answer all questions thoroughly. If you are agreeable, you will then sign informed consent.

An agreed upon time will be established with you for each of the interviews. This interview will be semi-structured using general questions that seek to determine, from the your standpoint as a therapist, what you view as the most common barriers to the completion of CBT homework. Additional clarifying and elaborating questions will be used to gain maximum information. The investigator will conduct (in person or on the phone) and audiotape each interview. After you have no new comments, the interview will terminate. It is estimated that each interview will take 30 to 60 minutes.

After all of the interviews have taken place, a research assistant will transcribe the audiotapes and the investigator will organize the material into tables. From these tables, the most frequently determined factors that may prevent a patient from completing their CBT homework will be organized into a draft assessment tool. The information you provide, along with a similar interview with ten CBT patients, and review of the CBT published literature, will assist in developing these items.

Subject's Risks/Benefits

It is estimated that there will be minimal risks associated with your participation. Some risks that may be associated with your participation relate to confidentiality and privacy. All interviews, which will contain personal opinions and information related to your CBT

Subject Initials _____

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

involvement, will be audiotaped which carries a risk related to inappropriate use and disclosure of confidential material. Your name will not be attached to the tapes or the transcribed interview.

Results of each interview and tapes will be coded by a unique subject identifier, i.e. 001 and higher that cannot be connected back to your name. There will be a research list that does connect the unique subject identifier to your name that will be kept in a locked file in the principal investigator's office. Only the principal investigator, research assistant, and data manager will have access to this list. All data, audiotapes, and subject information will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. The interviews may take some time out of your schedule. The investigator will make effort to set up a time for the interview that is convenient for you.

There are no direct benefits for your participation in the study. Long term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of MDD. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

NEW INFORMATION:

You will be informed of any new significant information that may affect your willingness to participate in this research study. You will be promptly notified if any new information develops during the course of this research study that may cause you to change your mind about continuing to participate.

COSTS AND PAYMENT:

You will not be paid for your participation in this study. You will not be charged for the study interview. Neither will your insurance be billed for any aspect of this study.

CONFIDENTIALITY:

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Subject Initials _____

Approval Date: 2/26/2004
University of Pittsburgh
Institutional Review Board
IRB # 0307128
Renewal Date: 9/25/2004

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW:

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future professional benefits. Please be informed that you can be withdrawn from this study without your consent if you fail to follow the study procedures.

VOLUNTARY CONSENT:

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me. Any questions which I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (412-578-8570).

Participant's Signature

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent Role in Research Study

Signature of Person Obtaining Consent

Date

Subject Initials _____

APPENDIX F: Phase I Measures

Interview Guide (Therapist)

1. Do you find that completion of CBT homework is a common issue/problem for depressed patients?
2. When you've been conducting CBT, what has seemed to be some of the barriers to the patient completing CBT homework?
3. Are there specific patient factors/attributes that impact a patient's inability to complete CBT homework?
4. Are there particular tasks that seem more difficult than others for some patients?
5. Are there elements of the therapy, therapist or therapy relationship that serve as barriers to the patient getting their homework done?
6. What kinds of therapist activities help to reduce barriers to the completion of homework?
7. Are there certain patient attributes that increase the chances of a patient doing homework? Decrease chances?
8. Are there some patients who refuse to do homework? What are they like?
9. Do you think CBT homework is a critical element in treatment response? Please explain.

Interview Guide (Patient)

1. If you've ever had difficulty completing your assigned cognitive therapy homework, can you tell me what made it difficult for you?
2. What things seem like barriers to completing CBT homework?
3. Are there things about you or how you were feeling that made it hard for you to complete your CBT homework?
4. Was it something about the specific homework assignment that made it difficult to complete? Something that affected your willingness to do the homework assignment?
5. Are some tasks that seem more difficult than others?
6. Was there anything about the way the therapist gave the task that made it difficult?
7. Was there anything about your relationship with the therapist or therapy activities that created barriers to doing the homework assignments?
8. Do you think completing your homework is important for your response? In what way? To what degree?

Study Entry Checklist (Patient)

ID _____

Initials _____

Date: / /
m m / d d / y y

	Inclusion	Yes	No
1	DSM-IV diagnosis on Major Depression (single, recurrent, or chronic episode)		
2	Duration of episode at least 4 weeks		
3	Patient is at least 18 years of age		
4	Currently in CBT therapy		

	Exclusion	Yes	No
1	Diagnosis of bipolar disorder, schizophrenia, obsessive-compulsive disorder and substance abuse of dependence in the last 6 months		
2	Inability to read or comprehend at the 8 th grade level		

Study Entry Checklist (Therapist)

ID _____

Initials _____

Date: / /
 m m / d d / y y

	Inclusion	Yes	No
1	At least 3 years of CBT experience		
2	Trained in Beck's version of CBT or a modified CBT that carries the basic theoretical precepts		

	Exclusion	Yes	No
1	Therapist does not routinely assign homework to patients		

Demographics (Patient)

ID _____

Initials _____

Date: / /
m m / d d / y y

1. Highest Degree Obtained (check one):

- | | |
|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> College Diploma |
| <input type="checkbox"/> High School Diploma | <input type="checkbox"/> Master's Degree |
| <input type="checkbox"/> GED | <input type="checkbox"/> Doctorate |
| <input type="checkbox"/> Associate/Technical Degree | <input type="checkbox"/> Medical Degree |

2. Years of Education: _____

3. Gender (check one):

- Male
 Female

4. Age (in years): _____

5. Current Marital Status:

- | | |
|--|------------------------------------|
| <input type="checkbox"/> Never Married | <input type="checkbox"/> Separated |
| <input type="checkbox"/> Cohabiting with Partner | <input type="checkbox"/> Divorced |
| <input type="checkbox"/> Married | <input type="checkbox"/> Widowed |

6. Estimated income:

- | | |
|--|--|
| <input type="checkbox"/> Less than \$10,000 | <input type="checkbox"/> \$50,000 - \$74,999 |
| <input type="checkbox"/> \$10,000 - \$19,999 | <input type="checkbox"/> \$75,000 - \$99,999 |
| <input type="checkbox"/> \$20,000 - \$29,999 | <input type="checkbox"/> \$100,000 - \$149,999 |
| <input type="checkbox"/> \$30,000 - \$39,999 | <input type="checkbox"/> \$150,000 or more |
| <input type="checkbox"/> \$40,000 - \$49,999 | |

7. Age at time of first depressive episode (see criteria for Major Depression): _____

Demographics (Patient)

ID _____

Initials _____

Date: / /
m m d d y y

8. Estimated number of depressive episodes: _____
9. Estimated length of time of current depressive episode (in months): _____
10. Length of time in Cognitive Behavioral Therapy (in weeks): _____

Demographics (Therapist)

ID _____

Initials _____

Date: / /
m m d d y y

1. Highest Degree Obtained (check one):

- | | |
|---|--|
| <input type="checkbox"/> None | <input type="checkbox"/> College Diploma |
| <input type="checkbox"/> High School Diploma | <input type="checkbox"/> Master's Degree |
| <input type="checkbox"/> GED | <input type="checkbox"/> Doctorate |
| <input type="checkbox"/> Associate/Technical Degree | <input type="checkbox"/> Medical Degree |

2. Years of Education: _____

3. Gender (check one):

- Male
- Female

4. Age (in years): _____

5. Type of Cognitive Behavioral Therapy (CBT) training (check one):

- Introductory (1 class on CBT)
- Intermediate (structured course on CBT, less than 1 year of supervision)
- Advanced (extramural training at Beck Institute, greater than 1 year of supervision)

6. CBT Supervision (check one):

- Yes
- No

7. Estimated hours of CBT supervision: _____

8. Number of years doing CBT

Full-time (greater than 20 hours per week) _____

Part-time (equal to or less than 20 hours per week) _____

Demographics (Therapist)

ID _____

Initials _____

Date: / /
m m d d y y

9. Number of patients treated with CBT (lifetime):

1-20

101-150

21-40

151-200

41-60

201+

60-100

Major Depression Educational Form

Five (or more) of the following symptoms during the same two week period and represents a change from previous functioning.

At least one of the symptoms must be #1 or #2.

1. **Depressed mood** most of the day, nearly every day.
2. **Loss of interest or pleasure** in almost all or all activities most of the day nearly every day.
3. **Significant weight loss or weigh gain or decreased/increased appetite** nearly every day.
4. **Difficulty sleeping or sleeping too much** nearly every day.
5. **Being physically restless or slowed down** nearly every day.
6. **Fatigue or loss of energy** nearly every day.
7. **Feelings of worthlessness or excessive or inappropriate guilt** nearly every day.
8. **Diminished ability to concentrate or make decisions** nearly every day.
9. **Recurrent thoughts of death, suicidal thoughts, and/or suicidal actions or plans.**

Approval Date: 09/04/2006
Renewal Date: 09/03/2007
University of Pittsburgh
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IRB #0508068

**CONSENT TO PARTICIPATE AS A SUBJECT
(THERAPIST VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT) Homework Completion Scale (Phase II)

PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

STUDY SPONSOR:

None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you have received specific training in CBT and are primarily identified as being a CBT therapist. Your participation in this study will last less than 30 minutes. It is estimated that up to 18 CBT therapists from this and other mental health practices in the greater Pittsburgh area will participate in the study.

This study is supported by a seed money grant from the MHIRC Study for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of the doctoral program at the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

Subject Initials _____

Purpose of the Study

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

Study Procedures

You are being asked to participate in the study because you conduct CBT at this mental health therapy clinic/practice. An agreed upon time will be set up between you and the investigator to discuss your participation. You will meet with the investigator (in person or on the phone) to review the purposes and procedures related to the study. If you are agreeable you will either sign the consent or you have provided verbal consent on the phone and will send the signed consent that will be mailed to you along with a self-addressed stamped envelope for its return to the investigator. Ample time will be allowed to answer all questions thoroughly. If you are agreeable, you will then sign informed consent. The investigator will ask you to provide information about yourself such as your age, educational level, CBT training background, hours of supervision, etc.

There will be posters and fliers in the waiting room (or your individual office if you have previously stated this preference) inviting patients to participate. Patients will contact the investigator about the study and have provided informed consent to participate in the study and to contact their therapist.

One third of the patients will complete the questionnaires in either the beginning, the middle, or later in their therapy. The investigator will let you know when it is time for the patient to complete the questionnaires. Patients will be given all of the questionnaires for the study, including the therapist questionnaires. Each study packet will have very detailed information about the procedures for completion of the questionnaires. All measurement points will have specific self-addressed stamped envelopes to send the questionnaires back to the investigator. At

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IRB #0508068

each measurement point, you will also be given your questionnaire to complete and will seal it in the enclosed envelope and ask the patient to place it in their self-addressed stamped envelope. On the week of the first CBT session identified (Session A), you will be asked to complete the Therapist Demographic Form. Patients will complete the Patient Demographic Form, the Beck Depression Inventory (BDI), and the Dysfunctional Attitudes Scale (DAS).

In the next CBT session (Session B) , patients will be asked to complete the “Barriers to CBT Homework Completion Scale” as well as the BDI and DAS. You will also be asked to complete the “Assignment Compliance Rating Scale” (ACRS) that references the homework from the previous session. The same procedure will occur in the following session. The sessions being referenced in the ratings will be the session prior to the actual rating. All research packets will also have an associated self-addressed envelope for the patients to seal their ratings (and your sealed ratings) to retain confidentiality.

Subject’s Risks/Benefit

All of your demographic information and ACRS ratings will be identified by your specific research identification code and not by name. There will be a research list that does connect the unique subject identifier, i.e. 001 and higher, to your name that will be kept in a research data base that is password protected. The principal investigator, research assistant, and data manager will have access to this list. All data and subject information will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. Exceptions to this are listed in the confidentiality section. Completion of the questionnaires may take some time out of your schedule.

In providing the requested information about patient completion of CBT homework, there may be an inadvertent breach of patient confidentiality. If this would occur, the investigator would remind the therapist that this particular information is not specifically authorized through patient consent.

There are no direct benefits for your participation in the study. Long term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of MDD. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

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NEW INFORMATION

You will be informed of any new significant information that may affect your willingness to participate in this research study. You will be promptly notified if any new information develops during the course of this research study that may cause you to change your mind about continuing to participate.

COSTS AND PAYMENT

You will not be paid for your participation in this study. There are no costs associated with participation in this study.

CONFIDENTIALITY

In addition to the investigator listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future professional benefits. Please be informed that you can be withdrawn from this study without your consent if you fail to follow the study procedures.

Subject Initials _____

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VOLUNTARY CONSENT

The above information has been explained to me and all of my questions have been answered. Any future questions I have about this research study will be answered by the investigator listed on the front page of this consent document at the telephone number given. Any questions I have about my rights as a research subject will be answered by the Human subjects Protection advocate at the IRB office, University of Pittsburgh (1-866-212-2668). By signing this form I agree to participate in this research study.

Participant's Signature

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Subject Initials _____

Approval Date: 09/04/2006
Renewal Date: 09/03/2007
University of Pittsburgh
Institutional Review Board
IRB #0508068

**CONSENT TO PARTICIPATE AS A SUBJECT
(PATIENT VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT) Homework Completion Scale (Phase II)

PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

STUDY SPONSOR:

None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you are currently depressed and in CBT at this mental health clinic. Your participation in this study will last from 45 to 60 minutes (divided among 3 occasions). Up to 70 male and female patients ages 18 and older will be participating in the study.

