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Adapted Behavior Therapy for Persistently Depressed Primary Care Patients: An Open Trial

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Abstract

Major depressive disorder is commonly treated in primary care settings. Psychotherapy occurring in primary care should take advantage of the unique aspects of the setting and must adapt to the problems and limitations of the setting. In this open trial, we used a treatment development model to adapt behavior therapy for primary care patients ($n = 12$) with persistent symptoms of depression, despite antidepressant medication treatment. Ten of 12 participants completed 10 sessions of therapy over the course of 4 months, and all endorsed high levels of treatment satisfaction. Participants' depression scores declined significantly over time, and 75% of participants experienced at least 50% change on a self-report measure of depression symptoms. There were trends for social functioning, pain, and general health perceptions to improve over time. These results highlight the acceptability and feasibility of adapting behavior therapy for primary care, and support the continuation of this research.

Keywords

depression; behavior therapy; primary care

Major depressive disorder (MDD) is one of the most common conditions occurring in primary care settings, with the prevalence ranging from 6–14% (Barrett, Barrett, Oxman, & Gerber, 1988; Coyne, Fechner-Bates, & Schwenk, 1994; Simon & VonKorff, 1995). Over half of all people treated for depression are treated—often with an antidepressant—in primary care (Wang et al., 2005; Williams et al., 1999). There are different ways in which behavioral health providers may work with primary care providers to treat depressed primary care patients. Blount (2003) describes three levels of care: coordinated (not co-located, but with basic communication between mental health and primary care providers), co-located (located within the same office space, and with regular collaboration), or integrated (co-located, and with one treatment plan and a team approach to managing the patient). Research has demonstrated that co-located (e.g., Schulberg et al., 1996) and integrated (e.g., Unutzer et al., 2002) mental health care improves treatment outcomes of primary care patients with depression.

There are both theoretical and practical reasons why co-location or integration of mental health care with primary care is attractive. On a theoretical level, mental and physical health problems often co-occur and interact with each other in complex ways. A treatment team that includes both a primary care physician and a mental health professional should be best equipped to manage these complex interactions. On a practical level, many primary care patients are reluctant to see mental health professionals (Williams et al., 1999); and up to one half may refuse a referral if offered (Orleans, George, Houpt, & Brodie, 1985; Von Korff & Myers, 1987). Co-located or integrated depression treatment in primary care may reduce feelings of stigma and cause less interpersonal stress (Schulberg et al., 1993). Therefore, co-located or integrated primary care may reach many more individuals than tertiary mental health care.

For many depressed primary care patients, the first line of treatment is antidepressant medication (Williams et al., 1999). For some, this is sufficient. However, even under controlled conditions such as clinical trials, 40%-50% of patients show a non- or partial-response to initial medication strategies (Schulberg, Katon, Simon, & Rush, 1998). For those who achieve partial remission, subthreshold levels of symptoms are associated with increases in both work and family dysfunction (Judd et al., 2000) and confer a higher risk for relapse (Faravelli, Ambonetti, Pallanti, & Pazzagli, 1986; Paykel, 1998).

Combined treatment (psychotherapy + medications) may be especially appropriate and cost-effective for this group of persistently depressed patients. Although combined treatment may not be more useful than single treatments (Mynors-Wallis, Gath, Lloyd-Thomas, & Tomlinson, 1995) or cost-effective as a first-line treatment (Byford et al., 2007) for *all* depressed patients, combined treatment may be preferable for *specific* groups of depressed patients, such as those with more severe or chronic depression (Friedman et al., 2004; Keller et al., 2000). Specific to primary care, a recent study found that telephone-administered CBT that began when an antidepressant medication was prescribed was superior to antidepressant medication treatment as usual (Ludman, Simon, Tutty, & Von Korff, 2007). However, depression severity served as a moderator of treatment outcome: those with less severe depression did not show differences in outcomes between the two treatment groups. Therefore, one could argue that combined treatments should be reserved for those with depression of at least moderate severity, chronic depression, or, perhaps, individuals who do not respond to initial single treatment strategies.

To the best of our knowledge, only one study has specifically compared combined treatment (medication + CBT) to other treatment strategies in a stepped care model with primary care patients. The Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study enrolled patients from both primary care and psychiatric settings (Fava et al., 2003). Participants who did not respond to citalopram in the first step were assigned to a 2nd step treatment strategy that could include augmentation of citalopram (with another medication or CBT) or switch to another strategy (a different medication or CBT). Results from this study suggest that cognitive therapy was associated with improvement rates comparable to the medication strategies (Thase et al., 2007). However, there was not a no-treatment control group, and improvement was modest for all augmentation and switch strategies (Thase et al., 2007). CBT was not specifically adapted for primary care and therapists were not required to be co-located with the prescribing physician.

