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Combining Computerized Home-Based Treatments for Generalized Anxiety Disorder: An Attention Modification Program and Cognitive Behavioral Therapy

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Abstract

Generalized anxiety disorder (GAD) is a common and disabling condition associated with significant personal and societal costs. Although efficacious treatments exist for GAD, the majority of these individuals fail to access our most effective treatments. In the current paper, we report the results of an open trial that examined the efficacy of a computer-delivered home-based treatment program for GAD. Twenty-one individuals seeking treatment for GAD received a self-administered program over 6 weeks that comprised two components: (1) an Attention Modification Program (AMP) designed to facilitate attentional disengagement from threat-relevant stimuli and (2) brief computer-delivered cognitive and behavioral treatment modules (CCBT). Fourteen of the 21 enrolled participants (67%) completed the treatment program. Intent-to-treat and completer analyses revealed that AMP+ CCBT resulted in significant reductions in clinician- and self-rated symptoms of anxiety, worry, depression, and functional impairment. Moreover, treatment completers displayed significant reductions in attentional bias for threat from pre- to postassessment. Change in attentional bias for threat from pre-to postassessment was associated with change in worry symptoms. Finally, 79% of participants no longer met *DSM-IV* criteria for GAD at postassessment and 36% were classified as remitted (Hamilton Rating Scale for Anxiety ≤7; Rickels et al., 2006). These results suggest that computer-delivered AMP+CCBT may serve as an effective and easily accessible treatment option for individuals with GAD.

Keywords

generalized anxiety disorder; treatment; dissemination; computerized; attention

Generalized anxiety disorder (GAD) is a common and debilitating psychiatric condition associated with medical overutilization, poor perceived health, low ratings of quality of life, and impairment at work that result in a significant economic and public health impact (Ballenger et al., 2001; Hoffman, Dukes, & Wittchen, 2008; Wittchen, 2002). GAD has a high lifetime prevalence (5.7%, Kessler et al., 2005; 8.5% in primary care setting, Roy-Byrne & Wagner, 2004) and is chronic, running an unremitting and disabling course (i.e., mean duration of 20 years; Ninan, 2001). Although efficacious psychosocial and pharmacological treatments exist for GAD (for reviews see Gould et al., 2004; Gould et al., 1997; Lydiard & Monnier, 2004; Nutt et al., 2002), the majority of these individuals do not access our most effective treatments (Collins, Westra, Dozois, & Burns, 2004). Moreover, even when individuals with GAD eventually access treatment, treatment-seeking delays are

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longer for GAD relative to all other anxiety and mood disorders (i.e., 14 years from the time of onset; Kessler, Olfson, & Berglund, 1998). Considered together, the substantial delays in treatment seeking, failure to access evidence-based treatments, and overutilization of medical services results in prolonged personal and economic costs. These findings highlight the need to develop efficient and cost-effective treatments that have the potential to be widely accessible to individuals with GAD.

Although the translation of evidence-based treatments developed in tightly controlled research settings into easily accessible interventions has many challenges, two of the most common obstacles include (a) treatment fidelity and (b) acceptability of evidence-based treatment approaches to clinicians and community health organizations (Chambless et al., 1996; Hollon et al., 2002; Persons, 1995; Wilson, 1995). Accordingly, the National Institute of Mental Health (NIMH) Psychosocial Intervention Development Workgroup recommended the "development of user-friendly interventions and non-traditional delivery methods to increase access to evidence-based interventions" (Hollon et al., 2002, p. 625). Consistent with these recommendations, researchers have increasingly used computer-based technologies to facilitate transportability of empirically supported treatments into the community. These procedures have the potential to overcome many barriers to accessing traditional forms of therapy, including cost, convenience, and limited availability of evidence-based therapies in routine clinical care (Przeworski & Newman, 2006). Moreover, such interventions can be delivered systematically and reliably to large segments of the public outside of clinical settings, thereby increasing accessibility among populations that would otherwise not seek or receive adequate treatment. Computer-based interventions have similar rates of patient satisfaction, acceptability, and attrition compared to standard clinic treatment (Marks & Cavanagh, 2009; Przeworski & Newman), suggesting they may provide a feasible cost-effective alternative for individuals who may otherwise not access evidence-based treatments. Although computerized treatments may reduce treatment barriers that are common across a number of psychiatric conditions, these interventions may be particularly relevant for individuals with GAD who tend to exhibit the longest treatment-seeking delays relative to other anxiety and mood disorders (Kessler et al., 1998).

The most commonly used strategy to date involves the translation of empirically supported psychosocial strategies (e.g., cognitive and behavioral techniques, applied relaxation) into computer-delivered formats such as the internet, palmtop or desktop computers, i.e., computerized-CBT (CCBT; Andersson, 2009; Marks & Cavanagh, 2009; Newman, Erickson, Przewoski & Dzus, 2003; Proudfoot, 2004; Przeworski & Newman, 2006). More recently, our program of research (e.g., Amir, Beard, Burns and Bomyea, 2009; Amir, Weber, Beard, Bomyea, & Taylor, 2008) and others (Schmidt, Richey, Buckner, & Timpano, 2009) have adapted experimental procedures used in cognitive science to develop a computerized Attention Modification Program (AMP) designed to target central cognitive mechanisms implicated in the maintenance of anxiety (Mathews & MacLeod, 2005). In the current paper, we describe our ongoing efforts to create an integrated computer-delivered treatment program (AMP+CCBT) that can be self-administered in the home (or other community settings) for individuals suffering from GAD.

The treatment program described in the current study comprises two components: AMP and CCBT. AMP is based on cognitive theories of anxiety that propose a causal role for selective attention to threat-relevant information in the maintenance of anxiety (e.g., Mathews & MacLeod, 2005; Williams, Watts, MacLeod, & Mathews, 1997). Consistent with these theories, 25 years of research provides evidence demonstrating that patients meeting diagnostic criteria for an anxiety disorder, including GAD (see Mogg & Bradley, 2005), preferentially attend to threat-relevant stimuli over neutral stimuli when the two compete for processing resources (for a review and meta-analysis see Bar-Haim, Lamy,

Pergamin, Bakermans-Kranenburg, & van IJzendoorn, 2007). More relevant to the causality hypothesis, recent studies have demonstrated that experimentally manipulating attentional allocation in the presence of threatening information confers differential susceptibility to anxiety under stress (e.g., Amir et al., 2008; Clarke, MacLeod, & Shirazee, 2008; MacLeod, Rutherford, Campbell, Ebsworthy, & Holker, 2002).