This study is supported by a seed money grant from the MHIRC for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of a doctoral dissertation in the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

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Approval Date: 09/04/2006
Renewal Date: 09/03/2007
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Institutional Review Board
IRB #0508068

Purpose of the Study

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

You have contacted the investigator after seeing a poster/flier at the mental health clinic where you receive CBT. You have been provided information from the investigator, in person or on the phone, as to the goals, procedures, risks and benefits of the study. Ample time has been allowed to answer all questions thoroughly.

Study Procedures

If you are agreeable you will either sign the consent document now or you have provided verbal consent on the phone. The investigator will mail the consent to you along with a self-addressed stamped envelope for its' return to the investigator. If you are agreeable, you will then sign informed consent and mail it back to the investigator. Following your consent, your therapist will be notified of your participation in the study as they are required to complete one questionnaire about your homework assignment completion as well.

One third of the patients will complete the questionnaires either in the beginning, the middle, or later on in their therapy. The investigator will let you know when it is time to complete the questionnaires. On the week of the first identified CBT session, you will be asked to complete 3 questionnaires that ask about your mood and general attitudes and a demographic form asking basic questions about you such as age, gender, etc. In the session following the identified CBT session, you will be asked to complete the "Barriers to CBT Homework Completion Scale." as well as the questionnaires about your mood and general attitudes. The same procedure will occur in the following session. The sessions being referenced in the ratings

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will be the session prior to the actual rating. You will be provided with an envelope that will be sealed so that your research questionnaires remain private. Your therapist will not view your ratings. You will then place the questionnaires in a self addressed envelope along with your therapist's sealed rating and place them in the US mail.

Risks and Benefits

It is estimated that there will be minimal risks associated with your participation. Some risks that may be associated with your participation relate to confidentiality and privacy. All questionnaires, which will contain personal opinions and information related to your CBT involvement will not have your name on them. Questionnaires will be coded by a unique subject identifier, i.e. 001 and higher that cannot be connected back to your name. There will be a research list that does connect the unique subject identifier to your name that will be kept in this study's research data base that is password protected. Only the principal investigator, research assistant, and data manager will have access to this list. All data will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. There may be other circumstances that may affect your confidentiality and are listed in the confidentiality section of this document.

Other risks may include embarrassment or psychological disturbance related to discussing your difficulties in completing the CBT homework. The investigator has 25 years in the psychiatric nursing field and will be prepared to help with any of your concerns. Completion of the questionnaires will take some time out of your schedule. It is estimated that each set of questionnaires will take no more than 20 minutes to complete.

Long term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of Major Depression. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

COSTS AND PAYMENT

You will receive \$20.00 to offset the time and effort of your participation in this study. You will not be charged for any part of your study participation. Neither will your insurance be billed for any aspect of this study.

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Approval Date: 09/04/2006
Renewal Date: 09/03/2007
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CONFIDENTIALITY

In addition to the investigator listed on the first page of this authorization (consent) form and her research staff, the following individuals may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. The mental health treatment center where you receive CBT is independent from this study. You are free to refuse to participate in this study, withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future mental health treatment or your relationship with your therapist. Please be informed that you can be withdrawn from this study without your consent if your therapist feels it is in your best interest, or if you fail to follow the study procedures. You are under no obligation to participate in any research study.

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Institutional Review Board
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CERTIFICATION OF INFORMED CONSENT

The above information has been explained to me and all of my questions have been answered. Any future questions I have about this research study will be answered by the investigator listed on the front page of this consent document at the telephone number given. Any questions I have about my rights as a research subject will be answered by the Human subjects Protection advocate at the IRB office, University of Pittsburgh (1-866-212-2668). By signing this form I agree to participate in this research study.

Participant's Signature

Date

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Subject Initials _____

APPENDIX G: Barriers Worksheet

Barriers

ID _____

Initials _____

Date: ____ / ____ / ____
 m m d d y y

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

Barrier No.	Patient Barrier Y N	Therapist Barrier Y N	Task Barrier Y N
Keywords:			

APPENDIX H: Barrier Keyword Spreadsheet

Barrier Keywords List

101	ability to monitor moods	149	geographical location
102	activated emotional state	150	getting started with HW
103	afraid to be judged by others	151	harder to face reality out of session
104	age-older increases HW	152	helplessness
105	age-younger decreases HW	153	history of following through
106	anger	154	history of non-compliance
107	anhedonia	155	hopelessness
108	anxiety	156	hostility
109	autotrophic	157	human nature
110	avoid feelings	158	HW not part of routine
111	avoiding thoughts	159	imposition
112	behavioral deficits	160	improvement-no need for HW
113	belief HW valuable	161	inability to do HW
114	belief must feel better before behavior changes	162	incorrect use of session
115	beliefs of self efficacy	163	inferiority
116	Borderline PD	164	intellectual capacity
117	boredom with HW	165	intimidated by assignment
118	change difficult	166	irritability
119	chaotic life	167	learned helplessness
120	character issues	168	level of education
121	coerced into treatment	169	logistics
122	cognitive impairment	170	low energy
123	comorbid diagnosis	171	low self esteem
124	co-morbid diagnosis	172	means to do assignment
125	comprehension	173	mood not improving
126	concentration	174	motivation
127	concreteness	175	negative cognitions with treatment
128	confidence	176	negative connotation with HW
129	crisis during treatment	177	not worth the hassles
130	defensive	178	OCD
131	dependence	179	omnipotent therapist
132	depression length	180	over ambitious patient
133	depression severity	181	over sensitive
134	disorganized	182	overwhelmed
135	don't buy into therapy	183	passive
136	don't want to acknowledge depression	184	passive aggressive
137	Dr. will fix them	185	passive dependent
138	excessive responsibilities	186	past history of therapy
139	familiarity with CBT	187	past therapy success
140	fear of criticism	188	patient no show
141	fear of failing	189	patient self discipline
142	financial	190	people pleaser
143	following rules	191	perfectionism
144	forget to bring HW to session	192	personality disorder
145	forgetfulness	193	poor sleep
146	frightened	194	prioritization
147	frustration	195	proactive
148	functioning level	196	problem solving skills

Barrier Keywords List

197	procrastination	247	getting better/fear of unknown
198	psychologically minded	248	history of abuse
199	psychomotor retardation	249	lack of assertiveness
200	pt communication of readiness unclear	250	positive reframes-negation of feelings
201	pt consistency with HW	251	sequential thinking
202	readiness	252	willingness to change
203	reading difficulty	501	alliance
204	remember to do HW during stress	502	being in tune with patient
205	seasonal depression	503	burdensome
206	secondary gain from not doing HW	504	collaboration
207	self care behaviors	505	counter transference
208	self conscious	506	designing do-able HW
209	sense of entitlement	507	doesn't address barriers
210	sociotrophic	508	don't refer to previous HW
211	substance abuse	509	examples
212	success level in life	510	flexibility
213	support level	511	goal setting
214	takes charge of life	512	humorless therapist
215	therapist accepting responsibility	513	HW importance not stressed
216	therapy expectations	514	HW not put on agenda
217	time management	515	HW not rehearsed
218	unpredictable factors	516	HW safe
219	unwilling to do HW	517	HW shows results
220	will disappoint therapist	518	hypothesis testing approach
221	willingness to be in treatment	519	incorporate skills to real life
222	willingness to change	520	initial success with HW
223	work ethic	521	keep structure of therapy
224	worthlessness	522	level of training
225	global thinking	523	no patient feedback
226	willingness to take risks	524	non-meaningful assignments
227	success with HW	525	not adequately explained
228	approach to life not consistent with therapy	526	Not checking HW
229	feels bad about HW-blocks it out	527	Not enough time spent on HW in session
230	gives up	528	overload with homework
231	disappointed	529	overlooking patient difficulties
232	inconsistent pattern of doing HW	530	patient designing own HW
233	ill	531	patient directing therapy
234	thinking too hard	532	phase of therapy
235	difficulty absorbing information	533	phone access for difficulties
236	privacy issues	534	poorly designed HW
237	automatic thoughts draining	535	positive reinforcement
238	sleep problems	536	power struggle patient/therapist
239	don't deserve to get better	537	problem solving approach
240	psychomotor agitation	538	pt watching own therapy tapes
241	health problems	539	pt/therapist relationship
242	time of day	540	repeated explanations
243	feel stupid	541	respect of patient
244	rough day	542	saving HW to the end of session
245	vulnerability difficult	543	short term therapy
246	intellectualization	544	short time between sessions

Barrier Keywords List

545	socialization to CBT model	813	how involved is assignment
546	tailored HW assignments	814	HW connecting emotions/thoughts
547	teacher-student relationship	815	keeping track assignments
548	therapist addresses non-compliance	816	length of assignment
549	therapist designs HW that's not applicable	817	mechanistic task
550	therapist empathy	818	mood log
551	therapist insensitivity to difficulty	819	not significant to improvement
552	therapist moving pt too quickly	820	only partial completion
553	therapist organization	821	personal experiments
554	therapist patience	822	reading materials have extreme examples
555	therapist skill	823	thought records
556	therapist variability	824	writing assignments
557	timing of HW	825	HW feels like a manipulation
558	too hard to grasp	826	confusing assignments
559	transference	827	assignment not in lay terms
560	trust	828	demeaning
561	over functioning therapist	829	generalities to specific
562	therapist creativity	830	negative to positive focus
563	therapist accepting responsibility	831	book assignments
564	HW is new	832	hour tower chart
565	therapy too structured	833	non-specific assignments
566	simplistic therapy	834	overlapping concepts
567	therapy not intrapersonal	835	small steps
568	sessions too short	836	reading assignments
569	scheduling	837	need portable way to do
570	shifting gears required	838	physical assignments
571	doesn't give assignments	839	lack of familiarity with task
572	taping sessions	840	taking notes on task helps
573	difficult assignments too early	841	incident still going on makes it harder
574	therapist too technical	842	reading material is vague
575	hw doesn't come from case conceptualization	843	scheduling pleasant events
576	poor case conceptualization	844	taking orderly notes
577	therapist normalizing dysfunctional thoughts	845	daily monitoring
578	hw not assigned consistently	846	tasks that increase anxiety
579	enthusiasm of therapist	847	problem lists
580	personal examples from therapist	848	breaking into smaller pieces
581	lack of consistent sessions	849	post it notes
582	too much time between sessions	850	advantages/disadvantages
801	activity schedule		
802	alternative beliefs		
803	behavioral experiments		
804	behavioral tasks		
805	can't think of a situation		
806	capturing automatic negative thoughts		
807	changing core beliefs		
808	complicated		
809	coping cards		
810	downward vertical arrow		
811	experiments involving others opinions		
812	harder than estimated		

APPENDIX I: Conceptual Grouping Example

CAUSES EMOTIONAL DISTRESS WOULD RATHER AVOID

Rater: 1

- 110 avoid feelings
- 111 avoiding thoughts
- 118 change difficult
- 136 don't want to acknowledge depres
- 151 harder to face reality out of sessio
- 226 willingness to take risks
- 229 feels bad about HW-blocks it out
- 237 automatic thoughts draining
- 245 vulnerability difficult
- 805 can't think of a situation
- 841 incident still going on makes it har
- 846 tasks that increase anxiety

APPENDIX J: Name of Concept by Rator

Study ID: 1001

Group Title	PI	RA	PsychPro
AVOIDANT BELIEFS	2		5
CBT TASK BEHAVIORS	3	4	
COGNITIVE ABILITY/FEATURES	2	1	1
DEPRESSION FEATURES	2	3	3
MOOD STATE	6	4	5
NATURE OF ASSIGNMENT		1	1
OPPOSITIONALITY	1	1	1
PATIENT BACKGROUND/DEMOGRAPHICS		1	
PATIENT BELIEFS	1	1	4
PATIENT-THERAPIST RELATIONSHIP		2	
PERSONALITY CHARACTERISTICS	2	4	1
PREDICTION OF GOOD RESPONSE			1
PSYCHOLOGICAL READINESS	2	1	
SELF EFFICACY/SELF ESTEEM	5	4	6
THERAPIST ACTIONS	4	3	2
THERAPIST QUALITIES	3	1	1
THERAPIST SKILL	1	5	2

APPENDIX K: Initial Rators Concept by Indentification per Interview

Study ID: 1001

Group Title	PI	RA	PsychPro
AVOIDANT BELIEFS	2		5
CBT TASK BEHAVIORS	3	4	
COGNITIVE ABILITY/FEATURES	2	1	1
DEPRESSION FEATURES	2	3	3
MOOD STATE	6	4	5
NATURE OF ASSIGNMENT		1	1
OPPOSITIONALITY	1	1	1
PATIENT BACKGROUND/DEMOGRAPHICS		1	
PATIENT BELIEFS	1	1	4
PATIENT-THERAPIST RELATIONSHIP		2	
PERSONALITY CHARACTERISTICS	2	4	1
PREDICTION OF GOOD RESPONSE			1
PSYCHOLOGICAL READINESS	2	1	
SELF EFFICACY/SELF ESTEEM	5	4	6
THERAPIST ACTIONS	4	3	2
THERAPIST QUALITIES	3	1	1
THERAPIST SKILL	1	5	2

