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A Randomized Clinical Trial of Cognitive-Behavioral Therapy and Applied Relaxation for Adults With Generalized Anxiety Disorder

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Abstract

This randomized clinical trial compared cognitive-behavioral therapy (CBT), applied relaxation (AR), and wait-list control (WL) in a sample of 65 adults with a primary diagnosis of generalized anxiety disorder (GAD). The CBT condition was based on the intolerance of uncertainty model of GAD, whereas the AR condition was based on general theories of anxiety. Both manualized treatments were administered over 12 weekly 1-hour sessions. Standardized clinician ratings and self-report questionnaires were used to assess GAD and related symptoms at pretest, posttest, and at 6-, 12-, and 24-month follow-ups. At posttest, CBT was clearly superior to WL, AR was marginally superior to WL, and CBT was marginally superior to AR. Over follow-up, CBT and AR were equivalent, but only CBT led to continued improvement. Thus, direct comparisons of CBT and AR indicated that the treatments were comparable; however, comparisons of each treatment with another point of reference (either waiting list or no change over follow-up) provided greater support for the efficacy of CBT than AR.

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The diagnostic features of generalized anxiety disorder (GAD) have undergone extensive change over the past 20 years. Once thought of as a mild condition characterized by an expansive set of anxious symptoms (*DSM-III*; American Psychiatric Association [APA], 1980), GAD is now recognized as a disabling disorder typified by excessive and uncontrollable worry (*DSM-IV-TR*; APA, 2000). Accordingly, psychological treatments for GAD have evolved from those based on a general understanding of anxiety (e.g., Suinn & Richardson, 1971) to those based on a specific conceptualization of pathological worry (e.g., Roemer & Orsillo, 2007). Although it is sometimes assumed that the recently developed interventions lead to better outcomes than the earlier treatments, the data thus far have not been convincing.

Of all general anxiety-reduction strategies, applied relaxation (AR) has received the most empirical support in the treatment of GAD. In fact, AR has been identified as one of the few empirically supported treatments for GAD (see Chambless et al., 1998; Chambless & Ollendick, 2001). Given its long history and demonstrated efficacy, AR has often been compared to other anxiety-reduction strategies (see Arntz, 2003; Barlow, Rapee, & Brown, 1992; Öst & Breitholz, 2000). Taken together, the extant data clearly support the efficacy of AR for the treatment of GAD in terms of diagnostic severity, worry, anxiety, depression, and general psychopathology.

Recently developed treatments for GAD differ from earlier ones (such as AR) in that they specifically target the cognitive, behavioral, and emotional processes thought to underlie pathological worry. To our knowledge, Borkovec and Costello (1993) are the only researchers who have compared a GAD-specific form of cognitive-behavioral therapy or CBT (based on the avoidance model of worry) to AR alone. Although other trials have included GAD-specific forms of CBT and AR (e.g., Borkovec, Newman, Pincus, & Lytle, 2002), these trials have combined AR with other treatment strategies such as self-control desensitization. Thus, only the Borkovec and Costello study allows for a direct comparison of GAD-specific CBT and AR. Overall, the results show that CBT and AR were equivalent at posttreatment and that both conditions led to the maintenance of treatment gains, with some evidence of further gains in CBT.

Like Borkovec and others (e.g., Roemer & Orsillo, 2007; Wells, 2006), our group has developed a treatment for GAD that is based on a conceptualization of pathological worry. Namely, our cognitive model posits that intolerance of uncertainty (a dispositional characteristic resulting from negative beliefs about uncertainty and its implications) plays a central role in the etiology of GAD by leading to biased cognitive processing. The model also underscores the role of positive beliefs about worry, negative problem orientation, and cognitive avoidance (see Dugas & Koerner, 2005, for a review). Accordingly, our treatment targets the aforementioned cognitive factors and ultimately attempts to aid individuals with GAD to develop beliefs about uncertainty that are less negative, rigid, and pervasive. To date, the treatment has been tested in three randomized clinical trials. The first study (Ladouceur et al., 2000) revealed that the CBT protocol was superior to a wait-list control condition on all outcomes. More importantly, the short- and long-term outcomes were at least as good as the best outcomes reported in the treatment literature for GAD (for reviews, see Covin, Ouimet, Seeds, & Dozois, 2008; Gould, Safren, O'Neill, & Otto, 2004). The