To modify attention, individuals complete a variant of the traditional probe detection task (MacLeod, Mathews, & Tata, 1986) that guides their attention *away* from threat-relevant cues by requiring them to respond to a visual probe that consistently follows benign (nonthreat) cues (e.g., couch) when these cues compete for processing resources with threat-relevant stimuli (e.g., illness). To our knowledge, three published studies have examined the efficacy of AMP in reducing symptoms in treatment-seeking individuals meeting diagnostic criteria for an anxiety disorder; two in generalized social phobia (GSP; Amir, Beard, Burns, et al., 2009; Schmidt et al., 2009) and one in generalized anxiety disorder (GAD; Amir, Beard, Burns, & Bomyea, 2009). All three studies were randomized placebo-controlled double-blind trials. The placebo group (Attention Control Condition, ACC) was identical to AMP except that the probe replaced the threatening and neutral stimuli with equal frequency. Participants completed AMP or ACC twice weekly for 4 weeks. Each training session was approximately 20 minutes in duration.

Across the three RCTs, AMP participants exhibited significantly larger reductions in clinician- and self-rated symptoms of anxiety and functional impairment relative to the ACC group. The magnitude of treatment effects was within the range of those obtained for existing empirically supported cognitive and behavioral and pharmacological treatments for anxiety (Barlow, 2007). Most relevant to the current study, in a sample of 29 individuals seeking treatment for GAD (Amir, Beard, Burns, et al., 2009), participants who completed AMP displayed large pre- to postassessment changes on the primary outcome measure, the interviewer-rated Hamilton Rating Scale for Anxiety (HRSA; Hamilton, 1959; Cohen's d=1.36; see also Hazen, Vasey, & Schmidt, 2009). Moreover, a significantly larger proportion of participants in the AMP group (50%) no longer met diagnostic criteria for GAD at postassessment compared to the ACC group (13%). Finally, a mediation analysis (Mackinnon, Lockwood, Hoffman, West, & Sheets, 2002) revealed that change in attentional bias for threat accounted for the reduction in interviewer-rated anxiety from pre- to postassessment.

Although most previous studies examined the efficacy of AMP in controlled laboratory settings, AMP possesses several unique features that support its transportability from the laboratory to real-world settings. First, AMP can be implemented in a consistent, highly reliable manner across settings. Administration of AMP is straightforward, requiring little technical knowledge or the need of specialized treatment settings, suggesting that it can be easily accessed from any location where the individual has access to a computer (e.g., home or work). Moreover, standardization of treatment delivery as well as implementation by participants also reduces the likelihood of variability and potential error in application of the intervention (cf. psychosocial treatments; Persons, 1995; Wilson, 1995). Accordingly, researchers have begun testing the effects of transporting AMP into real-world environments. For example, See, MacLeod, and Bridle (2009) administered a home-based internet-delivered AMP to a group of high school students during the 2 weeks prior to a naturalistic stressor (i.e., relocating overseas for university). Students who completed AMP prior to relocation exhibited significantly greater reductions in trait anxiety scores and attenuated state anxiety responses immediately following relocation relative to a control training group. These findings suggest that administering AMP in a home-based setting may have clinical value in reducing symptoms of anxiety. To our knowledge, however, studies

have yet to examine the efficacy of a home-based AMP in individuals meeting diagnostic criteria for an anxiety disorder.

Another unique advantage of AMP is that at least one primary, theory-driven outcome, change in attentional bias for threat, is not a self-report or clinician-rated measure and therefore is less likely to be influenced by demand characteristics. Thus, although less ideal than the gold-standard randomized controlled trial (RCT), AMP lends itself very well to single-group designs (e.g., open trials) because the investigator can use change on a behavioral measure of attentional bias (i.e., change in response latency) as a measure of treatment response. Moreover, by presenting participants with a different set of stimuli during the pre- and postassessment as well as training sessions, it is possible to test the generalizability of change in attentional bias from stimuli used during training to a distinct set of GAD-related threat-relevant stimuli (Amir, Beard, Burns, et al., 2009; MacLeod, Koster, & Fox, 2009).

The second component of our program involves computer-delivered CBT. Research supports the efficacy of computer-based cognitive and behavioral treatments for anxiety (for reviews see Andersson, 2009; Andersson et al., 2007; Cuijpers et al., 2009; Marks & Cavanagh, 2009; Przeworski & Newman, 2006, Reger & Gahm, 2009). A recent meta-analysis of 19 RCTs found that computer-based treatments for individuals meeting diagnostic criteria for an anxiety disorder were superior to wait-list and placebo groups (Cohen's d=.49 – 1.14; Reger & Gahm). Moreover, clinical effects of computer-based procedures did not differ relative to treatment-as-usual (TAU) with direct therapist contact. We are aware of one published clinical trial that examined the effects of computer-delivered clinician-assisted CBT for individuals seeking treatment for GAD specifically (Titov et al., 2009). Consistent with previous studies, participants in the CBT group displayed significantly larger reductions in symptoms of worry and depression from pre- to posttreatment relative to a wait-list condition.

The goal of the current study was to test the feasibility and efficacy of a home-based, self-administered computerized treatment program for GAD that integrated AMP and basic CBT didactic modules. Individuals seeking treatment for GAD were invited to take part in an initial diagnostic intake session followed by a brief tutorial intended to orient them to the program. Participants were then provided with the computer-based program that comprised AMP and 12 brief video-delivered CBT modules. The program was designed to be completed over 6 weeks, and participants received standardized weekly email contact. Feasibility of the program was assessed through (a) treatment completion rates, (b) treatment adherence (i.e., number of modules completed), and (c) amount of weekly contact. We also examined the effects of the program on clinician- and self-rated symptoms of anxiety, depression, and functional impairment as well as behavioral assessment of attentional bias for threat and worry.

Method

PARTICIPANTS

The sample comprised 21 treatment-seeking individuals meeting the diagnostic criteria for GAD (7 men, 14 women), based on a diagnostic interview using the Structured Clinical Interview for the DSM-IV (SCID; First, Spitzer, Gibbon, & Williams, 1994). The average age of the participants was 40.9 (SD=13.5; range=19 to 60). Fifteen participants self-identified as White, three as mixed ethnicity, one as Black, one as Hawaiian/Pacific Islander, and one as other.