APPENDIX L: Frequency of Barrier Keyword Identification Per Concept

CBT TASK BEHAVIORS

<u>Item Num.</u>	<u>Count of Items</u>	<u>Item Title</u>
801	7	activity schedule
802	8	alternative beliefs
803	7	behavioral experiments
804	7	behavioral tasks
809	2	coping cards
814	25	HW connecting emotions/thoughts
818	4	mood log
821	6	personal experiments
823	37	thought records
824	41	writing assignments
831	4	book assignments
832	4	hour tower chart
836	6	reading assignments
838	2	physical assignments
842	6	reading material is vague
843	1	scheduling pleasant events
845	1	daily monitoring
847	1	problem lists

APPENDIX M: Frequency of Keyword Identification by Rater

Rater Identified Patient Barriers (Phase I)

Patient	Principal Investigator	Non-Psychiatric Professional	Psychiatric Professional	Mean/ SD
001	30	52	17	33.0/17.7
002	23	18	5	15.3/9.3
003	20	24	10	18.0/7.2
004	31	25	16	24.0/7.6
005	16	16	20	17.3/2.3
006	17	20	19	18.7/1.5
007	13	20	16	16.3/3.5
008	22	25	8	18.3/9.1
009	14	17	7	12.7/5.1
010	15	14	7	12.0/4.4
011	11	14	7	10.7/3.5
012	17	23	11	17.0/6.0
013	11	16	5	10.7/5.5
014	20	33	12	21.7/10.6
015	16	14	6	12.0/5.3
016	12	22	7	13.7/7.6
017	11	10	6	9.0/2.7
018	18	19	18	18.3/6
019	15	18	21	18.0/3.0
020	24	26	20	23.3/3.1
Total/Mean/SD	356/17.8/5.9	426/21.3/9.0	238/11.9/5.8	

Rater Identified Therapist Barriers (Phase I)

Therapist	Principal Investigator	Non-Psychiatric Professional	Psychiatric Professional	Mean/ SD
001	37	36	35	36.0/1.0
002	29	36	35	33.3/3.8
003	43	41	24	36.0/10.4
004	31	30	16	25.7/8.4
005	35	40	33	36.0/3.6
006	31	37	22	30.0/7.6
007	38	37	24	33.0/7.8
008	27	24	21	24.0/3.0
009	27	26	22	25.0/2.7
010	29	28	22	26.3/3.8
011	36	45	24	35.0/10.5
012	40	38	25	34.3/8.1
013	27	25	18	23.3/4.7
014	41	28	18	29.0/11.5
015	30	20	12	20.7/9.0
016	26	25	14	21.7/6.7
017	45	33	40	39.3/6.0
018	33	27	20	26.7/6.5
019	26	22	16	21.3/5.0
020	25	24	19	22.7/3.2
Total/Mean/SD	656/32.8/6.2	622/31.1/7.2	460/23.0/7.5	

APPENDIX N: Versions of Instrument

Study ID _____ Measurement # _____ Date __/__/__

Barriers to CBT Homework Completion Scale

This questionnaire lists some of the barriers that might get in the way of completing CBT Homework assignments. Please examine each potential barrier and mark the degree to which the item may have interfered with the completion of the Homework assignment that was given in your most recent session.

1. Not at All
2. Slightly
3. Somewhat
4. Moderately
5. Quite a bit
6. Extremely

When I didn't complete my CBT homework (or completed it in a lesser degree than was expected) the following factors contribute:

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
1.	Didn't expect therapy to include homework						
2.	The therapy is too simplistic for me						
3.	There's a negative association with homework						
4.	Assertiveness						
5.	Patience of therapist						
6.	Therapist is too technical						
7.	Don't want to admit depression						
8.	Want to avoid painful feelings						
9.	Feel confident						
10.	Haven't had positive results from doing homework						
11.	Afraid of failing						

	Barrier	Not at all	Slightly	Somewhat	Moderately	Quite a bit	Extremely
12.	Low self esteem						
13.	Collaborating with therapist						
14.	Don't trust therapist						
15.	Power struggle with therapist						
16.	Therapist reminds me of someone I like						
17.	Don't want to do homework						
18.	Always do what I'm instructed to do						
19.	Inconsistent pattern of doing homework						
20.	History of not following through						
21.	Frustration						
22.	No motivation						
23.	Anxiety						
24.	Depression's been going on so long						
25.	Hopefulness						
26.	Poor concentration						
27.	Forgetfulness						
28.	Understood Assignment						
29.	Was organized						
30.	Making an activity schedule						
31.	Reading assignments						
32.	Mood logs						
33.	Thought records						
34.	Scheduling pleasant events						
35.	Being obsessive						
36.	A clinical problem other than depression						
37.	Depressed mood						
38.	Low energy						
39.	Low motivation						
40.	High self worth						
41.	Being physically slowed down						
42.	Chaotic life						
43.	Health problems						
44.	Crisis during treatment						
45.	The time of day						
46.	The means to do the assignment						
47.	Had a rough day						
48.	Not many responsibilities						
49.	CBT is not hard to grasp						
50.	Homework is a new to deal with in therapy						
51.	Belief that homework is valuable						

	Barrier	Not at all	Slightly	Somewhat	Moderately	Quite a bit	Extremely
52.	Don't buy into CBT model						
53.	Didn't want to do a therapy in which I have so much of the responsibility						
54.	CBT not showing results						
55.	Change isn't very hard						
56.	Can't do homework until I feel better						
57.	Perfectionism						
58.	Self conscious						
59.	Shouldn't have to do homework						
60.	Don't want to do homework by myself						
61.	Like to take risks						
62.	Therapist checks my homework						
63.	Therapist assigns meaningful assignments						
64.	Therapist doesn't rehearse the assignment in session						
65.	Therapist explains it several times						
66.	Homework is consistently on the agenda						
67.	Too much homework						
68.	Therapist consistently asks for my feedback						
69.	Procrastination						
70.	Assignment was confusing						
71.	Assignment too long						
72.	Assignment too involved						
73.	Assignment was tailored to my needs						
74.	Assignment was complicated						
75.	Assignment provoked anxiety						
76.	Not enough time in my schedule to do homework						
77.	Taking notes in session						
78.	Support						
79.	Always tend to follow the rules						
80.	Don't want to change						
81.	Don't get homework consistently						
82.	Therapist skill level						
83.	Thorough explanation of CBT model						
84.	Therapy moving too quickly						
85.	Therapy too structured						

Please list your homework assignment (s) from your previous therapy session.

Please rate your opinion on the difficulty of the assignment (s) on a scale of 1 to 10 (1 being not difficult at all and 10 being extremely difficult)

1__ 2__ 3__ 4__ 5__ 6__ 7__ 8__ 9__ 10__

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: / /
m m d d y y

Session _____ Therapist _____

Everyone misses all or part of a homework assignment during CBT sometime during treatment. This questionnaire lists some of the barriers that might get in the way of completing CBT Homework assignments. Please examine each potential barrier. Check the box that most accurately describes the degree to which each item may have interfered with the completion of the Homework assignment that was given in your most recent previous session.

- 0. Not at All
- 1. Slightly
- 2. Somewhat
- 3. Moderately
- 4. Quite a bit
- 5. Extremely

When I didn't complete my CBT homework (or completed it in a lesser degree than was expected) the following factors contributed:

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
1.	Didn't expect therapy to include homework						
2.	Homework brought up painful emotions						
3.	Any assignment involving writing						
4.	My individual personal characteristics						
5.	Impatience of therapist						
6.	Not enough time between sessions						
7.	Homework just reminds me that I'm depressed						
8.	Want to avoid painful feelings						
9.	The homework seems so mechanical						
10.	Doing homework doesn't seem to help						
11.	Afraid of failing						
12.	Don't feel very good about myself						
13.	Therapist and I don't act as a team						
14.	Don't trust therapist						
15.	My therapist always wants to be in charge						
16.	Homework feels like a burden						
17.	Didn't want to do homework						
18.	Feeling helpless						
19.	Not in a regular pattern of doing homework						
20.	Overwhelmed						
21.	Frustration						

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: / / /
m m d d y y

Session _____ Therapist _____

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
22.	Low motivation						
23.	Couldn't seem to take action						
24.	Depression's been going on so long						
25.	Felt Hopeless						
26.	Poor concentration						
27.	Forgot						
28.	Haven't been able to do too many things well in my life						
29.	Wasn't organized						
30.	Therapist and I don't have a good connection						
31.	When I'm mad or annoyed I just don't do what I'm asked						
32.	Couldn't set priorities						
33.	Completing dysfunctional thought records						
34.	Therapy moving too quickly						
35.	I think about the homework too much before I can get it done						
36.	A clinical problem other than depression						
37.	Depressed mood						
38.	Low energy						
39.	The therapy isn't flexible						
40.	When I didn't design it myself						
41.	My confidence went down when I didn't succeed with homework when I first started therapy						
42.	Chaotic life						
43.	I don't understand the emotions- behavior connection						
44.	Afraid to disappoint therapist						
45.	When I didn't do well with homework, it doesn't give me confidence to do it the next time						
46.	Didn't have the resources to do the assignment						
47.	Therapist assigned homework I couldn't do						
48.	Too many responsibilities						
49.	Therapist didn't stress the importance of homework						
50.	Homework is new to deal with in therapy						
51.	Don't buy into the CBT model						
52.	Didn't want to do a therapy that has so much work						
53.	Negative connection to the word "homework"						
54.	Therapist isn't flexible						
55.	I'm too much of a Perfectionist						
56.	Didn't want to do homework by myself						
57.	Therapist doesn't always check my homework						

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: / / / / /
m m / d d / y y

Session _____ Therapist _____

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
58.	Therapist didn't explain the homework thoroughly						
59.	Don't really think homework is important						
60.	Too much homework						
61.	Procrastination						
62.	Assignment was confusing						
63.	Assignment too involved						
64.	Assignment wasn't really designed to my specific needs						
65.	Assignment was complicated						
66.	Not enough time in my schedule to do homework						
67.	No support						
68.	Don't want to change						
69.	Therapist seems inexperienced						
70.	Therapist didn't really explain the CBT model completely						

71. Please list your homework assignment (s) from your previous therapy session.

72. Please circle your opinion of the difficulty of the assignment (s) on a scale of 1 to 10 (1 being not difficult at all and 10 being extremely difficult)

1 2 3 4 5 6 7 8 9 10

Not difficult at all Extremely difficult

73. Please indicate the percentage of the assignment you completed:

_____ %

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: / / / / /
m m d d y y

Session _____ Therapist _____

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
19.	Not in a regular pattern of doing homework						
20.	Overwhelmed						
21.	Frustration						
22.	Low motivation						
23.	Can't seem to take action						
24.	Depression's been going on so long						
25.	Feel Hopeless						
26.	Poor concentration						
27.	Forget						
28.	Haven't been able to do too many things well in my life						
29.	Wasn't organized						
30.	Therapist and I don't have a good connection						
31.	When I'm mad or annoyed I just don't do what I'm asked						
32.	Can't set priorities						
33.	Completing dysfunctional thought records						
34.	Therapy moving too quickly						
35.	I think about the homework too much before I can get it done						
36.	A clinical problem other than depression						
37.	Depressed mood						
38.	Low energy						
39.	The therapy isn't flexible						
40.	When I don't design my own homework						
41.	My confidence went down when I didn't succeed with homework when I first started therapy						
42.	Chaotic life						
43.	Haven't been the type who understand much about emotions and behavior connect						
44.	Afraid to disappoint therapist						
45.	When I do well with homework, it gives me confidence to do it the next time						
46.	Don't have the resources to do the assignment						
47.	Therapist assigns homework I can't do						
48.	Too many responsibilities						
49.	Therapist doesn't stress the importance of homework						
50.	Homework is new to deal with in therapy						
51.	Don't buy into the CBT model						
52.	Didn't want to do a therapy that has so much work						
53.	Negative connection to the word "homework"						

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: / /
m m d d y y

Session _____ Therapist _____

	Barrier	Not at All	Slightly	Somewhat	Moderately	Quite a Bit	Extremely
54.	Therapist isn't flexible						
55.	I'm too much of a Perfectionist						
56.	Don't want to do homework by myself						
57.	Therapist doesn't always check my homework						
58.	Therapist didn't explain the homework thoroughly						
59.	Don't really think homework is important						
60.	Too much homework						
61.	Procrastination						
62.	Assignment was confusing						
63.	Assignment too involved						
64.	Assignment wasn't really designed to my specific needs						
65.	Assignment was complicated						
66.	Not enough time in my schedule to do homework						
67.	No support						
68.	Don't want to change						
69.	Therapist seems inexperienced						
70.	Therapist didn't really explain the CBT model completely						

Please list your homework assignment (s) from your previous therapy session.

Please circle your opinion of the difficulty of the assignment (s) on a scale of 1 to 10 (1 being not difficult at all and 10 being extremely difficult)

1 2 3 4 5 6 7 8 9 10

Not difficult at all

Extremely difficult

Please indicate how much of the assignment you completed:

1 2 3 4 5 6 7 8 9 10

None

All

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: ___ / ___ / ___
m m d d y y

Session _____ Therapist _____

Everyone misses all or part of a homework assignment during CBT sometime during treatment. This questionnaire lists some of the problems that might get in the way of completing CBT Homework assignments. Please examine each potential problem. Check the box that most accurately describes the degree to which each problem may have interfered with the completion of the homework assignment that was given in your most recent previous session.