In sum, despite the fact that the majority of patients treated for depression are treated in primary care (Wang et al., 2005), there is very little information about second-line treatments for depression in this setting. Combined treatment may be an effective and cost-effective strategy after an initial trial of an antidepressant. The weekly time commitment required to participate in combined treatment may also seem more reasonable to patients who do not respond to initial treatments. Optimally, therapies that occur in primary care will take advantage of the unique aspects of the primary care setting (e.g., the opportunity to collaborate with the primary care

physician) and respond to unique demands of that setting (e.g., the need for more time-limited treatments and the need to address comorbid medical conditions).

The aim of the current study was to determine the feasibility and acceptability of combined (psychotherapy + medication) treatment for persistently depressed primary care patients. Following a stage model of treatment development (Rounsaville, Carroll, & Onken, 2001), we conducted an initial open trial of adapted behavioral therapy for primary care (ABT-PC) in patients who had been taking an antidepressant medication for at least 8 weeks and continued to experience significant depressive symptoms. We chose behavior therapy for these persistently depressed primary care patients for several reasons. First, there is reason to believe that the behavior activation component of CBT may produce equivalent results to the entire CBT package (Jacobson, Dobson, Truax, Addis, & et al., 1996), even though behavioral therapy consists of a smaller subset of CBT-related interventions (Hollon, 2001). Second, there is some preliminary evidence that behavior therapy may be effective in primary care, at least amongst a very specific sub-group (i.e., depressed primary care patients with cancer) (Hopko, Bell, Armento, Hunt, & Lejuez, 2005). Third, behavior therapy has several qualities that “fit” with the primary care setting: it can be a short-term therapy, it is easily adapted for patients with a range of psychological sophistication; the rationale is easy to explain to both patients and primary care physicians; and it is sufficiently flexible to be used to treat behavioral medicine-related problems (e.g., adherence to a medical regimen) as well as depression.

Problem-solving therapy- primary care (PST-PC) has been extensively tested as part of care management packages in primary care (Unutzer et al., 2002; Williams et al., 2000). PST-PC is a brief therapy and the primary focus is on teaching and practicing a model of problem-solving, with a very small amount of time spent on activity scheduling (Arean, Hegel, & Reynolds, 2001). Although there are some similarities between PST-PC and ABT-PC (i.e., they are both broadly focused on changing current behavior), there are also important differences. PST-PC is didactic and is conceptualized as skills training (to remediate a skills deficit that is common – but not universal- in depression), whereas ABT-PC is an ideographic approach that is less didactic and is based on establishing and using an understanding of important life goals to increase engagement in activities that are meaningful for the particular patient. Practically, PST, as has been utilized in primary care, is extremely structured and includes written homework, whereas ABT-PC is less structured and generally minimizes written homework. For these reasons, we believe that PST and ABT-PC may appeal to and be useful for different types of patients.

In the current study, we used an open trial design to examine the acceptability of ABT-PC and change in measures of depression, social and physical functioning, and physical health. We also conducted qualitative interviews with patients in order to understand their perspectives on acceptability and usefulness of adapted behavior therapy, as well as potential mechanisms of change. Although this was not an efficacy study, it represents a first step in a treatment development process occurring prior to an efficacy study.

Methods

Participants

Participants included primary care patients who were receiving treatment for depression and general health care at a large family medicine clinic. Participants were recruited through both waiting room screening for depression and via referrals from their primary care physician. Inclusion criteria were: 1) PHQ-9 score ≥ 10 , indicating clinically significant depression symptoms; 2) met criteria for major depressive disorder or dysthymia within the past year; 3) antidepressant use for at least the previous 8 weeks as prescribed by their primary care provider (PCP).¹ Exclusion criteria included: 1) current psychotherapy; 2) current significant suicidal

risk in need of emergency treatment; 3) history of bipolar disorder or psychotic symptoms outside of a mood episode; 4) psychotic symptoms within the previous year; 5) hazardous drug or alcohol use; and 6) current antisocial or borderline personality disorder.

Sixteen individuals met initial screening criteria (i.e., a PHQ-9 score ≥ 10 , current antidepressant use, and not currently in psychotherapy) and attended an in-person screening interview to determine eligibility. Of these, 12 participants were eligible and were enrolled in the study. The other four individuals were ineligible because of a history of mania or hypomania ($n = 3$) or hazardous substance use and borderline personality disorder ($n = 1$).