second study (Dugas et al., 2003) compared the treatment delivered in a group format to wait-list control. Although the findings were similar to those obtained in the first trial, one important difference emerged: not only were treatment gains maintained over the follow-up period, level of worry *decreased* from posttreatment to 24-month follow-up. Finally, the third study (Gosselin, Ladouceur, Morin, Dugas, & Baillargeon, 2006) contrasted the treatment to nondirective therapy in terms of their impact on medication discontinuation in long-term benzodiazepine users. Overall, the treatment was more effective than nondirective therapy in helping patients discontinue their use of benzodiazepines. In addition, relative to nondirective therapy, the treatment led to greater gains in terms of diagnostic remission and symptomatic improvement.

Although the findings presented above are encouraging, the treatment has yet to be compared to a directive and active treatment. Consequently, the main goal of this study was to compare the CBT protocol to AR in terms of its short- and long-term benefits and to replicate the superiority of both treatments to a wait-list control condition. Given that AR (a) is an empirically supported treatment for GAD (Chambless et al., 1998; Chambless & Ollendick, 2001); (b) is one of the most commonly administered nonpharmacological interventions for GAD (Turner, Beidel, Spaulding, & Brown, 1995); and (c) does not include components that overlap with those of our CBT protocol (Dugas & Robichaud, 2007), it was chosen as the comparison treatment condition for the current study. To address the study's main goal, we used three experimental conditions: cognitive-behavioral therapy (CBT), applied relaxation (AR), and wait-list control (WL). The hypotheses were as follows:

1. Both active treatments would be superior to wait-list at posttest.
2. CBT would be superior to AR over follow-up.
3. CBT (and not AR) would lead to continued improvement over follow-up.

One of the main challenges we faced in designing this study was addressing potential allegiance effects. Allegiance effects can occur when researchers wittingly or unwittingly favor a condition to which they feel a certain loyalty, such as a treatment they have developed. To counter potential allegiance effects, we hired independent assessors (senior doctoral students not involved with other aspects of the study) to administer diagnostic interviews and other assessment procedures at all measurement times. The assessors were not involved in treatment delivery and were unaware of participants' experimental condition. We also hired a psychologist who had not been trained in CBT—she had received training in psychodynamic therapy—to be the main therapist for both treatment conditions. By using a therapist who had not trained in CBT, we hoped to both limit allegiance effects *and* increase the external validity of the study (i.e., that its findings would generalize to more therapists, not only those who had extensive training in CBT). Finally, we hoped to counter allegiance effects by providing the study's main therapist with weekly clinical supervision by one "expert" in each treatment condition in the initial phases of the study (the first author for CBT and the second author for AR).

Method

PARTICIPANTS

The sample (*N*=65) consisted of 43 women and 22 men with a primary diagnosis of GAD, all of whom were Francophone. Participants had a mean age of 38.5 years (*SD*=12.0) and an average of 15.3 years of education (*SD*=3.4). The ethnic composition of the sample was 91% White/European, 5% Middle Eastern, 2% Hispanic, and 2% Asian. In addition, 62.5% of participants were employed, 10.9% were students, and 26.6% were unemployed.