- 0 Does not interfere at all
- 1 Interferes somewhat
- 2 Interferes moderately
- 3 Interferes very much
- 4 Interferes completely

When I didn't complete my CBT homework (or completed it in a lesser degree than was expected) the following factors contributed:

The following are problems that may be particular to you, how you were feeling, your attitudes or expectations about CBT therapy.

	Barrier	Not at All	Somewhat	Moderately	Very Much	Completely
1.	Didn't expect therapy to include homework					
2.	My individual personal characteristics					
3.	Homework just reminds me that I'm depressed					
4.	Want to avoid painful feelings					
5.	Doing homework doesn't seem to help					
6.	Afraid of failing					
7.	Don't feel very good about myself					
8.	Homework feels like a burden					
9.	Didn't want to do homework					
10.	Feeling helpless					
11.	Not in a regular pattern of doing homework					
12.	Overwhelmed					
13.	Frustration					
14.	Low motivation					
15.	Couldn't seem to take action					
16.	Depression's been going on so long					
17.	Felt Hopeless					
18.	Poor concentration					
19.	Forgot					

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: ___/___/___
m m d d y y

Session _____ Therapist _____

The following are issues related to the therapy itself or with your therapist.

	Barrier	Not at All	Somewhat	Moderately	Very Much	Completely
44.	Impatience of therapist					
45.	Not enough time between sessions					
46.	Therapist and I don't act as a team					
47.	Don't trust therapist					
48.	My therapist always wants to be in charge					
49.	Therapist and I don't have a good connection					
50.	Therapy moving too quickly					
51.	The therapy isn't flexible					
52.	Therapist assigned homework I couldn't do					
53.	Therapist didn't stress the importance of homework					
54.	Homework is new to deal with in therapy					
55.	Therapist isn't flexible					
56.	Therapist doesn't always check my homework					
57.	Therapist didn't explain the homework thoroughly					
58.	Therapist seems inexperienced					
59.	Therapist didn't really explain the CBT model completely					
68.	Assignment too involved					
69.	Assignment wasn't really designed to my specific needs					
70.	Assignment was complicated					

71. Please list your first homework assignment from your previous therapy session.

Please circle the level of difficulty of the assignment.

- 1 Not difficult at all
- 2 Somewhat difficult
- 3 Moderately difficult
- 4 Very difficult
- 5 Extremely difficult

Please indicate the percentage of the assignment you completed:

_____ %

APPENDIX O: Final Instrument

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: ___ / ___ / ___
m m / d d / y y

Session _____ Therapist _____

Everyone misses all or part of a homework assignment at some point during CBT treatment. This questionnaire lists some of the problems that might get in the way of completing CBT Homework assignments. Please examine each potential problem. Check the box that most accurately describes the degree to which each problem may have interfered with the completion of homework assignments since you began CBT therapy.

- 0 Did not interfere at all
- 1 Interfered somewhat
- 2 Moderately interfered
- 3 Interfered very much
- 4 Interfered completely

When I didn't complete my CBT homework (or completed it in a lesser degree than was expected) the following factors contributed:

The following are problems that may be particular to you, how you were feeling, your attitudes, or expectations about CBT therapy.

	Patient Barriers	Not at All	Somewhat	Moderately	Very Much	Completely
1.	I didn't expect therapy to include homework assignments.					
2.	My personal characteristics or style got in the way.					
3.	Homework just reminded me that I was depressed.					
4.	I wanted to avoid painful feelings.					
5.	Doing homework didn't seem to help.					
6.	I was afraid of failing.					
7.	I didn't feel very good about myself.					
8.	Homework felt like a burden.					
9.	I didn't want to do the homework.					
10.	I felt helpless.					
11.	I wasn't in a regular pattern of doing homework.					
12.	I was overwhelmed.					
13.	I was frustrated.					
14.	I wasn't very motivated.					
15.	I couldn't seem to take action.					
16.	This depression's been going on so long.					

Barriers to CBT Homework Completion Scale

Patient ID _____ Patient Initials _____ Date: ___/___/___
m m d d y y

Session _____ Therapist _____

The following are problems that exist with the makeup of homework or the specific task assigned.

Homework/Task Barriers		Not at All	Somewhat	Moderately	Very Much	Completely
44.	Certain homework assignments brought up painful emotions.					
45.	Any assignment involving writing seemed hard.					
46.	The homework seemed so mechanical.					
47.	I had a hard time completing dysfunctional thought records.					
48.	When I didn't design it myself it was harder to do.					
49.	I didn't really think homework was very important.					
50.	Assignment was confusing.					

The following are issues related to the therapy itself of with your therapist.

CBT Therapy/Therapist Barriers		Not at All	Somewhat	Moderately	Very Much	Completely
51.	The therapist was impatient.					
52.	There wasn't enough time between sessions to get it done.					
53.	My therapist and I didn't act as a team.					
54.	I didn't trust my therapist.					
55.	My therapist always wanted to be in charge.					
56.	My therapist gave too much homework.					
57.	My therapist and I didn't have a good connection.					
58.	The therapy moved too quickly.					
59.	CBT therapy didn't feel very flexible.					
60.	The therapist assigned homework I couldn't do.					
61.	The therapist didn't stress the importance of homework.					
62.	Homework was new to deal with in therapy.					
63.	My therapist wasn't very flexible.					
64.	My therapist didn't always check my homework.					
65.	My therapist didn't explain the homework completely.					
66.	My therapist seems new at this.					
67.	My therapist didn't really explain how CBT works very well.					
68.	My therapist gave me assignments that took too much time to do.					
69.	My therapist gave me homework that wasn't really planned around my specific needs.					
70.	My therapist gave me homework that was too complicated.					

APPENDIX P: Phase II Letters of Permission

June 5, 2006

Judith A. Callan RN, MSN
Doctoral Candidate, School of Nursing
University of Pittsburgh
Western Psychiatric Institute and Clinic
3811 O'Hara Street
Pittsburgh, PA 15213

Attention: Bellefield Towers – Room 849

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at the Mood Disorders Clinic located at the Department of Psychiatry at Vanderbilt University. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research; you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,



Steven D. Hollon Ph.D.
Professor of Psychology

Vanderbilt University Medical Center

Vanderbilt University School of Medicine
Department of Psychiatry
Adult Psychiatry Division

The Village at Vanderbilt
1500 21st Avenue South, Suite 2200
Nashville, TN 37212-3137
Phone: (615) 322-0387
Fax: (615) 322-1578

June 28, 2006

Judith A. Callan RN, MSN
Doctoral Candidate
University of Pittsburgh
School of Nursing

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects from the Vanderbilt Adult Psychiatry Outpatient Clinic, located at 1500 21st Ave. South, Suite 2200, Nashville, TN 37212. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide the appropriate therapist with immediate notification if any of our patients appear to be in acute psychological distress.

Sincerely,



Richard C. Shelton, M.D.
Professor of Psychiatry



UNIVERSITY of LOUISVILLE
Health Sciences Center

June 30, 2006

■ DEPARTMENT OF PSYCHIATRY
AND BEHAVIORAL SCIENCE

OUTPATIENT PSYCHIATRIC SERVICES

Ambulatory Care Building
School of Medicine
University of Louisville
Louisville, Kentucky 40292

Office: 502-852-5866

Fax: 502-852-5098

Judith A. Callan, RN, MSN
Western Psychiatric Institution Clinic
3811 O'Hara Street
Pittsburgh, PA 15213

Attn: Bellefield Towers, Room 849

Dear Ms. Callan,

I am writing to confirm that the department of Psychiatry and Behavioral Sciences at the University of Louisville will participate in your research study on cognitive-behavioral therapy homework. Our Depression Center at the University of Louisville has a highly experienced group of cognitive-behavioral therapists who has strongly endorsed participation in this study.

Homework completion has been considered as a key element of cognitive-behavioral therapy; yet, little control over search has been completed on this important component of treatment. We look forward to participation in this trial.

I acknowledge that I have been informed of the study procedures and agree to them. I understand that in doing the research all parties will abide by HIPPA guidelines and informed consent procedures. Patients who are in acute psychological distress will be identified and referred for urgent evaluation and treatment.

Sincerely,

Jesse H. Wright M.D., Ph.D
Professor and Chief of Clinical Adult Psychiatry
Department of Psychiatry and Behavioral Sciences
University of Louisville School of Medicine

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

Robin B. Jarrett, Ph.D.
Professor

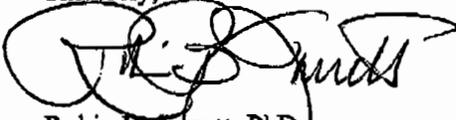
Department of Psychiatry

Judith A. Lis RN, MSN
Senior Program Coordinator
Mood Disorders Treatment Research Program
Western Psychiatric Institute and Clinic
3811 O'Hara St.
Pgh, PA. 15213

Dear Judy,

I would be pleased to participate in your dissertation research "Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale." I understand that this participation will include review and expert validation of an initial item pool. I understand that I will be asked to rule out items that do not seem appropriate. I believe research into cognitive therapy homework compliance to be a worthwhile endeavor for the field.

Sincerely,



Robin B. Jarrett, PhD
Professor of Psychiatry



**155 N. Craig Street, Suite 170
Pittsburgh, PA 15213
412 687-8700 / 687-9099**

August 4, 2005

Judith A. Callan RN, MSN
Doctoral Candidate
University of Pittsburgh
School of Nursing

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at my private practice, Cognitive Dynamics. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,

Robert M. Schwartz, Ph.D., Director

Lawrence M. Glanz, Ph.D., Co-director

Allegheny Mental Health Associates, P.C.

Christopher Coburn, Ph.D.
Lee Reichbaum, Ph.D.
Michael Greenwald, Ph.D.
Sander Kornblith, Ph.D.

Jay Goodman, Ph.D.
Donna Goberish, MSW
Pamela Hoopes, LSW
Thomas McHugh, MSW
Kimberly Morris, Ph.D.

August 3, 2005

Judith A. Callan, RN, MSN
Western Psychiatric Institute & Clinic
Bellefield Towers
100 N. Bellefield, Room 849
Pittsburgh, PA 15213

Dear Judy:

This letter serves as formal notice of permission to recruit subjects at various AMHA office waiting room locations. I acknowledge that we have been informed of all of the study procedures and agree to them. AMHA understands and expects that, in the conduct of this research, you will abide by all HIPPA guidelines and ethical guidelines for the protection of human subjects (American Psychological Association guidelines) and that you will provide AMHA with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,



Michael Greenwald, Ph.D.
Vice-President and Founding Partner, AMHA



University of Pittsburgh
Medical Center

Western Psychiatric Institute and Clinic

3811 O'Hara Street
Pittsburgh, PA 15213-2593

August 3, 2005

Judith A. Callan RN, MSN
Western Psychiatric Institute and Clinic
Bellefield Towers, Room 849
100 North Bellefield Ave.
Pittsburgh, PA 15213

Dear Ms. Callan:

This letter serves as formal notification of our permission to recruit subjects at Bellefield Clinic of UPMC. We acknowledge that we have been informed of all of the study procedures and agree to them. We also understand and expect that, in doing this research, you will abide by all HIPPA and UPMC guidelines and provide us with immediate notification if any of the Bellefield patients in the study appear to be in acute psychological distress.

Sincerely,

A handwritten signature in black ink that reads "John F. Cahalane PhD".

John F. Cahalane PhD
Chief, Adult Services

A handwritten signature in black ink that reads "Kelly O'Toole".

Kelly O'Toole MSW
Clinical Administrator, Adult Services

Maureen Maher-Bridge, LSW
5869 Forbes Avenue
Pittsburgh, PA 15217
Phone: 412-422-9160

August 1, 2005

Judith A. Callan RN, MSN
Doctoral Candidate
University of Pittsburgh
School of Nursing

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at my private practice located at: 5869 Forbes Avenue in Squirrel Hill. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,

A handwritten signature in black ink, appearing to read "Maureen Maher-Bridge, LSW". The signature is written in a cursive style with some overlapping letters.

Maureen Maher-Bridge, LSW

Karen L. Woodall, Ph.D.

(412) 683-6337

*155 N. Craig St., Suite 120
Pittsburgh, PA 15213*

August 2, 2005

Judith A. Callan RN, MSN
Doctoral Candidate
University of Pittsburgh
School of Nursing

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at my private practice at 155 North Craig St.; Ste 120; Pgh., PA 15213. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,



Karen L. Woodall, Ph. D.

December 31, 2006

Judith A. Callan
Doctoral Candidate
University of Pittsburgh
School of Nursing

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at my private practice located at 4716 Ellsworth Avenue. I acknowledge that I have been informed of all the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely


Carol W. Hughes LCSW

*Linda J. Ewing, Ph.D., RN
Psychologist
155 North Craig Street
Suite 120
Pittsburgh, PA 15213
Telephone: 412-683-0215*

December 21, 2005

Judith A. Callan RN, MSN
Doctoral Candidate
University of Pittsburgh
School of Nursing
Pittsburgh, PA

Dear Judy:

This letter serves as formal notification of my permission to recruit subjects at my private practice located at 155 North Craig Street, Pittsburgh, PA. I acknowledge that I have been informed of all of the study procedures and agree to them. I also understand and expect that, in doing this research, you will abide by all HIPPA guidelines and provide me with immediate notification if any of my patients appear to be in acute psychological distress.