Participants were recruited through posted announcements in community settings, local newspapers, and web-based media (e.g., search engines, online discussion forums and groups focused on anxiety). All announcements provided a telephone contact number as well as a weblink directing prospective study applicants to an internet site that provided information about the treatment study. Potential participants completed a brief telephone screening that assessed applicants' primary complaint and severity of worry. Applicants whose primary problem was judged to be clinically significant worry and who did not meet the study exclusion criteria (listed below) were invited to participate in a clinical interview held at the research clinic. Over a 3- month period of active recruitment, we received 103 inquires regarding the program. We were able to contact 73 of these individuals and provide them with information about the study; 57 individuals completed a phone screen to assess for eligibility; 32 applicants passed the phone screening and were invited to an in-person intake interview; 26 individuals attended the in-person interview and 21 met criteria for a primary diagnosis for GAD and were entered into the study.

Participants were included in the study if they: (a) had a principal *DSM-IV* (American Psychiatric Association, 2000) Axis I diagnosis of GAD, (b) showed no evidence of suicidal intent, (c) showed no evidence of substance dependence in the past 3 months, (d) had no evidence of current or past schizophrenia, bipolar disorder, or organic mental disorder, and (e) were not currently participating in any other therapy (e.g. CBT). Six participants met criteria for a concurrent Axis I disorder. Co-occurring diagnoses included: major depressive disorder (3); generalized social phobia (2); obsessive-compulsive disorder (1); and panic disorder without agoraphobia (1). The mean duration of GAD was 30.6 years (*SD*=17.8, range 1 to 55).

MEASURES

We administered a battery of clinician-rated and self-report instruments at pre- and postassessment that included measures of anxiety, worry, depression, and functional impairment. Participants also completed a modified probe detection task (MacLeod et al., 1986) to measure attentional bias for threat and a behavioral measure of worry (Borkovec, Robinson, Pruzinsky, & DePree, 1983). Clinical interviews were conducted by two postdoctoral fellows, a doctoral-level graduate student, and the study principal investigator. Reliability training procedures followed standardized protocols used in our research clinic (see Amir, Beard, Taylor, et al., 2009 for details).

Generalized Anxiety and Worry—Our primary clinician-rated outcome measure was the Hamilton Rating Scale for Anxiety (HRSA; Hamilton, 1959), a 14-item clinician-administered scale designed to quantify the severity of anxiety symptoms across numerous domains (e.g., anxious mood, tension, insomnia, intellectual impairment, cardiovascular symptoms, respiratory symptoms, gastrointestinal symptoms). Each item is scored from 0 (*not present*) to 4. This scale demonstrates good reliability and validity (Maier, Buller, Philipp, & Heuser, 1988) and is widely used in treatment outcome studies for GAD (e.g., Rickels, Rynn, Iyengar, & Duff, 2006). Our primary self-rated outcome measure was the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger & Borkovec, 1990), a 16-item scale that assesses a core feature of GAD, namely excessive, uncontrollable worry. The PSWQ demonstrates strong psychometric properties (e.g., Molina & Borkovec, 1994) and discriminates GAD from all other anxiety disorders (Brown, Antony, & Barlow, 1992). Participants also completed the trait version of the Spielberger State Trait Anxiety Inventory (STAI-T; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983) to assess general anxious mood.

Functional Impairment—The Sheehan Disability Scale (SDS; Leon, Olfson, Portera, Farber, & Sheehan, 1997), a three-item measure designed to assess functional impairment in multiple domains (social/leisure activities, work/school, and family/daily routine), was administered by interviewers to assess current level of interference due to GAD. The SDS generally demonstrates satisfactory psychometric properties (e.g., Leon et al., 1997).

Depression—We used the clinician-administered Hamilton Rating Scale for Depression (HAM-D; Hamilton, 1960) and self-rated Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996) to assess depressed mood. The psychometric properties of both scales are supported by an extensive literature (HAM-D: Hedlund & Vieweg, 1979; Rabkin & Klein, 1987; BDI-II: Beck et al., 1996; Dozois, Dobson, & Ahnberg, 1998).

Attention Bias Assessment—To examine the effect of treatment on participants' attentional bias for threatening information, participants completed the modified probe detection task (MacLeod et al., 1986) described in Amir, Beard, Taylor, et al. (2009) at pre- and postassessment. The stimuli comprised two sets of threat-neutral word pairs (sets A and B) containing 48 word-pairs each. Threatening words were selected to reflect fears of individuals with general anxiety (e.g., illness) and were taken from previous research (MacLeod et al., 2002). Neutral words were selected to represent a common category (i.e., household items). Words were matched for length and frequency (Francis & Kucera, 1982) and participants were randomly assigned to either Set A or B. Participants were tested at preassessment using half of their respective word set (e.g., A1) and were subsequently tested at postassessment on the other half of the word set (e.g., A2). Therefore, participants did not encounter the same stimuli during the pre- and postassessment blocks.

Each trial began with a fixation cross presented in the center of the computer screen for 500 ms. The cross was then replaced by a threat-neutral word pair presented in the center of the screen, one word 3 cm above the other, for 500 ms. The words were then replaced by a probe (i.e., the letter "E" or "F") that appeared in the location of the top or bottom word. Participants were instructed to decide whether the letter was an E or an F and press the corresponding mouse button. The letter probe remained on the screen until the participants responded. We recorded response latencies to identify the probe from probe onset to the button press. After the response, there was a 500 ms interval of a blank screen before the next trial began with a fixation cross. Participants saw 288 trials—192 trials consisted of threat-neutral word pairs—comprising all combinations of Probe Type (E or F), Probe Location (top or bottom), and Threat Location (top or bottom): 2 (Probe Type)×2 (Probe Location)×2 (Threat Location)×24 Threat-Neutral Word Pairs; the other 96 trials comprised neutral-neutral word pairs. Trials were presented in a new random order to each participant. Participants were seated approximately 30 cm from the computer screen. Stimuli were presented in 12-point Arial font in black on a grey background. The computer program was written in Delphi (Embarcadero, Inc.) for this experiment. The first 10 trials were excluded from the pretraining attention bias assessment to reduce practice effects.