We enrolled 11 women and 1 man in this study. Eleven participants were white and one was Asian; none reported being Hispanic/Latino. Mean age was 48.8 ($SD = 6.8$). Five participants were married or cohabiting; 6 were divorced or separated, and 1 was widowed. Five reported completing high school only; 6 had completed some college, and 1 had completed college. Four had a yearly family income below \$25,000; four had a family income between \$25,000 and \$50,000, and the remainder reported a higher income. Two participants were employed full-time; 3 part-time; 2 unemployed, and 5 were on disability (for either medical or psychiatric reasons). Many of the participants had chronic medical problems at baseline, including heart disease ($n = 5$), diabetes ($n = 5$), chronic back pain ($n = 5$), headache ($n = 2$), and hypertension ($n = 6$). Of these 6 chronic problems, the average number of medical problems that a participant had was 2.0 ($SD = 1.0$). Additionally, two people were diagnosed with cancer during the course of the study.

Nine participants met criteria for current major depression at baseline and three did not. Of the three who did not, one was diagnosed with dysthymia, and 2 with recent past major depressive disorder in partial remission. Of the 9 participants with a current major depression, three were unable to report the date of onset. Of the remaining six participants, four had been depressed for 5 months or less. Four had too many major depressive episodes to count; of the remaining participants, the mean number of depressive episodes was 2.8 ($SD = 1.9$). Eleven of the 12 participants were taking at least a “usual dose” of an antidepressant as defined by APA guidelines (American Psychiatric Association, 2008); 4 were taking a 2nd antidepressant or augmentation agent as well. Antidepressants prescribed included: fluoxetine ($n = 2$), citalopram ($n = 4$), paroxetine ($n = 2$), sertraline ($n = 2$) and bupropion ($n = 2$). Treatment duration of current antidepressant at current dosage ranged from 3 weeks to 5 years, with 9 participants being on the current antidepressant at the current dosage (which met criteria for at least a “usual dose”) for at least 4 months. That is, the majority of participants continued to have depressive symptoms despite an adequate course of antidepressant treatment.

Procedures

Procedures were approved by the Institutional Review Boards at the authors' home institution and at the site of the primary care practice. As this was an open trial, all participants received a course of psychotherapy for 4 months. Outcome measures were assessed at pre-treatment and at post-treatment (4 months from baseline).

Measures

Demographics—Demographics were assessed pre-treatment via patient self-report and included: gender, marital status, race, Hispanic/Latino ethnicity, education, family income, work status, and age.

¹The first participant in the trial did not meet this last criteria (current antidepressant use), although she had been taking a psychotropic medication (a benzodiazepine) for more than 8 weeks.

Diagnostic assessments—The *Structured Clinical Interview for DSM-IV Axis I Disorders- Patient Version, Mood Module and Psychotic Screen* (SCID-IP; (First, Spitzer, Gibbon, & Williams, 2001)) was used to diagnose mood disorders (i.e., major depression, dysthymia, and bipolar disorders) and psychotic symptoms. The SCID-IP is a commonly used assessment tool, with established reliability and validity. The *Structured Clinical Interview for DSM-IV Axis II Disorders* (SCID II; (First, Spitzer, Gibbon, & Williams, 1997)) was used to assess the presence of antisocial personality disorder and borderline personality disorder. Only the two modules relevant to those two diagnoses were used. All SCID-IP and SCID II interviews were administered by trained research assistants and discussed with the first author. Diagnosis was arrived at by consensus. The mood module was administered pre- and post-treatment; other modules were administered pre-treatment only.

Hazardous drug and alcohol use—The *Alcohol Use Disorders Identification Test* (AUDIT) (Babor, Higgins-Biddle, Saunders, & Monteiro, 2001; Saunders, Aasland, Babor, de la Fuente, & Grant, 1993) is a 10-item self-report inventory used to determine whether someone was drinking at a potentially hazardous level. We used a standard cut-off of 8 for this determination (Babor et al., 2001). The *Drug Use Disorders Identification Test* (DUDIT) (Berman, Bergman, Palmstierna, & Schlyter, 2005) is an 11-item self report inventory that was used to determine whether a participant was experiencing drug-related problems. We used standard cut-off scores of 2 for women and 6 for men (Berman et al., 2005). These measures were administered pre-treatment.