At intake, the mean duration of GAD was 13.9 years (*SD*=16.7), and the mean score for GAD was 5.7 (*SD*=1.2) on the 9-point (0 to 8) Clinician's Severity Rating of the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV; Di Nardo, Brown, & Barlow, 1994). Comorbid conditions were diagnosed in 58.5% of the sample, with 43.1% having one comorbid condition, 10.8% having 2 comorbid conditions, 1.5% having 3 comorbid conditions, and 3.1% having 4 comorbid conditions. Secondary conditions were panic disorder with/without agoraphobia (*n*=27), specific phobia (*n*=13), social anxiety disorder (*n*=9), dysthymic disorder (*n*=8), major depressive disorder (*n*=5), obsessive-compulsive disorder (*n*=3), and hypochondriasis (*n*=1). Finally, 55.4% of participants were taking anxiolytic or antidepressant medication and 43.1% had previously received CBT for an anxiety or mood disorder.

PROCEDURE

Participants were recruited from the Anxiety Disorders Clinic of the Hôpital du Sacré-Cœur de Montréal and through referrals from general practitioners and mental health specialists in the Montreal area. To increase the external validity of the study, media advertisements were *not* used to recruit participants (see Arntz, 2003). All patients referred to our clinic were assessed by a team psychiatrist using the Mini International Neuropsychiatric Interview, Version 4.4 (MINI; Sheehan et al., 1994). Patients who met criteria for primary GAD on the MINI were given a consent form explaining the goals and procedures of the study. Those wishing to participate in the study were referred for further diagnostic assessment by one of four doctoral students with the ADIS-IV. The students received training in the use of the ADIS-IV from the study's primary author, who had administered the interview in two previous clinical trials (i.e., Freeston et al., 1997; Ladouceur et al., 2000). After the administration of the ADIS-IV, patients completed a battery of questionnaires (see Measures).

Patients who received a primary diagnosis of GAD (the most severe/disabling of all diagnosed disorders) on both structured interviews and who also met the study's other inclusion criteria were invited to participate in the study. Inclusion criteria were: (a) a primary diagnosis of GAD with a Clinician's Severity Rating of at least 4/8 (moderate severity); (b) a difference of at least 2 points on the Clinician's Severity Rating between GAD and all comorbid conditions; (c) between 18 and 64 years of age; (d) no change in medication type or dose during 4 to 12 weeks before assessment (4 weeks for benzodiazepines, 12 weeks for antidepressants and hypnotics); (e) willingness to keep medication stable during the treatment phase of the study (no change in medication type or

increase in dose); (f) no evidence of suicidal intent; (g) no evidence of current substance abuse; and (h) no evidence of current or past schizophrenia, bipolar disorder, or organic mental disorder.

Between March 2001 and October 2004, a total of 83 patients were assessed for eligibility with the ADIS-IV. Of the 83 patients, 14 were excluded for one of the following reasons: GAD was not diagnosed (n =5); GAD was not the primary diagnosis (n = 5); the severity of a comorbid disorder was not at least 2 points less on the Clinician's Severity Rating (n=2); or a medical problem required immediate attention (n=2). In addition, 4 patients withdrew their consent following the ADIS-IV because of the time commitment required for continued participation in the study.

The 65 participants who made up the final sample were randomly allocated to CBT (n=23), AR (n=22), or WL (n=20). Allocation concealment and implementation were dealt with as follows: (1) the independent diagnostic assessments (MINI and ADIS-IV) were discussed during weekly team meetings; (2) a decision was reached to either include or exclude the patient; (3) when a patient was accepted into the study, the research coordinator applied a random allocation sequence; (4) following the meeting, the psychiatrist who administered the MINI contacted the patient to inform him/her of the team's decision (and of the result of randomization if the patient was accepted into the study). The therapy conditions consisted of 12 weekly 1-hour sessions with a clinical psychologist. Following the 12-week waiting period, wait-list participants were randomly allocated to one of the two active treatment conditions, which resulted in 33 participants being offered CBT and 31 being offered AR (1 participant dropped out following the 12-week waiting period). The ADIS-IV and all self-report questionnaires were administered at pretest-wait-list (for wait-list participants), pretreatment, posttreatment, and at 6-, 12-, and 24-month follow-ups. The Clinical Global Impression Improvement scale (CGI-I; Guy, 1976) was administered by the ADIS-IV interviewer at all measurement times. The final follow-up assessment was administered in October 2006; thus, the total duration of the study was 5 years, 7 months.