Behavioral Assessment—To examine the effect of treatment on a behavioral measure of worry, participants completed a worry induction procedure (Attention-Focus Task, AFT; Borkovec et al., 1983; Ruscio & Borkovec, 2004) at pre- and postassessment. The AFT is a time-sampling paradigm designed to assess thought intrusions before and after a period of experimentally induced worry. This task comprises three phases: (a) a 5-minute baseline period of breathing focus; (b) a 5-minute instructed worry period; and (c) a 5-minute post-worry period of breathing focus. Following the initial breathing focus period, participants identified their most salient current worry and were instructed to worry about this topic for 5 minutes while the experimenter left the room. During each breathing period, participants

were signaled by a computer-generated tone at four intervals to indicate whether they were: focused on their breathing, distracted by positive thoughts, negative thoughts, neutral thoughts or some other distraction. Previous research demonstrates that the frequency of negative thought intrusions during the post-worry breathing period distinguishes individuals with GAD from high worriers without GAD (Ruscio & Borkovec, 2004). Accordingly, the primary outcome in the current study was change in post-worry negative thought intrusions from before to after treatment. Participants also completed a measure of state anxiety (STAI-State; Spielberger et al., 1983) following the AFT as a measure of emotional response to worry.

TREATMENT

The treatment program comprised two components: (a) an Attention Modification Program (AMP; Amir, Beard, Burns, et al., 2009) designed to facilitate attentional disengagement from threat-relevant cues and (2) brief computer-delivered cognitive and behavioral treatment (CCBT) modules aimed at educating participants about the core concepts of CBT. The program was divided into 12 modules intended to be completed over 6 weeks (i.e., twice weekly); however, participants were free to access the program as many times as they desired as well as complete modules at their own pace. Participants were also permitted to complete the program for up to 12 weeks from the date when they received the program. Treatment was entirely computer-delivered and completed at the participant's home.

The following sequence of events occurred each time the participant accessed the program: First, participants were presented with a login screen that required them to enter a unique username and password. Upon successful login, the start-up screen for AMP appeared that presented the task instructions and start button. Following completion of a single AMP session, the program directed participants to the video interface that presented a directory of the 12 CBT modules. Participants could select among the various modules and were able to control video viewing using standard "play," "pause," "fast-forward," "rewind," and "stop" buttons. After viewing the selected CBT module, the program directed participants to a screen that allowed them to upload their recently completed session data to a secure server. Although the program was structured in a way that encouraged participants to first complete an AMP session before viewing a CBT module, they were permitted to exit out of the program at any point, thereby allowing individual flexibility in terms of program completion.

To chart participants' interactions with the program, the computer program automatically collected online (i.e., time and date-stamped) data of when a particular module was first accessed and then exited. For AMP, the program registered response latency and accuracy data for each trial, thereby allowing us to establish whether participants completed the required number of trials for a particular AMP training session. For CBT modules, the time and date stamp marked when the video/audio module was first activated and then terminated. Considered together, this data allowed us to establish whether participants completed a particular AMP or CBT module rather than whether it was simply accessed.

Attention Modification Program—The AMP comprised the probe detection paradigm described above, modified to facilitate an attentional bias away from threatening stimuli (see Amir, Beard, Burns, et al., 2009). Each AMP session comprised 288 trials: 2 (Probe Type: E or F)×2 (Probe Location: Top or Bottom)×2 (Threat Location: Top or Bottom)× 12 Threat-Neutral Word Pairs, repeated 3 times. On each trial, the probe always replaced the neutral word. Thus, although there was no specific instruction to direct attention away from the threat word, on all trials, the position of the neutral word indicated the position of the probe. Each AMP session was approximately 15 minutes in duration.

To ensure personal relevance to each participant's primary worries, the threat-relevant stimuli used in AMP were chosen *ideographically* by each participant during the preassessment interview. Participants generated a list of 24 words that were related to their specific GAD concerns and that were particularly distressing to them, rated as either −2 or −3 on a scale ranging from −3 (*very distressing*) to +3 (*very pleasant*). The interviewer reviewed the list of words generated by the participant to confirm that they were related to the target concerns identified during administration of the SCID-IV GAD module. Using the same rating scale, participants rated a preselected list of neutral words taken from previous research (Amir, Beard, Burns, et al., 2009; MacLeod et al., 2002). Twenty-four neutral words (rated as 0 or +1 on the −3 to +3 scale) were matched to the ideographically selected threat words, thereby creating one set of 24 threat-neutral word pairs used during training.

Computer-Delivered CBT Modules—We developed a series of 12 CBT modules based on previous computer-delivered programs for anxiety (Andersson, Stromgren, Strom, & Lyttkens, 2002; Carlbing, Eskelius, & Andersson, 2003; Ström, Pettersson, & Andersson, 2000; Zetterqvist, Maanmies, Ström, & Andersson, 2003). Nine modules were created to educate participants about the core concepts of CBT and were delivered by an actor via video: (a) Psychoeducation (three modules); (b) Cognitive Restructuring (two modules); (c) Exposure (two modules); (d) Breathing and Relaxation (one module); (e) Activity Scheduling (one module); and (f) Relapse Prevention (one module). The remaining three modules were audio-taped guided relaxation scripts that included standard progressive muscle relaxation techniques (Marks et al., 1998). The CBT videos were between 5 to 10 minutes in length. The audio scripts ranged from 14 to 30 minutes in duration. Participants were encouraged to complete the 12 modules in the predetermined order over the course of 6 weeks. See Table 1 for details.

MATERIALS

We provided each participant with a USB drive that included the treatment program (AMP +CCBT), program instructions (e.g., step-by-step instructions on how to open and load the program, upload their completed training module data to the internet), and weekly assignment monitoring sheets (e.g., activity scheduling log). They were also given a binder with hard copies of the program instructions and weekly handouts.

PROCEDURE

After providing written informed consent, participants completed an initial assessment session for eligibility that comprised the diagnostic intake (SCID-IV; First et al., 1994) as well as interviewer and self-report scales (described above). Eligible participants were invited to attend a second session that comprised the attentional bias assessment task (20 minutes; described above), worry induction task (15 minutes; described above), followed by an orientation to the treatment program (20 minutes). The introductory tutorial was primarily self-guided and involved a demonstration of the key components of the computer interface. Participants were provided with a binder that included instruction sheets for navigating through the program. They learned how to access and log in to the program, complete AMP training sessions, access and view CBT video and audio scripts, and upload their data to a secure server. During the tutorial, participants completed one practice AMP session and watched an introductory video that provided an overview of the program. A research assistant was available to address any questions that arose.