Depression severity—The *Quick Inventory of Depression Symptoms – Clinician Rating* (QIDS)(Rush et al., 2003) was used to assess severity of depression symptoms. The QIDS is an interviewer-rated measure similar to the Hamilton Depression Rating Scale (Hamilton, 1960). An advantage of the QIDS is that it corresponds exactly to DSM-IV major depression criteria. It has been used in other clinical trials, including the STAR*D trial. The QIDS has good psychometric properties (Rush et al., 2003). Twenty percent ($n = 5$) of the interviews for this trial were coded by two raters and showed good inter-rater reliability; ICC = .98 (95% confidence interval ranged from 0.79 to 1.0). The QIDS was administered pre- and post-treatment. The *Patient Health Questionnaire* (PHQ-9) (Kroenke, Spitzer, & Williams, 2001) is a self-report instrument also used to determine depression symptom severity. This instrument corresponds to DSM-IV major depression criteria and has good psychometric properties (Kroenke et al., 2001). It was developed specifically for use in primary care settings. Cronbach's alpha for the current sample is presented in Table 1. We administered the PHQ-9 at every therapy appointment as well as pre- and post-treatment.

Functioning—The *Short Form Health Survey* (SF-36; (Ware, Snow, Kosinski, & Gandek, 1993)). The SF-36 has been used extensively in general population surveys to assess health-related quality of life. For the purposes of this study, we included the following subscales: physical functioning (SF-PF), social functioning (SF-SF), general health perceptions (SF-GHP), and pain (SF-P). Cronbach's alphas for the current sample is presented in Table 1. The SF-36 was administered pre- and post-treatment.

Patient satisfaction—The *Client Satisfaction Questionnaire-8* (CSQ-8; (Larsen, Attkisson, Hargreaves, & al., 1979)) is an 8-item scale that yields a total score that reflects client/patient satisfaction with services. Scores range from 8 to 32, with 32 indicating high satisfaction. This scale has been used in mental health and other health centers, and has acceptable psychometric properties (Nguyen, Attkisson, & Stegner, 1983). The CSQ-8 was administered post-treatment.

Qualitative Interviews—A research assistant (RA) was trained to conduct qualitative interview post-treatment in order to elicit patients' views of ABT-PC. The RA asked a pre-

determined list of questions about the participants' reactions to counseling received. Please see Table 2 for a list of the specific questions used. The RA was trained to probe with further open-ended questions whenever responses were unclear. Interviews lasted approximately 15 minutes.

Current health problems—We derived a list of current health problems at the pre-treatment timepoint from the problem list in the electronic medical record.

Antidepressant use—The *Treatment Response to Antidepressant Questionnaire* (TRAQ; (Posternak & Zimmerman, in press)) was used to record antidepressant medication usage at pre-treatment. The TRAQ is a brief interview that asks about specific medications used, dates of their use, dosage, adherence to prescribed dosage, and perception of response to the medication.

Treatment

In the current study, behavior therapy was adapted to make it more appropriate for individuals with persistent depression in a family medicine primary care setting, and to take advantage of the opportunities for clinical collaboration with the primary care physicians. Adapted Behavior Therapy – Primary Care (ABT-PC) uses principles of modern behavior activation therapies (Lejuez, Hopko, & Hopko, 2001; Martell, Addis, & Jacobson, 2001), including: 1) a significant emphasis on helping patients to identify important and meaningful long-term life goals that then guide the choice of weekly behavioral goals (Lejuez, Hopko, & Hopko, 2001); and 2) therapists modeling acceptance of primary emotions, and, as described by Martell and colleagues (2001), not “engage[ing] in clients' struggles to rid themselves of feelings at any cost” (p.93). ABT-PC is perhaps more similar to behavior activation as described by Lejuez, Hopko, & Hopko (2001), as the primary emphasis of the intervention is on increasing approach behaviors. Because avoidance behavior is often incompatible with approach behaviors, avoidance behaviors should decrease; however, this is not emphasized as it is by Martell, Addis, & Jacobson (2001). Explicit cognitive interventions (such as cognitive restructuring, the use of thought records, or identification of core beliefs) were not included. However, we do note that we expected that cognitive change might occur in concert with behavior change or as a result of behavioral change (Hollon, 2001).

ABT-PC also includes several elements that we believe to be consistent with behavior therapy and important for the context of primary care. First, all sessions took place in the primary care clinic and psychotherapy notes were part of the patient's medical record. Second, we worked closely with primary care physicians in an informal manner (i.e., through use of a shared medical record as well as brief consultations), particularly with regard to behavior change related to medical issues and antidepressant medication management. Third, similar to other models that integrate mental health specialists into primary care settings (Hegel et al., 2002; Tutty, Ludman, & Simon, 2005), we monitored antidepressant medication use; we also attempted to activate patients to discuss medication use with their physician. Fourth, we included an explicit emphasis on behavior change related to physical health issues. Fifth, similar to other models of therapy in primary care (Hegel et al., 2002; Tutty et al., 2005), we provided fewer sessions than are often provided in trials conducted in tertiary care settings (Dimidjian et al., 2006). Sixth, consistent with the “culture” of family medicine (Campbell, McDaniel, & Cole-Kelly, 2003), we invited patients to include family members in sessions as they saw fit; the goal was to have a family member attend at least one session. Family members could attend one session or multiple sessions if their attendance felt supportive to the patient. The goal of the family member attending the session was to de-mystify the therapy process, and engage the family member in assisting patients' progress toward goals whenever possible. The family member was conceptualized as a “coach” or “support person,” not as a patient, and

techniques that focused on the family system rather than the individual patient (e.g., analyzing family members' patterns of interaction or teaching communication skills to all family members) were not utilized.