MEASURES

Diagnostic and Symptom Measures

Mini International Neuropsychiatric Interview, Version 4.4 (MINI; Sheehan et al., 1994): The MINI is a structured diagnostic interview designed for use in research and clinical settings. The MINI covers mood disorders, anxiety disorders, substance use disorders, psychotic disorders, eating disorders, and suicidal risk. It also includes optional sections for the assessment of other related disorders. The MINI has adequate psychometric properties (Sheehan et al., 1997). Although the interview typically does not provide severity ratings, we used the 9-point Clinician's Severity Rating scale (see ADIS-IV, below) to obtain information about the severity of MINI diagnoses. By having independent raters provide severity ratings using two interviews, we were able to compute interrater agreement on the severity of diagnosed conditions —rather than limiting agreement calculations to the presence/absence of conditions.

Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV; Di Nardo et al., 1994): The ADIS-IV assesses anxiety disorders, and screens for mood disorders, somatoform disorders, psychoactive substance use disorders, psychotic disorders, and medical problems. The interview provides information on the presence of Axis I disorders with severity ratings on a 9-point Clinician's Severity Rating scale ranging from 0 (*absent or none*) to 8 (*very severe or very severely disturbing/disabling*), with a rating of 4 (*moderate or definitely disturbing/disabling*) corresponding to the threshold of clinical significance. In the remainder of the text, the Clinician's Severity Rating from the ADIS-IV will simply be referred to as the CSR. Brown, Di Nardo, Lehman, and Campbell (2001) found that the diagnostic reliability of the anxiety disorders obtained with the ADIS-IV is good, with improvements over the previous edition of the interview, the ADIS-R (Di Nardo & Barlow, 1988).

Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990): The PSWQ includes 16 items that assess excessive and uncontrollable worry. Items are rated on a 5-point scale, ranging from 1 (*not at all typical of me*) to 5 (*very typical of me*). The PSWQ has high internal consistency, α=.86 to .95, and good test-retest reliability over 4 weeks, r=.74 to .93 (Molina & Borkovec, 1994). It also shows evidence of convergent, divergent, and discriminant validity in non-clinical and clinical populations (Brown, Antony, & Barlow, 1992; Meyer et al., 1990; Molina & Borkovec, 1994). In the current sample, the internal consistency of the PSWQ was α=.83.

Worry and Anxiety Questionnaire (WAQ; Dugas et al., 2001): The WAQ contains 11 items covering *DSM-IV* diagnostic criteria for GAD. Previous research shows that the WAQ has good known-groups validity and satisfactory test-retest reliability over 9 weeks (diagnostic sensitivity: 75%; diagnostic specificity: 82%; Dugas et al.). To complement the PSWQ and to allow for comparisons with our previous treatment studies, only the Somatic sub-scale of the questionnaire (WAQ-Som) was retained for the current study. The WAQ-Som assesses the presence/severity of each somatic symptom of GAD on a 5-point scale ranging from 1 (*not at all*) to 5 (*very severely*). The internal consistency of the WAQ-Som in the present sample was α=.71.

Ancillary Measures

State Trait Anxiety Inventory (Form Y), Trait version (STAI-T; Spielberger, 1977): The STAIT-T is a 20-item measure of individual differences in anxiety proneness or trait anxiety. Each item is rated on a 4-point scale, ranging from 1 (*almost never*) to 4 (*almost always*). The STAI-T has high internal consistency in anxiety disorder samples, α=.89, and has been shown to reliably distinguish between patients with anxiety disorders and non-clinical controls (Bieling, Antony, & Swinson, 1998). In the current sample, the internal consistency of the STAI-T was α=.86.