Following completion of the tutorial, participants were given their binder and USB to take home. Participants were encouraged to complete two sessions each week (i.e., two AMP +CCBT modules). Participants received standardized weekly contact via email or telephone by a research assistant. These weekly probes specifically inquired about any technical

difficulties that participants may have encountered with the program and did not involve any discussion about the program content itself. At the completion of the program, participants were scheduled to complete an in-person postassessment interview, including clinician- and self-report instruments and attentional bias assessment.

Results

TREATMENT COMPLETION AND UTILIZATION

Participants were classified as treatment completers if they finished at least half of the assigned treatment modules over the 12-week period. Fourteen of the 21 enrolled participants completed the treatment program (67% completion rate). Of the 7 non-completers: 4 failed to complete a single treatment module at home following the initial orientation session (2 people cited lack of time or motivation, 1 person reported the death of a family member as reasons for failure to initiate the program, 1 person could not be contacted); 2 participants reportedly attempted the program but discontinued prior to completing a single session due to computer-related difficulties (1 participant reportedly was unable to load the program onto their home computer from the USB drive and declined an invitation to return to the clinic for a new USB and tutorial; 1 participant reported problems accessing the idiographic stimulus file and uploading data to our secure server and opted to complete the treatment at our research clinic); and 1 participant withdrew from the study at the end of Week 2, reportedly because the program was not addressing the participant's primary concerns. Treatment completers did not differ from noncompleters on any demographic or clinical characteristics at baseline (all *p*s>.10).

We calculated the length of time that participants were actively engaged in the at-home program by summing the total number of days between the first and last completed treatment module. On average, participants completed the treatment program within 43 days (*SD*=17.7; range=12 to 91) or approximately 6 weeks. To assess frequency of program usage in treatment completers, we examined the total number of modules participants completed while enrolled in the program (i.e., AMP training sessions and CCBT modules). On average, participants completed 10.6 AMP sessions (*SD*=4.3, range=4 to 18) and 7.8 CCBT modules (*SD*=3.1, range=4 to 13). To assess user-friendliness of the program, we examined the amount of contact that participants had with project staff throughout the program. We divided the type of contact into three categories and report average contact *per week*: (a) positive contact (i.e., participant uploaded data or responded to our weekly probe indicating that the program was functioning well; *M*=1.4, *SD*=.7, range=.8 to 2.8); (b) contact regarding technical problems associated with the program (e.g., participant was unable to upload data to the server; *M*=.2, *SD*=.2, range=0 to .8); and (c) contact regarding general life circumstances or stresses (e.g., family member passed away and participant was required to leave town; participant relocated to a new residence; *M*=.1, *SD*=.1, range=0 to .2). The most common technical problems involved uploading data to the online server and reviewing previously seen videos. These problems were resolved by instructing the participant to update their internet browser to the most recent version and by giving additional instructions as to how to bypass training in order to review a video. Considered together, these findings suggest that the home-delivered program was user-friendly to participants and required minimal staff involvement.

EFFECT OF TREATMENT ON SYMPTOMS

We examined the impact of treatment on change in symptoms from pre- to postassessment in the sample of treatment completers (i.e., those who completed at least 5% of the modules, *n*=14) as well as the intent-to-treat sample (ITT; i.e., those accepted into the study who attended the initial orientation session, *n*=21). In the ITT sample, preassessment scores for

each measure were carried forward to postassessment for noncompleters. Within each sample, we conducted a series of repeated measures (Time: pre, postassessment) multivariate analyses of variance (MANOVAs) on groups of conceptually related measures (i.e., GAD and anxiety symptoms; depression) and a univariate ANOVA on the measure of functional impairment (SDS).[1] See Tables 2 and 3 for means and standard deviations of the completer and intent-to-treat samples, respectively.

Treatment Completer Sample—As a test of treatment effects on GAD and anxiety symptoms, the MANOVA conducted on the HRSA, PSWQ, and STAI-Trait revealed a significant main effect of Time, $F(3, 10)=14.31$, $p=.001$, $\eta_p^2=.81$. Each follow-up univariate ANOVA was also significant; HRSA, [$F(1, 13) = 39.22$, $p<.001$, $\eta_p^2=.75$]; PSWQ, [$F(1, 12) = 19.03$, $p = .001$, $\eta_p^2=.61$]; STAI-Trait, [$F(1, 12)=13.36$, $p=.003$, $\eta_p^2=.53$], which indicated that treatment was associated with significant reductions in symptoms of anxiety and worry from pre- to postassessment.

The MANOVA conducted on the measures of depression (HAMD and BDI-II) revealed a significant main effect of Time, $F(2, 11)=13.12$, $p=.001$, $\eta_p^2=.71$. The follow-up univariate ANOVAs were also significant; HAMD, [$F(1, 13)=29.46$, $p<.001$, $\eta_p^2=.69$]; BDI-II, [$F(1, 12)=8.21$, $p=.014$, $\eta_p^2=.41$], which indicated that treatment was also associated with significant reductions in symptoms of depression.

The ANOVA conducted on the SDS revealed a significant main effect of Time, $F(1, 13)=44.19$, $p<.001$, $\eta_p^2=.77$, suggesting that treatment was associated with significant reductions in functional impairment due to symptoms of GAD.

We also explored whether there was a dose response relationship by computing Pearson's correlations between the number of modules completed (i.e., AMP only, CBT only, total) and change in interview-rated HRSA. Results revealed that number of modules completed was moderately, albeit not significantly correlated with treatment response, rs=.17, .45, and .33 for number of AMP, CCBT, and total modules completed, respectively (all $p>.10$).

ITT Sample—The MANOVA conducted on the HRSA, PSWQ, and STAI-Trait revealed a significant main effect of Time, $F(3, 17)=6.41$, $p=.004$, $\eta_p^2=.53$. Each follow-up univariate ANOVA was also significant; HRSA [$F(1, 20)=20.46$, $p<.001$, $\eta_p^2=.51$]; PSWQ [$F(1, 19)=12.60$, $p=.002$, $\eta_p^2=.40$]; STAI-Trait [$F(1, 19)=9.90$, $p=.005$, $\eta_p^2=.34$]. These findings indicated that treatment was associated with significant reductions in symptoms of anxiety and worry from pre- to postassessment.