Structure of sessions—ABT-PC is described in a treatment manual. ABT-PC included 10 sessions over the course of 4 months. The goal is to meet more frequently (i.e., weekly) during the first 4-6 weeks of treatment, and biweekly thereafter. However, there is no set schedule. This type of flexibility is very important in the primary care setting, as participants frequently cancel and reschedule appointments, in part due to issues such as the necessity of managing numerous medical problems and also practical barriers such as transportation.

The initial two sessions consisted primarily of discussion of any barriers to psychotherapy, orientation to treatment, assessment, and long-term goal determination. As part of the orientation to treatment, participants were introduced to the idea of behaving in accordance with important life goals despite the fact that they might be feeling depressed (or experiencing other negative emotions). We presented a visual model showing how depressive feelings and not participating in valued activities were inter-related, and suggested that, rather than waiting for depressive feelings to resolve before participating in valued activities, they might try to change behavior first. We then assisted participants in determining what their long-term life goals were meaningful and important to them, and helped to make these as concrete as possible. Therapists always made sure to include health-related goals (e.g., checking sugar levels regularly for a diabetic patient) as part of the discussion, although patients were free to choose which goals they wanted to work toward. Therapists assisted patients with choosing the 3-4 most important long-term life goals on which to begin. During this initial time period, the therapist also spoke with the physician, briefly describing the intervention, asking for their input on any health-related (or other) goals, and, if relevant, getting the physician perspective on any health issues.

The following 8 sessions were similar in structure to each other. Please see Table 3 for an outline of the session structure. Sessions began with a depression assessment (the PHQ-9) and a brief review of the week. During this review, therapists made efforts to point out and reinforce any instances in which the patients took informal active steps towards long-term goals or acted in line with important goals despite experiencing a negative mood.

Second, the therapist checked with the participant on their use of antidepressant medications, any health problems, and any visits to the PCP since the previous session. Therapists always encouraged adherence to the medication regimen as prescribed, and conducted informal problem-solving with the patient if that was not occurring. Therapists always encouraged (and provided suggestions for, if needed) open communication between the patient and the PCP. For example, if the patient did not think that the antidepressant medication was helping, the therapist encouraged them to schedule an appointment to discuss that issue with their physician. Therapists might also help patients formulate questions for their physician regarding physical health issues. Therapists would then also provide physicians with feedback about issues that the patient might be unclear about.

The body of the session was spent reviewing goals from the previous week and setting new concrete short-term weekly goals that were in line with the participant's long-term life goals. The patient's self-reported long-term life goals were used to motivate patients to work on the weekly goals. As a motivational strategy, therapists would frequently ask: "Why is this goal important to you? Why would you want to do this?" We hoped that repeated pairing the short-term goals with valued long-term goals would serve to increase the reinforcement values of the short-term goals. Long-term life goals could be revised or adjusted at any session,

depending on what was most important and relevant for the patient to be working on at that time.

Finally, in order to end the session, the therapist asked the patient for feedback on and reactions to the conversation occurring at that session.

The final three sessions followed the same format, although they also included a discussion of relapse prevention, including a listing of most important lessons learned in therapy and of goals which the patient wanted to continue to work towards.

As mentioned above, the patient and therapist might decide to have family members attend one or more sessions. Sessions including family members followed the same basic format, with the patient being asked to explain the rationale for different components of therapy or patient goals to the family member.

Therapists always contacted the PCP at the beginning and end of treatment, and PCPs were kept apprised of patient progress through the use of the shared medical record. Additional contacts with the PCP were made whenever necessary, including when a patient had difficulty with an antidepressant medication, when a patient (or therapist) thought the medication was not working, and when the patient had physical health problems that were not well-controlled and were the object of the weekly goals. For example, a therapist might consult frequently with a physician if a patient was having difficulty monitoring her/his diabetes, and adherence to a particular monitoring schedule was one of the weekly goals.