Sincerely,

Linda J. Ewing, Ph.D.

Linda J. Ewing, Ph.D., RN
Psychologist

APPENDIX Q: Recruitment Posters

Completion of Cognitive Behavioral Therapy Homework Assignments Can Seem Difficult

Judy Callan RN MSN, a PhD student at the University of Pittsburgh, is conducting a research study at Norton Psychiatric Center to learn about the barriers that get in the way of people completing their CBT homework.

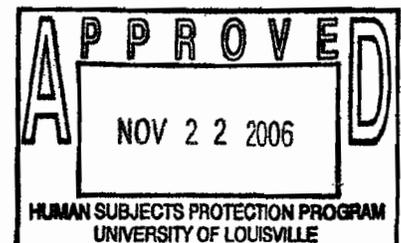
If you are 18 years or over and are receiving CBT for depression you may be eligible.

She is requesting that you fill out a few questionnaires about what gets in the way of completing CBT homework and how you're currently feeling.

YOUR PARTICIPATION IS VOLUNTARY AND WILL NOT INTERFERE WITH YOUR THERAPY IN ANY WAY. YOUR NAME WILL NOT BE RECORDED ON THESE QUESTIONNAIRES.

Participants will receive \$20.00 for participation in this research.

If interested in participating please call Judy Callan at
(412) 246-5734 or
1-888-427-1532 (toll free).



Completion of Cognitive Behavioral Therapy Homework Assignments Can Seem Difficult

Judy Callan RN MSN, a PhD student at the University of Pittsburgh, is conducting a research study to learn about the barriers that get in the way of people completing their CBT homework.

She is requesting that you fill out a few questionnaires about what gets in the way of completing CBT homework and how you're currently feeling.

YOUR PARTICIPATION IS VOLUNTARY AND
WILL NOT INTERFERE WITH YOUR THERAPY
IN ANY WAY. YOUR NAME WILL NOT BE
RECORDED ON THESE QUESTIONNAIRES.

Participants will receive \$20.00 for participation
in this research.

If interested in participating please call Judy Callan at (412) 246-5734 or Jessica Wilson at (412) 246-5767.

Completion of Cognitive Behavioral Therapy Homework Assignments Can Seem Difficult

Judy Callan RN MSN, a PhD student at the University of Pittsburgh, is conducting a research study to learn about the barriers that get in the way of people completing their CBT homework.

She is requesting that you fill out a few questionnaires about what gets in the way of completing CBT homework and how you're currently feeling.

YOUR PARTICIPATION IS VOLUNTARY AND
WILL NOT INTERFERE WITH YOUR THERAPY
IN ANY WAY. YOUR NAME WILL NOT BE
RECORDED ON THESE QUESTIONNAIRES.

Participants will receive \$20.00 for participation
in this research.

If interested in participating please call Judy
Callan at (412) 246-5734 or
1-888-427-1532 (toll free).

APPENDIX R: Phase II IRB Approval



University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1146 (fax)

MEMORANDUM:

TO: Judith A. Callan, MSN

FROM: Christopher Ryan, Ph.D., Vice Chair 

DATE: September 1, 2005

SUBJECT: IRB# 0508068: Development of a Scale: Barriers to CBT Homework Completion Scale (Phase II)

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (7).

Please note that the advertisement that was submitted for review has been approved as written.

Also note that the waiver for the requirement to obtain a written informed consent for telephone screening has been approved.

If applicable, please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: September 1, 2005
Renewal Date: August 31, 2006
University of Pittsburgh
Institutional Review Board
IRB# 0508068

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 412-383-1504 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center) and FWA00000600 (Children's Hospital of Pittsburgh).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:ky



University of Pittsburgh

School of Nursing

Office of the Dean
350 Victoria Building
3500 Victoria Street
Pittsburgh, PA 15261
Fax: 412-624-2401
www.nursing.pitt.edu

Jacqueline Dunbar-Jacob
PhD, RN, FAAN
Dean
412-624-7838
Email: dunbar@pitt.edu

August 2, 2005

Susan A. Albrecht
PhD, RN, FAAN
Associate Dean for Student/Alumni
Services and Development
412-624-2403
Email: saa01@pitt.edu

TO: IRB Committee

RE: Judith Callan, RN, MSN
Doctoral Candidate, School of Nursing

Helen K. Burns, PhD, RN
Associate Dean for Clinical
Education
412-624-6616
Email: hburnsh@pitt.edu

FROM: Jacqueline Dunbar-Jacob, PhD, RN, FAAN
Professor and Dean, School of Nursing

Janice S. Dorman, PhD
Associate Dean for Scientific
and International Affairs
412-624-8392
Email: jsd@pitt.edu

As Ms. Callan's dissertation advisor, I am writing in support of the proposed study submitted to the IRB for review by Judith Callan. Ms. Callan has completed her required course work for her doctoral degree. During her course of study she completed supervised training in Cognitive Behavioral Therapy, a component of which forms the core of her dissertation research. Ms. Callan has successfully passed her qualifying examination and dissertation proposal approval. She is ready to continue her dissertation research (Phase I of her dissertation research is completed).

Cynthia E. Allshouse, MBA, CPA
Assistant Dean for Administration
412-624-6905
Email: cea32@pitt.edu

Ms. Callan's dissertation committee, which will supervise her research, consists of:

Jacqueline Dunbar-Jacob, PhD, RN, FAAN; Professor of Nursing, Epidemiology, and Occupational Therapy at the School of Nursing. In addition to being a registered nurse I am a licensed (inactive) psychologist in the state of Pennsylvania

Susan Sereika, PhD; Associate Professor of Nursing, Epidemiology, and Biostatistics, Director, Center for Research and Evaluation, at the School of Nursing

Ellen Olshansky, PhD, RN, Professor and Chair, Health and Community Systems Department at the School of Nursing

Clement Stone, PhD; Professor and Director, Psychology in Education Program, at the School of Education

Michael Thase, MD; Professor of Psychiatry at the School of Medicine



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Judith A. Callan, RN, MSN

FROM: Christopher Ryan, PhD, Vice Chair 

DATE: September 7, 2005

SUBJECT: IRB #0307128: Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Compliance Scale

Your renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (8). **This approval is for analysis of data only.**

Approval Date: September 7, 2005

Renewal Date: September 6, 2006

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00006600 (Children's Hospital of Pittsburgh).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:dj



University of Pittsburgh
Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1508 (fax)

MEMORANDUM

TO: Judith A. Callan, RN, MSN

FROM: Christopher Ryan, PhD, Vice Chair 

DATE: March 17, 2006

SUBJECT: IRB #0508068: Development of a Scale: Barriers to CBT Homework Completion Scale

The Institutional Review Board reviewed the recent modifications to your protocol and consent form(s) and find them acceptable for expedited review. These changes, noted in your submission of February 28, 2006, are approved.

Please include the following information in the upper right-hand corner of all pages of the consent form(s), if modifications were made to the consent form(s):

Current Approval Date: September 1, 2005
Modification Approval Date: March 17, 2006
Renewal Date: August 31, 2006
University of Pittsburgh
Institutional Review Board
IRB #0508068

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00000600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

If your research proposal involves an investigational drug, please forward a copy of this approval letter along with a copy of the Cover Sheet, protocol, consent form(s) and drug brochure to Investigational Drug Service, PUH Pharmacy.

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:kh



University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
412-578-3424
Fax: 412-578-8553

July 20, 2006

**Judith Callan, PhD
UPMC/Western Psychiatric Institute and Clinic**

**SUBJECT: Permission Document, University of Louisville
 Pitt IRB #: 0508068**

Dear Dr. Callan,

Thank you for forwarding the permission document from the University of Louisville. The Pitt IRB notes that you have secured permission from the University of Louisville to enroll patient/participants and staff therapists from this location in your study: "Development of a Scale: Barriers to CBT Homework Completion Scale", IRB #: 0508068.

This permission document will be added to our file on your study.

In the future, should you arrange to conduct your study at other non-local sites, please forward a similar permission document from that site to the Pitt IRB staff.

As a reminder, your study is currently approved up until the Renewal date of August 31, 2006.

Sincerely,

A handwritten signature in cursive script, appearing to read "Chris".

**Christopher Ryan, PhD
Director,
University of Pittsburgh
Institutional Review Board**

NORTON® HEALTHCARE RESEARCH OFFICE

Beth MacCracken, CCRA, Research Director
Misty Hooper, CPA, Operations Manager
Sarah Merrill, MPH, Compliance Manager
Regina Schaefer, Research Billing Coordinator
Sharon Taylor, Research Regulatory Coordinator

Medical Towers North
233 E. Gray St., Ste 201, M-05
Louisville, KY 40202
(502) 629-3905 Fax: (502) 629-3496
NHRO@nortonhealthcare.org

12/19/06

Jesse Wright, MD, PhD
500 So. Preston Street, Ste 210A
Louisville, KY 40292

NHRO 1144/HSPPO 465.06/Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Scale

Dear Dr. Wright,

The Norton Healthcare Research Office (NHRO) is pleased to notify you that your application to conduct the above-mentioned research study in a Norton Healthcare (NHC) facility has been approved.

The following items must be submitted to the NHRO as appropriate:

- Annual Progress Report/Continuation Review form
- Annual Approval letters and current Informed Consent Forms approved by the IRB, if applicable
- Amendments and Amendment Approval letters dealing with each change in personnel, accrual goal, treatment plan or safety
- Revised HIPAA documents such as revised Partial Waivers/Complete Waivers of authorization for each change in personnel
- Changes in the Conflict of Interest status
- Status change of study, i.e. closed to enrollment, study termination etc.

To comply with HIPAA regulations:

- A copy of the Partial Waiver of Authorization must be filed with the medical record of every patient screened for the study.
- For retrospective chart reviews, a copy of the Complete Waiver of Authorization must be filed with the medical record of every patient whose chart is reviewed for the study.
- Those studies that fall under the Rule of 50 category are exempt from these requirements.

For studies utilizing an Informed Consent Form, a **signed copy of the Informed Consent Form and Research Authorization must be filed with the medical record of each subject enrolled in your study.**

The Research Patient ID form must be submitted to the NHRO each Monday & Wednesday in any week with activity. The Subject ID Form for chart reviews and registry studies must be submitted to the NHRO quarterly. For specific instructions regarding the notification of your subject enrollment at NHC, please contact Misty Hooper at 629-3480.

We look forward to the successful completion of your study. If you have any further questions or need assistance, please contact the NHRO at 629-3905.

Sincerely,



Beth MacCracken
Research Director
Norton Healthcare

Norton Hospital • Kosair Children's Hospital • Norton Audubon Hospital
Norton Southwest Hospital • Norton Suburban Hospital
Norton Immediate Care Centers



UNIVERSITY of LOUISVILLE

dare to be great

HUMAN SUBJECTS PROTECTION
PROGRAM OFFICE

University of Louisville
MedCenter One, Suite 200
501 E. Broadway
Louisville, Kentucky 40202-1798

Office: 502-852-5188
Fax: 502-852-2164

November 22, 2006

Jesse Wright, MD
(Judith Callan, RN, MSN)
Psychiatry & Behavioral Science
200 E. Chestnut St.
Louisville, KY 40202

RE: 465.06/ Development of a Scale: "Barriers to Cognitive Behavioral Therapy Homework Scale

Dear Doctor Wright:

The revised Informed Consents (2), Advertisement and HIPAA Complete Waiver of Authorization for the above referenced study has been received and contains the changes requested in our letter of 10/4/06.

This study has been reviewed by the chair of the Institutional Review Board (IRB) and approved through the Expedited Review Procedure, according to 45 CFR 46.110(b), since the research is on individual or group characteristics or behaviors.

The following items have been approved:

- Protocol, not dated
- Subject Informed Consent (Therapist Version), dated 10/30/06
- Subject Informed Consent (Patient Version), dated 10/30/06
- HIPAA Complete Waiver of Authorization
- Advertisement

This study now has final IRB approval through **11/21/2007**. The committee will be advised of this action at their next full Board meeting.

Please note that the IRB follows the principles of the Belmont Report, is in compliance with Good Clinical Practice Guidelines as defined by the U.S. Food and Drug Administration and the Department of Health and Human Services under the Code of Federal Regulations (21 CFR Parts 50 and 56; 45 CFR 46) and International Conference on Harmonization (ICH) Guidelines (Section E6).

You should complete and return the Progress Report/Continuation Request Form EIGHT weeks prior to 11/21/2007, in order to ensure that no lapse in approval occurs. Best wishes for a successful study.

Please send all inquires and electronic revised/requested items to our office email address at hsppofc@louisville.edu.