Beck Depression Inventory II (BDI-II; Beck, Steer, & Brown, 1996): The BDI-II includes 21 groups of 4 items reflecting different degrees of depressive symptoms (e.g., sadness, pessimism, loss of interest). Respondents indicate which item within each group best describes them during the past 2 weeks, with scores ranging from 0 to 3. The BDI-II has

very good internal consistency, α=.92, and excellent test-retest reliability over a 1-week period, *r* =.93 (Beck et al., 1996). The questionnaire also shows evidence of convergent and divergent validity (Steer & Clark, 1997). The internal consistency of the BDI-II was α=.87 in the present sample.

Clinical Global Impression, Improvement scale (CGI-I; Guy, 1976): The clinician-administered CGI-I assesses the degree of change in a patient's overall condition relative to baseline. In the present study, global change was rated on a 7-point scale ranging from 1 (*very much improved*) to 7 (*very much worse*). The CGI-I is a sound measure of global change and is sensitive to the effects of treatment (Leucht & Engel, 2006; Zaider, Heimberg, Fresco, Schneier, & Liebowitz, 2003).

Measures of Common Therapy Factors

Credibility and Expectancy Scale for GAD (CES-GAD; Ladouceur et al., 2000): Based on the CES (Borkovec & Nau, 1972), the CES-GAD contains 6 items that measure the credibility of the treatment and participant expectations of therapeutic change with regards to the symptoms of GAD (whereas the original CES refers to the fear of public speaking). Items are rated on a 5-point scale ranging from 1 (*extremely weak*) to 5 (*extremely strong*). The internal consistency of the CES was α=.86 in the original validation study (Borkovec & Nau), and the internal consistency of the CES-GAD was α=.80 in the current study.

Nijmegen Motivation List (NML; Keijsers, Hoogduin, & Schaap, 1991): The NML includes 17 items, rated on a 5-point scale ranging from 1 (*not at all applicable to me*) to 5 (*completely applicable to me*), that assess treatment motivation. The NML has weak to acceptable internal consistency, ranging from α=.53 to .66. In the current sample, the internal consistency of the NML was acceptable at α=.63.

Therapist Rating Scale (TRS; Williams & Chambless, 1990): The TRS is made up of 25 items that assess participant perceptions of the following therapist characteristics: caring/involved, modeling self-confidence, unconditionally accepting, challenging, explicit, and willing to be known. Each item is rated on a 7-point scale ranging from 1 (*strongly agree*) to 7 (*strongly disagree*). The TRS subscales have good internal consistency, α=.71 to .94, and the scale has adequate test-retest reliability over 2 to 4 weeks, τ=.44 to .66 (Williams & Chambless). The internal consistency of the TRS was α=.77 in the current study. We have used all three measures of common therapy factors in our previous treatment studies of GAD (Dugas et al., 2003; Gosselin et al., 2006; Ladouceur et al., 2000).

THERAPISTS

The study's main therapist (Renée Leblanc), who treated 61 of the 65 participants, was a licensed psychologist who had not received extensive training in CBT—her graduate-level training had been in the area of psychodynamic therapy. At the outset of the study, she had 5 years of clinical experience, which was the result of holding a part-time private practice for mood, anxiety, and adjustment disorders. She was trained using the CBT and AR treatment manuals, and weekly supervisions were held with the senior study authors. Specifically, the therapist received about 8 hours of formal training in each treatment condition (from the first

author for CBT; from the second author for AR). In addition, she received about 1 hour of weekly supervision in each treatment condition for the duration of the study (with most of the CBT supervision provided by the first author and most of the AR supervision provided by the second author). To further facilitate the training of the main therapist, the first author treated 4 participants (2 in each condition) during the early stages of the study—this allowed the main therapist to observe the administration of each treatment and discuss any issues requiring clarification.

EXPERIMENTAL CONDITIONS

CBT—Cognitive-behavioral therapy consisted of 12 weekly 1-hour sessions and covered the following treatment phases.