The MANOVA conducted on the measures of depression (HAMD and BDI-II) revealed a significant main effect of Time, $F(2, 18)=7.61$, $p=.004$, $\eta_p^2=.46$. The follow-up univariate ANOVAs were also significant: HAMD [$F(1, 20)=17.21$, $p<.001$, $\eta_p^2=.46$]; BDI-II [$F(1, 19) = 6.82$, $p = .017$, $\eta_p^2=.26$], which indicated that treatment was also associated with significant reductions in symptoms of depression.

[1]One participant did not complete the postassessment self-report measures. This missing data is reflected in the varying degrees of freedom in the MANOVAs and follow-up ANOVAs for the symptom measures.

The ANOVA conducted on the SDS revealed a significant main effect of Time, $F(1, 20)=21.25$, $p<.001$, $\eta_p^2=.52$, suggesting that treatment was associated with significant reductions in functional impairment due to symptoms of GAD.

EFFECT OF TREATMENT ON THE BEHAVIORAL WORRY TASK

We examined response to the behavioral worry task from pre- to postassessment in the sample of treatment completers.[2] Paired-samples *t*-tests (Time: pre-, postassessment) were conducted on (a) the number of negative thought intrusions following the post-worry period and (b) STAI-S following the worry task. Results revealed that participants experienced significantly fewer negative thought intrusions at postassessment (M=0.8, SD= 1.1) compared to preassessment (M= 1.4, SD=.9), $t(11)=3.48$, p=.005, d=.70. Participants also reported experiencing significantly less anxiety in response to the worry task at postassessment (M=38.6, SD=12.0) relative to preassessment (M=50.8, SD=8.4), $t(10)=2.61$, p=.026, d=1.45.[3]

EFFECT OF TREATMENT ON ATTENTIONAL BIAS FOR THREAT

We examined the effects of AMP + CCBT on attentional bias for threat in treatment completers.[4] First, we examined participant accuracy to correctly identify the visual probe following presentation of the word stimuli. Overall participant accuracy was high (98% preassessment; 93% postassessment).[5] Response latency data were prepared in keeping with recommendations from Ratcliff (1993). Trials with incorrect responses were removed (2.4%). Response latencies at the bottom or top 1% of the sample distribution were eliminated from analysis of the pre- and posttraining assessment tasks. Response latencies ± 3 *SD* from each participant's mean response latency were also eliminated from analysis of the pre- and posttraining assessment tasks (1.3% of remaining trials).

Next, we computed an attentional bias score using response latencies for critical trials as follows: 0.5 * (Threat Location-Bottom/Probe Location-Top+ Threat Location-Top/Probe Location-Bottom − Threat Location-Bottom/Probe Location-Bottom − Threat Location-Top/Probe Location-Top) (MacLeod & Mathews, 1988). To examine the effects of treatment on attentional bias for threat, we submitted attentional bias scores to a paired samples *t*-test (Time: pre-, postassessment). Results revealed that participants displayed a significant decrease in their attentional bias for threat from pre- to postassessment, $t(13)=2.75$, p=.02, d=.77. A one-sample *t*-test compared against a score of zero (no attentional bias) revealed that whereas participants tended to display an attentional bias toward threat at preassessment (M=8.44, SD=15.3), $t(13)=2.06$, p=.06, they no longer displayed an attentional bias at postassessment (M=−3.31, SD=14.1), $t(13)=-.88$, p=.40. We explored whether change in attentional bias for threat was associated with change on the primary outcome measures. Results revealed that decrease in attentional bias for threat from pre- to postassessment correlated significantly with the magnitude of reduction in self-reported worry on the PSWQ, $r(13)=.74$, p=.004[1], but not the HRSA, $r(14)=-.16$, p=.59.

MAINTENANCE OF TREATMENT GAINS

Follow-up self-report and interviewer data collected approximately 5 months following the postassessment (range 93 to 264 days; M=159 days, SD=24) was obtained from 11 of 14

[2]Two participants did not complete an in-person posttreatment assessment and therefore did not complete the behavioral worry task.
[3]One participant did not receive a post-worry task STAI-S.
[4]For the two participants who did not complete an in-person posttreatment assessment, we used the response latency data from their last session completed at home as the postassessment data point.
[5]Two participants displayed poor accuracy (< 80%) on the postassessment attentional bias assessment task. Thus, we used the response latency data from their last session completed at home as the postassessment data point.

treatment completers (79%). See Table 2. To examine whether the effects of AMP+CCBT were enduring, we conducted separate within-subjects MANOVAs (Time: pre, post, follow-up) on the measures of GAD symptoms (HRSA, PSWQ, STAI-T) and depression (HAM-D, BDI-II), and a within-subjects ANOVA (Time: pre, post, follow-up) on the SDS. Results revealed significant main effects of time across all measures (all $p<.01$). Simple follow-up contrasts indicated that participants displayed significant reductions on all measures of GAD symptoms, depression, and functional impairment from pre- to postassessment (all $p<.05$). The posttreatment and follow-up scores were not significantly different (all $p>.10$), which indicates that those changes were maintained at follow-up.

RESPONDER STATUS

At postassessment, 11 of the 14 treatment completers (79%) no longer met diagnostic criteria for GAD. Only one treatment completer (7%) met criteria for a concurrent Axis I disorder at postassessment compared to 5/14 (36%) at preassessment. Using a more stringent criteria to obtain remission (i.e., HRSA ≤ 7; Rickels et al., 2006), 36% (5/14) of our sample was considered remitted at posttreatment. Moreover, 55% (6/11) of participants who provided follow-up data were classified as remitted at follow-up. We also used normative data for the PSWQ from a large community sample (Gillis, Haaga, & Ford, 1995) and the procedures outlined by Jacobson and Truax (1991) to evaluate clinically significant change on the PSWQ. A participant was classified as meeting criteria for clinically significant change if (a) their posttreatment score fell within the range (mean ± two standard deviations) of the normative sample and (b) if they displayed a statistically reliable reduction in scores from pre- to postassessment using the reliable change index (Jacobson & Truax). The percentage of patients who had achieved clinically significant improvement on the PSWQ was 29% (4/14) at postassessment and 45% (5/11) at follow-up.