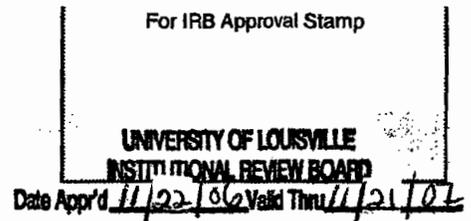
Sincerely,



Patricia K. Leitsch, Ph.D., Chair,
Social/Behavioral/Educational Institutional Review Board

PKL/crn

APPENDIX S: Phase II Consents



Subject Informed Consent Document

Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Completion Scale (Patient Version)

PRINCIPAL INVESTIGATOR:

Jesse Wright M.D., Ph.D.
Professor and Associate Chairman
Chief of Adult Psychiatry
Department of Psychiatry and Behavioral Services
200 East Chestnut Street
P.O. Box 35070
Louisville, KY 40232-5070
(502)-629-8850

CO-PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

Introduction and Background Information

You are invited to participate in a research study. Jesse Wright M.D., Ph.D., and Judith A. Callan RN, MSN are conducting the study. The study is being conducted at the University of Louisville, Department of Psychiatry and Behavioral Sciences. The study will take place at Norton Psychiatric Center. Approximately 50 to 70 subjects will be invited to participate.

Purpose

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

You have contacted the investigator after seeing a poster/flier at the mental health clinic where you receive CBT. You have been provided information from the investigator, in person or on the phone, as to the goals, procedures, risks and benefits of the study. Ample time has been allowed to answer all questions thoroughly.

Procedures

If you are agreeable, you will sign the consent document. The investigator will mail the consent to you along with a self-addressed stamped envelope for its return to the investigator. You will then sign the informed consent and mail it back to the investigator. Following your consent, your therapist will be notified of your participation in the study, as they are required to complete one questionnaire about your homework assignment completion as well.

One third of the patients will complete the questionnaires either in the beginning, the middle, or later on in their therapy. The investigator will let you know when it is time to complete the questionnaires. On the week of the first identified CBT session, you will be asked to complete 3 questionnaires that ask about your mood and general attitudes and a demographic form asking basic questions about you such as age, gender, etc. In the session following the identified CBT session, you will be asked to complete the "Barriers to CBT Homework Completion Scale." as well as the questionnaires about your mood and general attitudes. The same procedure will occur in the following session. The sessions being referenced in the ratings will be the session prior to the actual rating. You will be provided with an envelope that will be sealed so that your research questionnaires remain private. Your therapist will not view your ratings. You will then place the questionnaires in a self-addressed envelope along with your therapist's sealed rating and place them in the US mail.

Potential Risks

It is estimated that there will be minimal risks associated with your participation. Some risks that may be associated with your participation relate to confidentiality and privacy. All questionnaires, which will contain personal opinions and information related to your CBT involvement, will not have your name on them. A unique subject identifier, i.e. 001 and higher that cannot be connected back to your name will code questionnaires. There will be a research list that does connect the unique subject identifier to your name that will be kept in this study's research database that is password protected. Only the principal investigator, research assistant, and data manager will have access to this list. All data will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. There may be other circumstances that may affect your confidentiality and are listed in the confidentiality section of this document.

Other risks may include embarrassment or psychological disturbance related to discussing your difficulties in completing the CBT homework. The investigator has 26 years in the psychiatric nursing field and will be prepared to help with any of your concerns. Completion of the questionnaires will take some time out of your schedule. It is estimated that each set of questionnaires will take no more than 20 minutes to complete.

Potential Benefits

The information collected may not benefit you directly. Long-term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments.

Compensation

You will be compensated a total of \$20.00 to offset the time and effort of completing all study assessments. There will be a \$10.00 payment for the first completed assessment and then \$5 for each of the 2 assessments completed thereafter. You will not be charged for any part of your study participation. Neither will your insurance be billed for any aspect of this study.

Confidentiality

Exceptions to this strict confidentiality will be any concerns related to concerns about patient's safety. If Dr. Wright or Ms. Callan believes a patient is at risk, i.e., BDI scores are extremely high, reports suicidal ideation, or expresses serious clinical concerns, they will contact the therapist to address this concern. Normally the therapist will have no access to the patient's research data, but in safety matters related to clinical acuity, this confidentiality assurance will be violated.

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. The following may look at your research and medical records:

- The sponsor and others hired by the sponsor to oversee the research
- The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
- People who are responsible for research and HIPAA oversight at the institutions where the research is conducted
- Government agencies, such as:
 - Office for Human Research Protections (OHRP),
 - Office of Civil Rights,
- People who make sure that billing is submitted correctly.

Conflict of Interest

This study does not involve a conflict of interest.

HIPAA Research Authorization

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for protected health information (PHI). Examples of PHI are your name, address, and birth date. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this study. Your PHI cannot be used or shared without your agreement,

unless it meets one of the HIPAA exceptions. You will be asked to sign a "Research Authorization" form. This allows the use and sharing of your PHI by those listed in the "Research Authorization."

Voluntary Participation

Taking part in this study is voluntary. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

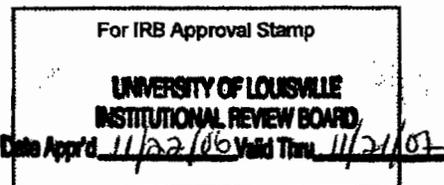
Research Subject's Rights, Questions, Concerns, and Complaints

If you have any concerns or complaints about the study or the study staff, you have three options.

You may contact the principal investigator at 502-629-8850 or the co-principal investigator at 412-624-6111

If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Human Subjects Protection Program Office (HSPPO) (502) 852-5188. You may discuss any questions about your rights as a subject, in secret, with a member of the Institutional Review Board (IRB) or the HSPPO staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

If you want to speak to a person outside the University, you may call 1-877-852-1167. You will be given the chance to talk about any questions, concerns or complaints in secret. This is a 24-hour hot line answered by people who do not work at the University of Louisville.



Subject Informed Consent Document

Development of a Scale: Barriers to Cognitive Behavioral Therapy Homework Completion Scale (Therapist Version)

PRINCIPAL INVESTIGATOR:

Jesse Wright M.D., Ph.D.
Professor and Associate Chairman
Chief of Adult Psychiatry
Department of Psychiatry and Behavioral Services
200 East Chestnut Street
P.O. Box 35070
Louisville, KY 40232-5070
(502)-629-8850

CO-PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellevue Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

Introduction and Background Information

You are invited to participate in a research study. Jesse Wright M.D., Ph.D., and Judith A. Callan RN, MSN are conducting the study. The study is being conducted at the University of Louisville, Department of Psychiatry and Behavioral Sciences. The study will take place at Norton Psychiatric Center. Approximately 50 to 70 subjects will be invited to participate.

Purpose

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

Procedures

You are being asked to participate in the study because you conduct CBT at this mental health therapy clinic/practice. An agreed upon time will be set up between you and the investigator to discuss your participation. You will meet with the investigator (in person or on the phone) to review the purposes and procedures related to the study. If you are agreeable you will either sign the consent or you have provided verbal consent on the phone and will send the signed consent that will be mailed to you along with a self-addressed stamped envelope for its return to the investigator. Ample time will be allowed to answer all questions thoroughly. If you are agreeable, you will then sign informed consent. The investigator will ask you to provide information about yourself such as your age, educational level, CBT training background, hours of supervision, etc.

There will be posters and fliers in the waiting room (or your individual office if you have previously stated this preference) inviting patients to participate. Patients will contact Dr. Wright or Ms. Callan about the study and have provided informed consent to participate in the study and to contact their therapist.

One third of the patients will complete the questionnaires in either the beginning, the middle, or later in their therapy. The investigator will let you know when it is time for the patient to complete the questionnaires. Patients will be given all of the questionnaires for the study, including the therapist questionnaires. Each study packet will have very detailed information about the procedures for completion of the questionnaires. All measurement points will have specific self-addressed stamped envelopes to send the questionnaires back to the investigator. At each measurement point, you will also be given your questionnaire to complete and will seal it in the enclosed envelope and ask the patient to place it in their self-addressed stamped envelope. On the week of the first CBT session identified (Session A), you will be asked to complete the Therapist Demographic Form. Patients will complete the Patient Demographic Form, the Beck Depression Inventory (BDI), and the Dysfunctional Attitudes Scale (DAS).

In the next CBT session (Session B), patients will be asked to complete the "Barriers to CBT Homework Completion Scale" as well as the BDI and DAS. You will also be asked to complete the "Assignment Compliance Rating Scale" (ACRS) that references the homework from the previous session. The same procedure will occur in the following session. The sessions being referenced in the ratings will be the session prior to the actual rating. All research packets will also have an associated self-addressed envelope for the patients to seal their ratings (and your sealed ratings) to retain confidentiality.

Potential Risks

All of your demographic information and ACRS ratings will be identified by your specific research identification code and not by name. There will be a research list that does connect the unique subject identifier, i.e. 001 and higher, to your name that will be kept in a research database that is password protected. The principal investigator, research assistant, and data manager will have access to this list. All data and subject information will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. Exceptions to this are listed in the confidentiality section. Completion of the questionnaires may take some time out of your schedule.

Benefits

The information collected may not benefit you directly. Long-term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of Major Depression. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

Compensation

You will not be paid for your participation in this study. There are no costs associated with participation in this study.

Confidentiality

Exceptions to this strict confidentiality will be any concerns related to concerns about patient's safety. If Dr. Wright or Ms. Callan believes a patient is at risk, i.e., BDI scores are extremely high, reports suicidal ideation, or expresses serious clinical concerns, they will contact the therapist to address this concern. Normally the therapist will have no access to the patient's research data, but in safety matters related to clinical acuity, this confidentiality assurance will be violated.

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. The following may look at your research and medical records:

- The sponsor and others hired by the sponsor to oversee the research
- The University of Louisville Institutional Review Board, Human Subjects Protection Program Office, Privacy Office and others involved in research administration at the University
- People who are responsible for research and HIPAA oversight at the institutions where the research is conducted
- Government agencies, such as:
 - Office for Human Research Protections (OHRP),
 - Office of Civil Rights,
- People who make sure that billing is submitted correctly.

Conflict of Interest

This study does not involve a conflict of interest.

HIPAA Research Authorization

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for protected health information (PHI). Examples of PHI are your name, address, and birth date. PHI may also include your medical history, results of health exams and lab tests, drugs taken and results of this study. Your PHI cannot be used or shared without your agreement, unless it meets one of the HIPAA exceptions. You will be asked to sign a "Research Authorization" form. This allows the use and sharing of your PHI by those listed in the "Research Authorization."

Voluntary Participation

Taking part in this study is voluntary. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

Research Subject's Rights, Questions, Concerns, and Complaints

If you have any concerns or complaints about the study or the study staff, you have three options.

You may contact the principal investigator at 502-629-8850 or the co-principal investigator at 412-624-6111

If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Human Subjects Protection Program Office (HSPPO) (502) 852-5188. You may discuss any questions about your rights as a subject, in secret, with a member of the Institutional Review Board (IRB) or the HSPPO staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

If you want to speak to a person outside the University, you may call 1-877-852-1167. You will be given the chance to talk about any questions, concerns or complaints in secret. This is a 24-hour hot line answered by people who do not work at the University of Louisville.

Approval Date:
University of Pittsburgh
Institutional Review Board
IRB #
Renewal Date:

**CONSENT TO PARTICIPATE AS A SUBJECT
(THERAPIST VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT) Homework Completion Scale (Phase II)

PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

STUDY SPONSOR:

None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you have received specific training in CBT and are primarily identified as being a CBT therapist. Your participation in this study will last less than 30 minutes. It is estimated that up to 18 CBT therapists from this and other mental health practices in the greater Pittsburgh area will participate in the study.

This study is supported by a seed money grant from the MHIRC Study for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of the doctoral program at the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

Subject Initials _____

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Institutional Review Board
IRB #
Renewal Date:

Purpose of the Study

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

Study Procedures

You are being asked to participate in the study because you conduct CBT at this mental health therapy clinic/practice. An agreed upon time will be set up between you and the investigator to discuss your participation. You will meet with the investigator (in person or on the phone) to review the purposes and procedures related to the study. If you are agreeable you will either sign the consent or you have provided verbal consent on the phone and will send the signed consent that will be mailed to you along with a self-addressed stamped envelope for its return to the investigator. Ample time will be allowed to answer all questions thoroughly. If you are agreeable, you will then sign informed consent. The investigator will ask you to provide information about yourself such as your age, educational level, CBT training background, hours of supervision, etc.

There will be posters and fliers in the waiting room (or your individual office if you have previously stated this preference) inviting patients to participate. Patients will contact the investigator about the study and have provided informed consent to participate in the study and to contact their therapist.

One third of the patients will complete the questionnaires in either the beginning, the middle, or later in their therapy. The investigator will let you know when it is time for the patient to complete the questionnaires. Patients will be given all of the questionnaires for the study, including the therapist questionnaires. Each study packet will have very detailed information about the procedures for completion of the questionnaires. All measurement points will have specific self-addressed stamped envelopes to send the questionnaires back to the investigator. At

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each measurement point, you will also be given your questionnaire to complete and will seal it in the enclosed envelope and ask the patient to place it in their self-addressed stamped envelope. On the week of the first CBT session identified (Session A), you will be asked to complete the Therapist Demographic Form. Patients will complete the Patient Demographic Form, the Beck Depression Inventory (BDI), and the Dysfunctional Attitudes Scale (DAS).