Therapists

ABT-PC was intended to be delivered by a mental health professional with training in behavioral or cognitive-behavioral therapies. The first author (LU) treated 9 of the patients; the third author (RH) treated the remaining 3. Dr. Uebelacker is a Ph.D.-level psychologist with several years of experience conducting cognitive and behavioral therapies; at the time of the study, Dr. Haggarty was a master's level graduate student in clinical psychology. Dr. Haggarty received weekly supervision from Dr. Uebelacker throughout the trial.

Data Analysis

Quantitative analysis—In order to assess change on outcome measures (PHQ-9, QIDS, and SF-36 subscales), we conducted paired samples t-tests. We also calculated effect size (Cohen's d) using procedures described by Cohen (1988). For the PHQ-9, we defined response as achieving a 50% reduction in scores pre-treatment to post-treatment, and remission as achieving a score of 4 or less post-treatment (Kroenke et al., 2001). For the QIDS, we defined response as achieving a 50% reduction in scores pre-treatment to post-treatment, and remission as achieving a score of 5 or less post-treatment; this corresponds to a score of 7 or less on the 17-item Hamilton Rating Scale for Depression (Rush et al., 2003). We conducted both intent-to-treat and completer analyses.

Qualitative analysis—Qualitative feedback from study participants can be very useful at this stage of treatment development in order to gain new insights into what is perceived to be helpful or unhelpful with a new treatment, as well as potential mechanisms of change. We used an editing organizing style (Miller & Crabtree, 1999) to analyze qualitative data provided in the post-treatment interviews. Data were available from all 12 participants. Data analysis started with transcription of the narrative data. Next, we used software designed for qualitative data analysis, Atlas.ti (Muhr & Friese, 2004), and read through interviews line by line in order to mark quotes, which we next labeled (in a description fashion), and then sorted and grouped into categories and then into larger concepts. This occurs in an iterative process; transcriptions

are read through multiple times in order to verify that categories and concepts seem to accurately reflect the data (quotes). During this process, team members specifically look for quotes that challenge previous interpretations. Both the first author (LU) and second author (RW) participated in this iterative process. Any disagreements between the two were resolved by consensus.

Results

Acceptability

Patient acceptability appeared high: only 2 patients dropped out of ABT-PC, 1 of whom left because she obtained a job (which was one of her treatment goals). The mean score on the CSQ-8 was 31 (out of a possible 32; $SD = 1.2$), indicating that all patients reported high levels of satisfaction. Five out of 12 participants invited a family member to attend at least one session. Number of sessions attended by a family member ranged from 1 to all 10, with the mean number of sessions attended being 1.6 ($SD = 3.0$).

Change Over Time

Intent-to-Treat—We assessed depression using the PHQ-9 (self-report) and the QIDS (interviewer-administered.) We found a significant decrease in both measures over time (please see Table 1). Seventy-five percent of participants showed a response using the PHQ-9 criteria, and 50% of participants showed a response using QIDS criteria. Thirty-three percent of participants achieved remission, according to either the PHQ-9 or the QIDS criteria. We also assessed presence of a current MDE at pre and post-treatment. Nine participants met criteria pre-treatment; of those, only 2 did post-treatment. One person who did not meet criteria pre-treatment did meet criteria post-treatment. We also examined pre-post changes in physical functioning, social functioning, pain, and general health perceptions as assessed by the SF-36 (see Table 1). In this small sample, there were trends for significant improvements in all but physical functioning.

Completer Analyses—When we conducted completer analyses (excluding the two participants who dropped out of treatment), results were very similar. We found statistically significant change on the PHQ-9 ($t(9) = 4.22, p < .01$) and the QIDS ($t(9) = 5.14, p < .01$) over time. Seventy percent of participants showed a response using the PHQ-9 criteria, and 50% of participants showed a response using QIDS criteria. Forty percent of participants achieved remission, according to either the PHQ-9 or the QIDS criteria. Finally, when we examined changes in physical functioning, social functioning, pain, and general health perceptions, none of the changes reached significance (t -values ranging from -1.23 to -1.69 with 5 degrees of freedom), although all were in the expected direction.

Qualitative Feedback

Behavior changes occurring during therapy—When asked what they felt to be helpful, seven participants mentioned aspects of goal-setting, including the importance of having a concrete plan, “learning to break a goal into little things instead of just one big thing,” and prioritizing goals. One person said that: “it gave me projects to do, versus just concentrate on how I felt.” Participants believed that being in therapy increased their motivation to reach goals: one participant said that, prior to therapy, “I needed a push, I knew that [a particular activity] was bad for me and causing my depression, but I couldn't move my butt off the couch.” Finally, participants also mentioned specific goals that they thought important, including getting a job, exercising, going out, socializing, increasing enjoyable activities, personal hygiene, and charting health behaviors.