Discussion

The goal of the current study was to test the feasibility and efficacy of a self-administered home-based treatment program for GAD that comprised an AMP and CCBT. Fourteen of the 21 enrolled participants completed the treatment program (67% completion rate). ITT and completer analyses revealed that AMP+CCBT resulted in significant symptom reductions from pre- to postassessment across clinician-rated, self-rated, and behavioral assessments. The magnitude of treatment effects was medium to large across all measures. Moreover, 79% of patients no longer met diagnostic criteria for GAD at postassessment and 36% were considered remitted (HRSA ≤ 7; Rickels et al., 2006). Considered together, these findings suggest that AMP + CCBT may be an effective and easily accessible treatment option for individuals with GAD.

Our first aim was to test the feasibility of implementing AMP+CCBT using a home-based method of delivery. A central question when transporting a treatment developed within a tightly controlled laboratory environment to real-world settings is whether and to what extent the intervention is used by the target population. The current treatment completion rate of 67% is within the range of previous studies involving dissemination of computer-delivered minimal contact treatments for anxiety (Proudfoot, 2004). Participants on average completed nearly 11 AMP sessions and 8 CCBT modules (cf. the recommended 12 modules), although some variability in frequency of program usage was observed across individuals. These findings support the feasibility of transporting a self-administered version of AMP+CCBT into a home environment. It is notable that only one of the seven participants who discontinued treatment prematurely completed a single AMP+CCBT session at home. The remaining treatment noncompleters either failed to attempt an initial treatment session or did not complete any sessions after encountering technical problems with the program. Thus, for individuals who completed a single treatment session at home,

the majority of them remained actively engaged in the program. Future research should incorporate strategies designed to increase participant motivation and engagement at the outset of the program as well as facilitate participant interactions with the computerized method of delivery, particularly for individuals with limited computer literacy.

Because the current study is the first to transport AMP+CCBT outside of the laboratory, we intentionally maintained weekly contact with participants through standardized probes inquiring about difficulties encountered with the program. We charted the frequency and nature of participants' contact with project staff to provide a proxy for the ease of program self-administration in a home-based setting. Results revealed that the amount of weekly contact that required direct staff involvement (i.e., resolution of technical issues) was minimal, suggesting that AMP+CCBT was generally user-friendly and amenable to a self-administered format. Whereas many computer-assisted treatments involve therapist contact that includes discussion and feedback regarding the content of treatment exercises (e.g., Andersson et al., 2006; Carlbing et al., 2003), project staff in the current study comprised research assistants who only responded to queries involving technical aspects of the computer program. Future research should examine the role of contact in treatment adherence and response. For example, research suggests that structured versus on-demand contact (i.e., leaving it to the patient to contact staff when they needed help) produces differential outcomes in terms of compliance and improvement (Kenwright, Marks, Graham, Franses & Mataix-Cols, 2005). Thus, research should examine optimal contact that will produce the best response to AMP+CCBT while maintaining its cost-effectiveness.

A second aim of the current study was to test the effects of AMP+CCBT on symptom reduction. Treatment completers demonstrated significant reductions in symptoms of anxiety, worry, depression, and functional impairment from pre- to postassessment. These outcomes were consistent across measures of information processing, clinician-report, self-report, and behavioral assessments. Overall, the magnitude of treatment effects (pre- to postassessment effect sizes: HRSA, d=2.60; PSWQ, d=1.40) were comparable to those reported in controlled trials of computer-delivered CCBT (Cuijpers et al., 2009; Reger & Gahm, 2009) and AMP (Amir, Beard, Burns, et al., 2009; Amir, Beard, Taylor, et al., 2009) for anxiety disorders as well as clinician-delivered psychosocial (Borkovec & Ruscio, 2001; Gould et al., 2004) and pharmacological treatments for GAD (Rickels et al., 2006). These findings are notable, given the brevity of the intervention (i.e., 6 weeks), absence of therapist involvement, and implementation of the program outside of a controlled laboratory setting. Thus, AMP+CCBT may serve as a transportable and widely accessible treatment for individuals with GAD who are unable to or choose not to access existing treatments. One avenue for future research involves testing the utility of implementing AMP+CCBT within a stepped-care approach to treatment before more costly treatment options are explored. Moreover, identifying patient characteristics that predict response to AMP+CCBT may optimize allocation of less expensive treatment resources to those who are most likely to benefit from them (Newman, 2000).

Because the current treatment program combined AMP and CCBT, it is not possible to disentangle the unique contribution of each intervention to the observed treatment effects. Although each component has been shown to be efficacious as a stand-alone treatment for GAD (AMP, Amir, Beard, Taylor, et al., 2009; CCBT, Andersson, 2009), AMP and CCBT comprise a distinct set of procedures with different mechanisms of action and patient requirements. CCBT is a behavioral, skills-based training approach that requires conscious control and practice (i.e. top-down processing). In contrast, AMP targets a less consciously controlled mechanism of anxiety maintenance, namely attentional disengagement from threatening stimuli (i.e., bottom-up processing). Thus, by targeting top-down versus bottom-up processes, respectively, CCBT and AMP may operate through different pathways to

anxiety reduction (e.g., Bishop, 2008). One implication of this distinction is that a two-pronged approach that combines AMP and CCBT may be more effective (i.e., produce larger clinical improvement) and/or efficient (i.e., produce more rapid response to treatment; Taylor & Amir, 2010). Research is needed to examine the relative effectiveness of AMP +CCBT compared to each singular treatment alone as well as examine whether the implementation of one treatment component facilitates the change process of another treatment (e.g., Borkovec & Costello, 1993).

The current study has limitations. The most obvious limitation concerns the lack of a comparison group, which prevents controlling for the effects of history, maturation, and treatment expectancies. It is notable, however, that the current sample presented with moderate to severe symptoms of GAD and a chronic course of illness (mean duration ~ 30 years). Given that GAD rarely spontaneously remits (Ninan, 2001), it seems unlikely that nonspecific treatment or maturation effects alone would produce the observed treatment gains. Moreover, at least one of our treatment outcome measures (i.e., change in attentional bias for threat) is less susceptible to demand characteristics than self-report, which bolsters confidence in the observed treatment effects. Nonetheless, research is needed to compare AMP + CCBT to established treatments.