In the next CBT session (Session B), patients will be asked to complete the "Barriers to CBT Homework Completion Scale" as well as the BDI and DAS. You will also be asked to complete the "Assignment Compliance Rating Scale" (ACRS) that references the homework from the previous session. The same procedure will occur in the following session. The sessions being referenced in the ratings will be the session prior to the actual rating. All research packets will also have an associated self-addressed envelope for the patients to seal their ratings (and your sealed ratings) to retain confidentiality.

Subject's Risks/Benefit

All of your demographic information and ACRS ratings will be identified by your specific research identification code and not by name. There will be a research list that does connect the unique subject identifier, i.e. 001 and higher, to your name that will be kept in a research data base that is password protected. The principal investigator, research assistant, and data manager will have access to this list. All data and subject information will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. Exceptions to this are listed in the confidentiality section. Completion of the questionnaires may take some time out of your schedule.

In providing the requested information about patient completion of CBT homework, there may be an inadvertent breach of patient confidentiality. If this would occur, the investigator would remind the therapist that this particular information is not specifically authorized through patient consent.

There are no direct benefits for your participation in the study. Long term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of MDD. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

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NEW INFORMATION

You will be informed of any new significant information that may affect your willingness to participate in this research study. You will be promptly notified if any new information develops during the course of this research study that may cause you to change your mind about continuing to participate.

COSTS AND PAYMENT

You will not be paid for your participation in this study. There are no costs associated with participation in this study.

CONFIDENTIALITY

In addition to the investigator listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future professional benefits. Please be informed that you can be withdrawn from this study without your consent if you fail to follow the study procedures.

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**CONSENT TO PARTICIPATE AS A SUBJECT
(PATIENT VERSION)**

TITLE: Development of a Scale: Barriers to Cognitive Behavioral Therapy (CBT) Homework Completion Scale (Phase II)

PRINCIPAL INVESTIGATOR:

Judith A. Callan, RN, MSN
Doctoral Candidate
University of Pittsburgh School of Nursing
Program Director
Bellefield Towers
100 North Bellefield Avenue
Pittsburgh, PA 15213
(412) 246-6111 24 hour number

STUDY SPONSOR:

None

INTRODUCTION:

You are being asked to participate in a research study that is attempting to find out what things might get in the way of a patient completing their CBT homework. You are being asked to participate in this study because you are currently depressed and in CBT at this mental health clinic. Your participation in this study will last from 45 to 60 minutes (divided among 3 occasions). Up to 70 male and female patients ages 18 and older will be participating in the study.

This study is supported by a seed money grant from the MHIRC for Mood and Anxiety Disorders of the University of Pittsburgh (Western Psychiatric Institute and Clinic) and is the final requirement for completion of a doctoral dissertation in the School of Nursing. Before agreeing to participate in this research study, it is important that you read and understand this form. It describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. If you participate, you will receive a copy of this form to keep for your records.

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Purpose of the Study

The purposes of the Study are to:

- Determine the reliability of a draft questionnaire that will assess the most commonly experienced obstacles to the completion of CBT homework for depressed patients.
- Determine if the questionnaire is able to predict difficulty with homework completion and/or actual inability to complete CBT homework. It is hoped that knowledge of the barriers to completion of homework may assist the therapist to clinically intervene to assist the patient in completion.

You have contacted the investigator after seeing a poster/flier at the mental health clinic where you receive CBT. You have been provided information from the investigator, in person or on the phone, as to the goals, procedures, risks and benefits of the study. Ample time has been allowed to answer all questions thoroughly.

Study Procedures

If you are agreeable you will either sign the consent document now or you have provided verbal consent on the phone. The investigator will mail the consent to you along with a self-addressed stamped envelope for its' return to the investigator. If you are agreeable, you will then sign informed consent and mail it back to the investigator. Following your consent, your therapist will be notified of your participation in the study as they are required to complete one questionnaire about your homework assignment completion as well.

One third of the patients will complete the questionnaires either in the beginning, the middle, or later on in their therapy. The investigator will let you know when it is time to complete the questionnaires. On the week of the first identified CBT session, you will be asked to complete 3 questionnaires that ask about your mood and general attitudes and a demographic form asking basic questions about you such as age, gender, etc. In the session following the identified CBT session, you will be asked to complete the "Barriers to CBT Homework Completion Scale." as well as the questionnaires about your mood and general attitudes. The same procedure will occur in the following session. The sessions being referenced in the ratings will be the session prior to

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the actual rating. You will be provided with an envelope that will be sealed so that your research questionnaires remain private. Your therapist will not view your ratings. You will then place the questionnaires in a self addressed envelope along with your therapist's sealed rating and place them in the US mail.

Risks and Benefits

It is estimated that there will be minimal risks associated with your participation. Some risks that may be associated with your participation relate to confidentiality and privacy. All questionnaires, which will contain personal opinions and information related to your CBT involvement will not have your name on them. Questionnaires will be coded by a unique subject identifier, i.e. 001 and higher that cannot be connected back to your name. There will be a research list that does connect the unique subject identifier to your name that will be kept in this study's research data base that is password protected. Only the principal investigator, research assistant, and data manager will have access to this list. All data will be kept in a locked cabinet. Strict confidentiality will be maintained on all data collected. There may be other circumstances that may affect your confidentiality and are listed in the confidentiality section of this document.

Other risks may include embarrassment or psychological disturbance related to discussing your difficulties in completing the CBT homework. The investigator has 25 years in the psychiatric nursing field and will be prepared to help with any of your concerns. Completion of the questionnaires will take some time out of your schedule. It is estimated that each set of questionnaires will take no more than 20 minutes to complete.

Long term benefits for CBT practitioners and patients may include increased knowledge about the barriers that may interfere with completion of homework assignments. Compliance with CBT homework has been associated with improved outcome in the treatment of Major Depression. This study may assist therapists to better identify barriers to HW completion and allow appropriate therapeutic intervention

COSTS AND PAYMENT

You will receive \$20.00 to offset the time and effort of your participation in this study. You will not be charged for any part of your study participation. Neither will your insurance be billed for any aspect of this study.

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Renewal Date:

CONFIDENTIALITY

In addition to the investigator listed on the first page of this authorization (consent) form and her research staff, the following individuals may have access to identifiable information related to your participation in this research study: Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of 5 years and for as long (indefinite) as it may take to complete this research study.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. Your refusal to participate in this study will involve no penalty or loss of benefits to which you are otherwise entitled. The mental health treatment center where you receive CBT is independent from this study. You are free to refuse to participate in this study, withdraw consent and discontinue the study at any time. Such a decision on your part will not penalize or influence the availability of future mental health treatment or your relationship with your therapist. Please be informed that you can be withdrawn from this study without your consent if your therapist feels it is in your best interest, or if you fail to follow the study procedures. You are under no obligation to participate in any research study.

Subject Initials _____

APPENDIX T: Phase II Measures

Study Entry Checklist (Patient)

ID _____

Initials _____

Date: / /
m m / d d / y y

	Inclusion	Yes	No
1	DSM-IV diagnosis on Major Depression (single, recurrent, or chronic episode)		
2	Duration of episode at least 4 weeks		
3	Patient is at least 18 years of age		
4	Currently in CBT therapy		

	Exclusion	Yes	No
1	Diagnosis of bipolar disorder, schizophrenia, obsessive-compulsive disorder and substance abuse of dependence in the last 6 months		
2	Inability to read or comprehend at the 8 th grade level		

Demographics (Patient) Phase II

ID _____

Initials _____

Date: ____ / ____ / ____
 m m d d y y

Please select the response that is the most appropriate for questions 1 thru 8.

1. Gender (check one):

Male

Female

2. Age (in years): _____

3. Current Marital Status:

Never Married

Separated

Cohabiting with Partner

Divorced

Married

Widowed

4. Highest Degree Obtained (check one):

None

College Diploma

High School Diploma

Master's Degree

GED

Doctorate

Associate/Technical Degree

Medical Degree

5. Years of Education: _____

6. Estimated income:

Less than \$10,000

\$50,000 - \$74,999

\$10,000 - \$19,999

\$75,000 - \$99,999

\$20,000 - \$29,999

\$100,000 - \$149,999

\$30,000 - \$39,999

\$150,000 or more

\$40,000 - \$49,999

7. Race (check all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Refuse

**Demographics (Patient)
Phase II**

ID _____

Initials _____

Date: ____ / ____ / ____
 m m d d y y

8. Do you consider yourself Hispanic or Latino(a)?

No (Not Hispanic or Latino(a))

Yes (A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race)

Questions 9 thru 12 refer to details about your depression and current treatment. Please refer to the attached "Major Depression Education Form" regarding the diagnostic guidelines for Major Depression to answer questions 9 thru 11.

9. Age at time of first depressive episode (see criteria for Major Depression): _____

10. Estimated number of depressive episodes: _____

11. Estimated length of time of current depressive episode (in months): _____

12. Length of time in Cognitive Behavioral Therapy (in weeks): _____

**Demographics (Therapist)
Phase II**

ID _____

Initials _____

Date: / / / / /
m m d d y y

1. Gender (check one)

Male

Female

2. Age (in years): _____

3. Highest Degree Obtained (check one):

None

College Diplom

High School Diploma

Master's Degree

GED

Doctorate

Associate/Technical Degree

Medical Degree

4. Years of Education: _____

5. Type of Cognitive Behavioral Therapy (CBT) training (check one)

Introductory (1 class on CBT)

Intermediate (structured course on CBT, less than 1 year of supervision)

Advanced (extramural training at Beck Institute, greater than 1 year of supervision)

6. CBT Supervision (check one)

Yes

No

7. Estimated hours of CBT supervision: _____

8. Number of years doing CBT:

Full-time (greater than 20 hours per week) _____

Part-time (equal to or less than 20 hours per week) _____

9. Number of patients treated with CBT (lifetime):

1-20

101-150

21-40

151-200

41-60

201+

60-100

**Demographics (Therapist)
Phase II**

ID _____

Initials _____

Date: ____ / ____ / ____
m m d d y y

10. Race (check all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Refuse

11. Do you consider yourself Hispanic or Latino(a)?

No (Not Hispanic or Latino(a))

Yes (A person on Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race)

**Demographics (Patient)
Phase II**

ID _____

Initials _____

Date: ____ / ____ / ____
m m d d y y

Major Depression Educational Form

Five (or more) of the following symptoms during the same two week period and represents a change from previous functioning. At least one of the symptoms must be #1 or #2.

1. **Depressed mood** most of the day, nearly every day.
2. **Loss of interest or pleasure** in almost all or all activities most of the day nearly every day.
3. Significant **weight loss or weigh gain** or **decreased/increased appetite** nearly every day.
4. **Difficulty sleeping or sleeping too much** nearly every day.
5. Being **physically restless or slowed down** nearly every day.
6. **Fatigue or loss of energy** nearly every day.
7. Feelings of **worthlessness** or **excessive or inappropriate guilt** nearly every day.
8. **Diminished ability to concentrate or make decisions** nearly every day.
9. **Recurrent thoughts of death, suicidal thoughts, and/or suicidal actions or plans.**

DAS

ID _____

Date / /
m m d d y y

This inventory lists different attitudes or beliefs which people sometimes hold. Read EACH statement carefully and decide how much you agree or disagree with the statement.

For each of the attitudes, show your answer by placing a checkmark (✓) under the column that **BEST DESCRIBES HOW YOU THINK**. Be sure to choose only one answer for each attitude. Because people are different, there is no right or wrong answer to these statements.

To decide whether a given attitude is typical of your way of looking at things, simply keep in mind what you are like **MOST OF THE TIME**.

<u>EXAMPLE</u> ATTITUDES/BELIEFS	T O T A L L Y A G R E E (1)	A G R E E V E R Y M U C H (2)	A G R E E S L I G H T L Y (3)	N E U T R A L (4)	D I S A G R E E S L I G H T L Y (5)	D I S A G R E E V E R Y M U C H (6)	T O T A L L Y D I S A G R E E (7)
1. Most people are O.K. once you get to know them.			✓				

Look at the example above. To show how much a sentence describes your attitude, you can check any point from "totally agree" to "totally disagree." In the above example, the checkmark at "agree slightly" indicates that this statement is somewhat typical of the attitudes held by the person completing the inventory.

Remember that your answer should describe the way you think **MOST OF THE TIME**.

NOW TURN THE PAGE AND BEGIN

DAS

ID _____

Date / /
m m d d y y

ATTITUDES/BELIEFS	T O T A L L Y A G R E E (1)	A G R E E V E R Y M U C H (2)	A G R E E S L I G H T L Y (3)	N E U T R A L (4)	D I S A G R E E S L I G H T L Y (5)	D I S A G R E E V E R Y M U C H (6)	T O T A L L Y D I S A G R E E (7)
1. It is difficult to be happy unless one is good looking, intelligent, rich and creative.							
2. Happiness is more a matter of my attitude towards myself than the way other people feel about me.							
3. People will probably think less of me if I make a mistake.							
4. If I do not do well all the time, people will not respect me.							
5. Taking even a small risk is foolish because the loss is likely to be a disaster.							
6. It is possible to gain another person's respect without being especially talented at anything.							
7. I cannot be happy unless most people I know admire me.							
8. If a person asks for help, it is a sign of weakness.							
9. If I do not do as well as other people, it means I am an inferior human being.							
10. If I fail at my work, then I am a failure as a person.							
11. If you cannot do something well, there is little point in doing it at all.							