Cognitive changes occurring during therapy—Although explicit cognitive interventions (e.g., cognitive restructuring) were not used in ABT-PC, many participants discussed cognitive change that occurred while in therapy. First, participants described cognitions associated with behavior change, including increased knowledge of the association between achieving goals and depression; increased self-confidence, especially in the ability to change one's own behavior; and the idea that feelings do not always have to drive decision-making or behavior (i.e., the rationale for behavioral treatment). One participant described this idea well: “One thing [the therapist] used to say, ‘If we wait to want to do something we’ll never do it.’ So on days when I didn’t want to come here and see [the therapist], I’d think, ‘I’m never going to want to see [the therapist], so get up and go do it.’” Second, participants described increased hopefulness, decreased self-criticism, and increased acceptance of one's own moods and of situations that cannot be changed. Finally, participants talked about having increased insight into or perspective on their own life.

Social changes occurring during therapy—Two participants mentioned being appreciative that their partner had attended some therapy sessions, two mentioned seeking more social support in their environment, and three talked about trying new approaches when interacting with their family.

General improvement occurring during therapy—Six participants commented that they were “feeling better” or more hopeful than they had at the start of therapy.

Primary care setting—Although there were few comments about the setting, the comments we did get were that it was comfortable and less stigmatizing seeing a behavioral health specialist in primary care, and that patients appreciated the increased communication between physician, therapist, and patient.

Counseling process—There were many comments on the qualities of the therapists. Five participants mentioned that they liked the personality of their therapist, felt comfortable discussing problems with her or him, and appreciated advice that the therapist gave them. Eight participants stated that they found it helpful to “be able to sit and talk with someone,” particularly someone who was not part of their life, and to know that they were not alone. Six participants mentioned that they would have liked more sessions; three thought that the number of sessions was just right. Two participants mentioned that it was important that they wrote things down, and one said that she liked completing the PHQ-9 each week because it gave her a sense of how her symptoms changed over time.

Difficulties—Although we explicitly asked for difficulties with therapy or aspects of therapy that participants did not like, we received relatively few comments. Two participants mentioned that it was difficult making it in to the office (one because of physical problems, one because of lack of motivation). Other difficulties cited by one participant each included: filling out questionnaires, “opening up” to the therapist, and “writing things down and setting goals.” The most serious comment was from one participant who mentioned that sometimes she felt great after leaving the session and sometimes she felt “10 times worse.” This participant was someone with fairly severe depression symptoms and a severe physical illness who did not, in fact, improve over the course of treatment. Worth noting, however, she also reported to the interviewer that she thought treatment was “great” and that she wished she could continue therapy with this particular therapist.

Discussion

Persistently depressed primary care participants appeared to find ABT-PC acceptable when it was added to their antidepressant medication regimen. Ten of 12 participants completed a full

course of treatment, and all reported being satisfied with treatment. This dropout rate was comparable to that seen in behavioral activation in a tertiary care setting (Dimidjian et al., 2006). Despite the fact that all participants had persistent depression (i.e., 11/12 had been taking an antidepressant at baseline; 9/12 had been taking that medication for at least 4 months), and many patients had significant physical health problems, a substantial percentage improved during the time that they were in treatment. We did observe improvements not only in depression symptoms, but also in social functioning, pain, and general health perceptions.

Because we did not have a control group in this preliminary study, we cannot attribute changes occurring during treatment to treatment itself. However, it is informative to compare our results to those published in previous research. Probably the best comparison sample is that of STAR*D, which was also a stepped-care trial, albeit a randomized controlled trial with a more carefully controlled medication regimen (although we note that all but 1 of the participants in the current trial were taking at least a “usual dose” of antidepressant medications.) In STAR*D, the group of participants who received CBT in addition to medication in the 2nd step of this trial had a response rate (50% change in QIDS-SR score) of 35% (Thase et al., 2007). Therefore, the response rate of 50% (for the QIDS) or 75% (for the PHQ-9) in the current trial appears to be reasonable, keeping in mind that non-randomized trials such as the current study may yield larger estimates of effect size than randomized trials (Ioannidis et al., 2001). Due to the lack of a control group in the current trial, and the fact that all 2nd step participants in STAR*D received either an augmentation of or switch away from the initial treatment strategy, it is unknown what the response rate would be in a control group that did not have a switch or augmentation (i.e., they simply continued the 1st step psychopharmacological treatment).