Another caveat is that change in attentional bias correlated with change on only one of our two primary outcome measures (i.e., PSWQ but not HRSA). Although participants displayed significant pre- to posttreatment changes on both measures, change on the PSWQ was not significantly associated with change on the HRSA, $t(13)=.16$, $p=.61$. These findings are consistent with previous research indicating that the PSWQ and HRSA display low correlations in GAD samples (e.g., −0.02; Brown et al., 1992). Moreover, Koerner, Antony, and Dugas (2010) have argued that the PSWQ provides a more sensitive assessment of core features of GAD (e.g., excessive, uncontrollable worry) compared to the HRSA. It is also possible that because interviewers were not blind to treatment status, interviewer bias may have in part accounted for the lack of significant relationship between change in attentional bias and HRSA. Future research is needed to resolve this issue. The current sample was also relatively small in size, and thus, replication in larger samples is needed. Moreover, in the absence of longer-term follow-up assessments, the longevity of treatment effects remains to be established. Future research should also examine the effects of AMP+CCBT beyond symptoms of GAD (e.g., panic, social anxiety) or on related vulnerability factors (e.g., anxiety sensitivity, distress tolerance).

The reader is also cautioned that the criterion for treatment completers (i.e., 50% completion rate) was an arguably conservative one in terms of establishing the efficacy of AMP+CCBT, but liberal in terms of establishing feasibility. We found a modest, albeit nonsignificant relationship between the number of AMP or CCBT modules completed and treatment response. Research in larger GAD samples is needed to determine the optimal dose of AMP +CCBT. In terms of establishing feasibility, our data on the actual number of AMP and CCBT modules completed likely presents a more accurate indication of treatment completion. Participants on average completed approximately three fewer CCBT modules than AMP sessions. Several explanations may account for those findings. First, the structure of the program, by requiring participants to access AMP modules before CCBT modules, may have inflated the number of AMP sessions completed relative to CCBT. Second, some participants may not have found all CCBT modules to be relevant, suggesting that a more idiographic delivery of CCBT components may be beneficial (see Carlbring et al., in press). Third, these findings may indicate that the large battery of CCBT modules was not needed. It should also be noted that although we tracked the number of times participants viewed CCBT videos, we did not assess homework completion. Doing so may have provided a more sensitive index of the extent to which participants engaged in CBT-related activities

throughout the program. These limitations notwithstanding, the current findings suggest that AMP+CCBT may be a promising treatment option for individuals who have limited access to or are otherwise unwilling to seek out currently available treatments.

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Highlights

- Many individuals diagnosed with generalized anxiety disorder (GAD) fail to access our most effective treatments.
- We examined the efficacy of a computer-delivered home-based treatment program in 21 patients with GAD.
- The 6-week program comprised an Attention Modification Program (AMP) and cognitive and behavioral treatment modules (CCBT).
- AMP+CCBT resulted in significant reductions in symptoms of anxiety, worry, depression, and functional impairment.
- Computer-delivered AMP+CCBT may serve as an effective and easily accessible treatment option for individuals with GAD.

Table 1

Summary of Computer-Delivered CBT Modules

Week	Content	Duration (minutes:seconds)
1a	Psychoeducation Part 1	9:52
1b	Psychoeducation Part 2	9:09
2a	Cognitive Components of Anxiety	6:34
2b	Physiological Behavioral Components of Anxiety	8:16
3a	Exposure Part 1	5:35
3b	Exposure Part 2	8:35
4a	Breathing and Relaxation	6:31
4b	Relaxation Script 1	30:00
5a	Relaxation Script 2	19:30
5b	Activity Scheduling and Giving Back	4:50
6a	Relaxation Script 3	14:08
6b	Review & Relapse Prevention	5:10

Table 2

Means and Standard Deviations of Symptom Measures at Pre- and Postassessment for Treatment Completers (n=14)

	Pre-Assessment	Post-Assessment	Follow-up Assessment[a]	Pre- to post-treatment d[b]
GAD and Anxiety Symptoms				
HRSA	25.0 (5.4)	10.9 (6.2)	9.5 (9.0)	2.60
PSWQ	68.2 (7.0)	58.4 (9.2)	55.7 (14.2)	1.40
STAI-Trait	61.4 (8.2)	51.5 (11.6)	48.6 (13.7)	1.19
Depressive Symptoms				
HAMD	19.1 (4.7)	9.2 (6.0)	7.5 (7.3)	2.09
BDI-II	23.4 (11.8)	14.5 (13.1)	14.7 (15.1)	0.76
Functional Impairment				
SDS	20.5 (4.3)	11.4 (6.7)	9.8 (6.8)	2.10

Note.

[a] 11 participants completed the follow-up assessment.

[b] Within group pre- to post-treatment effect sizes=[(pretreatment mean − posttreatment mean)/pretreatment standard deviation)]. GAD = Generalized Anxiety Disorder; HRSA = Hamilton Rating Scale for Anxiety; PSWQ = Penn State Worry Questionnaire; STAI = State-Trait Anxiety Inventory; HAMD = Hamilton Depression Rating Scale; BDI-II = Beck Depression Inventory – II; SDS = Sheehan Disability Scale.

Table 3

Means and Standard Deviations of Symptom Measures at Pre- and Postassessment for Intent-to-Treat Sample (n=21)

	Pre-Assessment	Post-Assessment	d^a
GAD and Anxiety Symptoms			
HRSA	24.2 (6.0)	14.8 (8.6)	1.57
PSWQ	69.2 (7.8)	62.8 (10.9)	0.82
STAI-Trait	60.5 (9.7)	54.1 (12.2)	0.66
Depressive Symptoms			
HAMD	18.7 (5.1)	12.1 (7.2)	1.29
BDI-II	24.4 (12.4)	18.6 (14.3)	0.47
Functional Impairment			
SDS	20.3 (4.3)	14.7 (7.6)	1.30

Note.

[a]Within group pre- to posttreatment effect sizes = [(pretreatment mean − posttreatment mean)/pretreatment standard deviation)]. GAD = Generalized Anxiety Disorder; HRSA = Hamilton Rating Scale for Anxiety; PSWQ = Penn State Worry Questionnaire; STAI=State-Trait Anxiety Inventory; HAMD = Hamilton Depression Rating Scale; BDI-II = Beck Depression Inventory – II; SDS = Sheehan Disability Scale.