DAS

ID _____

Date / /
m m d d y y

ATTITUDES/BELIEFS	T O T A L L Y A G R E E (1)	A G R E E V E R Y M U C H (2)	A G R E E S L I G H T L Y (3)	N E U T R A L (4)	D I S A G R E E S L I G H T L Y (5)	D I S A G R E E V E R Y M U C H (6)	T O T A L L Y D I S A G R E E (7)
12. Making mistakes is fine because I can learn from them.							
13. If someone disagrees with me, it probably indicates he does not like me.							
14. If I fail partly, it is as bad as being a complete failure.							
15. If other people know what you are really like, they will think less of you.							
16. I am nothing if a person I love doesn't love me.							
17. One can get pleasure from an activity regardless of the end result.							
18. People should have a reasonable likelihood of success before undertaking anything.							
19. My value as a person depends greatly on what others think of me.							
20. If I don't set the highest standards for myself, I am likely to end up a second-rate person.							
21. If I am to be a worthwhile person, I must be truly outstanding in at least one major respect.							
22. People who have good ideas are more worthy than those who do not.							
23. I should be upset if I make a mistake.							

DAS

ID _____

Date / /
m m / d d / y y

ATTITUDES/BELIEFS	T O T A L L Y A G R E E (1)	A G R E E V E R Y M U C H (2)	A G R E E S L I G H T L Y (3)	N E U T R A L (4)	D I S A G R E E S L I G H T L Y (5)	D I S A G R E E V E R Y M U C H (6)	T O T A L L Y D I S A G R E E (7)
24. My own opinions of myself are more important than others' opinions of me.							
25. To be a good, moral, worthwhile person, I must help everyone who needs it.							
26. If I ask a question, it makes me look inferior.							
27. It is awful to be disapproved of by people important to me.							
28. If you don't have other people to lean on, you are bound to be sad.							
29. I can reach important goals without slave driving myself.							
30. It is possible for a person to be scolded and not get upset.							
31. I cannot trust other people because they might be cruel to me.							
32. If others dislike you, you cannot be happy.							
33. It is best to give up your own interests in order to please other people.							
34. My happiness depends more on other people than it does on me.							
35. I do not need the approval of other people in order to be happy.							

DAS

ID _____

Date / /
m m d d y y

ATTITUDES/BELIEFS	T O T A L L Y A G R E E (1)	A G R E E V E R Y M U C H (2)	A G R E E S L I G H T L Y (3)	N E U T R A L (4)	D I S A G R E E S L I G H T L Y (5)	D I S A G R E E V E R Y M U C H (6)	T O T A L L Y D I S A G R E E (7)
36. If a person avoids problems, the problems tend to go away.							
37. I can be happy even if I miss out on many of the good things in life.							
38. What other people think about me is very important.							
39. Being isolated from others is bound to lead to unhappiness.							
40. I can find happiness without being loved by another person.							

BDI24

ID _____

Date ____ / ____ / ____
m m d d y y

This questionnaire is about YOURSELF. On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling the PAST WEEK, INCLUDING TODAY. CIRCLE the number next to the statement you picked. If several statements in the group seem to apply equally well, circle each one. BE SURE TO READ ALL THE STATEMENTS IN ONE GROUP BEFORE MAKING YOUR CHOICE. Then move on to the next group of sentences.

1. 0 I do not feel sad.
 1 I feel sad.
 2 I am sad all the time and I can't snap out of it.
 3 I am so sad or unhappy that I can't stand it.

2. 0 I am not particularly discouraged about the future.
 1 I feel discouraged about the future.
 2 I feel I have nothing to look forward to.
 3 I feel that the future is hopeless and that things cannot improve.

3. 0 I do not feel like a failure.
 1 I feel I have failed more than the average person.
 2 As I look back on my life, all I can see is a lot of failures.
 3 I feel I am a complete failure as a person.

4. 0 I get as much satisfaction out of things as I used to.
 1 I don't enjoy things the way I used to.
 2 I don't get real satisfaction out of anything anymore.
 3 I am dissatisfied or bored with everything.

5. 0 I don't feel particularly guilty.
 1 I feel guilty a good part of the time.
 2 I feel quite guilty most of the time.
 3 I feel guilty all of the time.

6. 0 I don't feel I am being punished.
 1 I feel I may be punished.
 2 I expect to be punished.
 3 I feel I am being punished.

7. 0 I don't feel disappointed in myself.
 1 I am disappointed in myself.
 2 I am disgusted with myself.
 3 I hate myself.

BDI24

ID _____

Date / / /
m m d d y y

8. 0 I don't feel I am any worse than anybody else.
1 I am critical of myself for my weaknesses or mistakes.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.
9. 0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.
10. 0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.
11. 0 I am no more irritated now than I ever am.
1 I get annoyed or irritated more easily than I used to.
2 I feel irritated all the time now.
3 I don't get irritated at all by the things that used to irritate me.
12. 0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.
13. 0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions than before.
3 I can't make decisions at all any more.
14. 0 I don't feel I look any worse than I used to.
1 I am worried that I am looking old or unattractive.
2 I feel there are permanent changes in my appearance that make me look unattractive.
3 I believe that I look ugly.
15. 0 I can work about as well as before.
1 It takes an extra effort to get started at doing something.
2 I have to push myself very hard to do anything.
3 I can't do any work at all.
16. 0 I can sleep as well as usual.
1 I don't sleep as well as I used to.
2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3 I wake up several hours earlier than I used to and cannot get back to sleep.

BDI24

ID _____

Date / /
 m m / d d / y y

17. 0 I don't get more tired than usual.
1 I get tired more easily than I used to.
2 I get tired from doing almost anything.
3 I am too tired to do anything.
18. 0 My appetite is no worse than usual.
1 My appetite is not as good as it used to be.
2 My appetite is much worse now.
3 I have no appetite at all anymore.
19. 0 I haven't lost much weight, if any, lately.
1 I have lost more than 5 pounds.
2 I have lost more than 10 pounds.
3 I have lost more than 15 pounds.
- * I am purposely trying to lose weight by eating less.
Yes _____ No _____
20. 0 I am no more worried about my health than usual.
1 I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2 I am very worried about physical problems and it's hard to think of much else.
3 I am so worried about my physical problems, that I cannot think about anything else.
21. 0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I am much less interested in sex now.
3 I have lost interest in sex completely.
22. 0 I haven't put on much weight, if any, lately.
1 I have put on between 5-10 pounds.
2 I have put on more than 10 pounds.
23. 0 I sleep as much as or less than usual.
1 I sleep at least 1-2 hours more than usual.
2 I sleep 3 hours or more than usual.
24. 0 I am not drowsy during the day.
1 I get tired and sleepy for no reason in the middle of the day.
(around _____ o'clock)
2 I get so drowsy or fatigued in midday that I fall asleep briefly if I sit or lie down.
3 I can't control myself from napping in midday.

TOTAL

APPENDIX U: Script of Verbal Consent

Request for Consent to Phone Screen

Hello, I suppose you saw my poster in the waiting room (or flier in your therapist's office) so you know my name is Judy Callan. Thanks for calling. I'm a nurse and I'm currently in the doctoral program at the University of Pittsburgh School of Nursing. The research that was described on the poster (flier) is part of my dissertation, which is the final step before I reach receive my PhD.

The purpose of this research is to try to test a questionnaire that is hoping to help patients and CBT therapists look at some of the problems that patients have in completing their CBT homework. It's not uncommon for most patients, at some time during their CBT treatment to have these problems. I'm hoping that if the questionnaire proves useful, therapists can use the questionnaire to help their patients look at the barriers to completing their CBT homework.

What's involved with this research is the completion of some questionnaires. They will be looking at the barriers to completing CBT homework, your mood, general attitudes, and information about yourself like your marital status, educational level, etc. Altogether they should take no more than 60 minutes and will be done over 3 therapy sessions. Do you think you might be interested in participating?

{IF NO}: Thank you very much for calling.

{IF YES}: But before enrolling in the study, I need to determine if you're eligible. And so what I would like to ask you are some basic symptoms about your mood and some other symptoms when you began CBT therapy and in the past. There is a possibility that some of these questions may make you uncomfortable. I'd like you to let me know if they do and you are always free to refuse to answer if you don't want to. You also need to understand that all of the information you give me will be confidential and always kept under lock and key or in a computer that can only be accessed by a specific password. The questions I ask are only asked to determine if you are eligible for this research. Also, please remember that your participation is completely voluntary. You do not have to answer these questions if you choose not to.

Do I have your permission to ask you these questions?

APPENDIX V: Specific Items Associated with Concepts

Barriers to CBT Homework Completion Scale Concepts and the Associated Scale Items¹

Concept		Barrier Item (s)	
No.	Concept Title	No.	Item text
1	Dislike/Cynicism re: CBT model	46	The homework seemed so mechanical.
2	Psychological Readiness	1	I didn't expect therapy to include homework assignments.
		30	I didn't understand the emotions- behavior connection.
3	Oppositionality	15	I couldn't seem to take action.
		37	The word "homework" just has such a negative meaning to me.
4	Therapist Skill	58	The therapy moved too quickly.
		59	CBT therapy didn't feel very flexible.
		66	My therapist seems new at this.
		67	My therapist didn't really explain how CBT works very well.
5	Therapist Qualities	63	My therapist wasn't very flexible.
6	Avoidant Beliefs	3	Homework just reminded me that I was depressed.
		4	I wanted to avoid painful feelings.
7	Self-Efficacy/Self-Esteem	6	I was afraid of failing.
		7	I didn't feel very good about myself.
		31	I was afraid to disappoint my therapist.
		32	When I didn't do well with homework, it didn't give me confidence to do it the next time.
8	Patient-Therapist Relationship	54	I didn't trust my therapist.
		57	My therapist and I didn't have a good connection.
9	Patient Background/Demographics	20	I was never able to do too many things well in my life.
10	Non-compliance	9	I didn't want to do the homework.
		11	I wasn't in a regular pattern of doing homework.
11	Mood State	10	I felt helpless.
		12	I was overwhelmed.
		13	I was frustrated.
		14	I wasn't very motivated.
		17	I felt hopeless.
12	Cognitive Abilities/Features	2	My personal characteristics or style got in the way.
		18	I had poor concentration.
		19	I forgot.
		21	I wasn't organized.
13	CBT Task Behaviors	44	Certain homework assignments brought up painful emotions.
		45	Any assignment involving writing seemed hard.
		47	I had a hard time completing dysfunctional thought records.
14	Comorbid	24	I thought about the homework so much, I couldn't get it done.
		25	I had another clinical problem other than depression that interfered.
15	Depression Features	16	This depression's been going on so long.
		26	I was so depressed.
		27	I didn't have much energy.

Concept		Barrier Item (s)	
No.	Concept Title	No.	Item text
16	External Factors	8	Homework felt like a burden.
		29	Too much was going on in my life.
		33	I didn't have the means to do the assignment.
		34	I just had too many other responsibilities.
17	Knowledge of CBT Model	62	Homework was new to deal with in therapy.
18	Personality Characteristics	22	When I was mad or annoyed I just didn't do what I was asked.
		38	I had to do everything perfectly all of the time.
		39	I didn't want to do homework by myself.
19	Therapists Actions	60	The therapist assigned homework I couldn't do.
		61	The therapist didn't stress the importance of homework.
		64	My therapist didn't always check my homework.
		65	My therapist didn't explain the homework completely.
20	Procrastination	40	I waited until the last minute and then don't get it done.
21	Nature of Assignment	5	Doing homework didn't seem to help.
		50	Assignment was confusing.
		68	My therapist gave me assignments that took too much time to do.
		69	My therapist gave me homework that wasn't really planned around my specific needs.
		70	My therapist gave me homework that was too complicated.
22	Positive CBT Tools	23	I couldn't decide what was the most important thing to do first.
		41	I didn't have enough time in my schedule to do homework.
		48	When I didn't design it myself it was harder to do.
23	Prediction of Good Response	28	When I first started therapy if I didn't succeed with homework my confidence went down.
		42	I didn't have much support.
		43	I didn't want to change.
24	Patient Beliefs	35	I didn't believe in the CBT approach.
		36	I didn't want to do a therapy that took so much effort.
		49	I didn't really think homework was very important.

APPENDIX W: Specific Concepts Associated with Subscales

Concepts Associated with each Subscale

Subscale		Concepts	
1	Patient	2	Psychological Readiness
		3	Oppositionality
		6	Avoidant Beliefs
		7	Self-Efficacy/Self-Esteem
		9	Patient Background/Demographics
		10	Non-compliance
		11	Mood State
		12	Cognitive Abilities/Features
		13	CBT Task Behaviors
		14	Comorbid
		15	Depression Features
		16	External Factors
		17	Knowledge of CBT Model
		20	Procrastination
22	Positive CBT Tools		
23	Prediction of Good Response		
24	Patient Beliefs		
2	Therapist/Task	1	Dislike/Cynicism re: CBT Model
		4	Therapist Skill
		5	Therapist Qualities
		8	Patient-Therapist Relationship
		18	Personality Characteristics
		19	Therapists Actions
		21	Nature of Assignment

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