The qualitative data analysis provided the research team with the patients' perspectives on several issues. First, the feedback suggests that participants understood and “bought” one of the central tenets of ABT-PC: to base one's behavior on important life goals rather than on current emotions. This is important in that research suggests that acceptance of the treatment rationale may contribute to success in psychotherapy (Addis & Jacobson, 2000). Second, it seems that the emphasis on behavior change as it relates to physical health was useful in this population. Not only did patients have a lot of chronic illnesses, and set goals related to physical health, but they also commented in qualitative interviews that these types of goals were important. Finally, consistent with research on therapeutic alliance (Scott & Watkins, 2004), perceptions of their relationship with the therapist appeared to be very important to participants – many commented on their bond with their therapist, and the fact that it was important to have someone to talk to. Participants' comments suggest mechanisms of change to investigate in future research, including the degree to which a participant agrees with the treatment rationale, the degree to which a participant meets her/his behavioral goals, and therapeutic alliance.

Part of this stage of the treatment development process involves refining the manual based on therapist experiences and feedback (both formal and informal) from research participants (Rounsaville et al., 2001). Because feedback was largely positive, the refinements made to the manual based on this open trial were not substantive; most involved greater description of how to accomplish certain tasks or goals (e.g., how to help a patient make an abstract goal more concrete).

Given the small sample and open nature of this trial, the conclusions that we can draw are necessarily limited. However, the data on acceptability and change in depression and other symptoms over time are encouraging, and the next step in the treatment development process (Rounsaville et al., 2001), namely, a pilot randomized clinical trial of ABT-PC with persistently depressed primary care patients, seems warranted. Given the large number of depressed individuals being treated in primary care, and the cost of providing treatment to individuals, it is imperative that we find ways to target more intensive treatment toward those depressed

primary care patients who need it. Future research on ABT-PC should also include a consideration of how this strategy may be part of a larger system of integrated primary care programs that manage the problem of depression in primary care from a population perspective.

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Table 1
Pre-Treatment and Post-Treatment Scores on Outcome Measures

	Chronbach's Alpha	Pre-Treatment		Post-Treatment		<i>t(df)</i>	<i>d</i>
		Mean	SD	Mean	SD		
PHQ-9	0.93	18.50	4.40	7.83	7.23	4.93(11)**	1.42
QIDS	N/A	14.33	3.85	8.50	6.01	3.28(11)**	0.95
SF-PF ^a	0.95	53.75	35.93	69.38	31.56	-1.36(7) [†]	0.48
SF-SF ^a	0.88	39.06	30.21	57.81	24.03	-1.98(7) [†]	0.70
SF-P ^a	0.66	42.81	22.02	55.00	18.42	-1.97(7) [†]	0.70
SF-GHP ^a	0.81	40.63	23.06	48.91	19.90	-2.20(7) [†]	0.78

Note. PHQ-9 = Patient Health Questionnaire, 9-item. QIDS = Quick Inventory of Depressive Symptoms -- Clinician Rating. SF-PF = Short-Form Health Survey, Physical Functioning subscale. SF-SF = Short Form Health Survey, Social Functioning subscale. SF-P = Short-Form Health Survey, Pain subscale. SF-GHP = Short-Form Health Survey, General Health Perceptions subscale.

^a SF-36 data were missing from 4 participants due to an administrative oversight unrelated to the participants.

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p < .01.

[†]
p < .10.

Table 2
Post-Treatment Qualitative Interview Questions

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1. In general, what did you think about the depression counseling that you received as part of this research project?
 2. What aspects of the counseling did you find beneficial?
 3. What aspects of the counseling did you find difficult or unhelpful?
 4. What did you think about the length of counseling?
 5. What did you get out of doing the counseling? Is there anything that you think about differently or do differently as a result?
-

Table 3
Session Outline (for sessions 3-10)

1	Greeting and patient completes PHQ-9
2	Set agenda
3	Mood check <ul style="list-style-type: none"> a. Review PHQ-9 b. Review any important events this week. Investigate relation between patients' active coping and mood changes.
4	Biological <ul style="list-style-type: none"> a. Assess antidepressant use, side effects, and concerns about antidepressants. b. Assess any physical health problems
5	Psychological <ul style="list-style-type: none"> a. Review goals set for previous week. b. Set short-term goals for the following week(s).
6	Other (as needed) <ul style="list-style-type: none"> a. Discussion of how to prioritize goals or make abstract goals more concrete b. (If family attends) Group discussion of how family members can best support patient as they work towards their goals c. (Sessions 8, 9, 10) End of treatment <ul style="list-style-type: none"> i. Discussion of most important lessons learned in therapy ii. List of key goals that the patient would like to continue working on
7	Wrap-up and session evaluation

Note. Amount of time spent on each item may vary from session to session.