1. *Psychoeducation and worry awareness training (1 session).* The therapist first explained that the goal of CBT was to learn to recognize and reduce worry, thereby decreasing overall levels of worry, anxiety, and tension. Patients learned to monitor their worrying on a day-today basis, and to distinguish between worries about current problems (e.g., meeting deadlines at work) and worries about hypothetical situations (e.g., being involved in an accident).

2. *Uncertainty recognition and behavioral exposure (3 sessions).* The therapist then helped patients to understand the role of intolerance of uncertainty in worry and anxiety, to realize that uncertainty-inducing situations are largely unavoidable, to recognize the various manifestations of intolerance of uncertainty, and to seek out and experience uncertainty-inducing situations.

3. *Reevaluation of the usefulness of worry (1 session).* In the next treatment phase, patients learned to identify and reevaluate their positive beliefs about worry (e.g., “my worries prepare me for bad things that might happen”) using strategies such as the lawyer-prosecutor role play.

4. *Problem-solving training (3 sessions).* Patients then learned to address worries about current problems by using a problem-solving procedure targeting problem orientation, problem definition and goal formulation, generation of alternative solutions, decision making, and solution implementation and verification (see D’Zurilla, 1986).

5. *Imaginal exposure (3 sessions).* Finally, patients learned to use imaginal exposure for worries about hypothetical situations. With the help of the therapist, patients developed a scenario describing their worst fear using the downward arrow technique, and recorded the scenario on a looped tape for repeated exposure. They then listened to the recording for 20 to 60 minutes (long enough to experience a decrease in anxiety) everyday and continued to “expose” themselves to the scenario until it no longer provoked anxiety (typically 10 to 15 exposure sessions). See Dugas and Robichaud (2007) for a detailed description of the CBT protocol.

AR—Applied relaxation also consisted of 12 weekly 1-hour therapy sessions covering the following treatment phases.

1. *Psychoeducation and tension awareness training (1 session).* During the first phase of treatment, the therapist explained that the goal of AR was to learn to recognize muscle tension and to apply relaxation methods, thereby reducing overall levels of tension, anxiety, and worry. Patients also learned to monitor their levels of muscle tension on a daily basis.
2. *Tension-release training (4 sessions).* Patients learned to tense then relax different muscle groups (moving from 16 to 4 muscle groups) until full relaxation was achieved.
3. *Relaxation by recall (2 sessions).* Once the tension-relaxation procedure with 4 muscle groups had been mastered, patients learned to relax their muscles without tensing them first.
4. *Relaxation by counting (1 session).* At the end of sessions when patients had achieved full relaxation through recall alone, the therapist slowly counted from 1 to 10, asking patients to imagine their relaxation becoming even deeper. Once the patients had successfully integrated the counting into the recall procedure, they learned to relax by counting alone.
5. *Conditioned relaxation (3 sessions):* In this phase of treatment, patients learned to apply relaxation skills in everyday situations using a graded hierarchy. This enabled them to achieve relaxation in response to a self-produced cue (e.g., by counting to 10) in real-life stressful situations. For a detailed description, see Bernstein and Borkovec (1973) and Öst (1987).

For both CBT and AR, the final session was devoted to the prevention of relapse. Patients were encouraged to regularly evaluate their success in using the treatment strategies and to persevere when things became difficult. Both treatment conditions also made use of standard forms for the between-session exercises to increase compliance with therapist recommendations. Finally, at the end of each phase of CBT and AR, patients received a written summary describing the main issues addressed in that particular segment of treatment. By the end of therapy, patients had a complete manual that could be used as a relapse prevention guide.

WL—The duration of the WL condition was 12 weeks. Wait-listed participants were contacted by telephone every three weeks by the psychiatrist who had administered the MINI to monitor their state.

Results

DIAGNOSTIC RELIABILITY

Interrater agreement for the primary diagnosis on the MINI and the ADIS-IV was examined to determine diagnostic reliability. Criteria for inter-rater agreement were (a) concurrence of primary diagnosis and (b) agreement on severity of primary diagnosis (defined as a difference of no more than 1 point on the severity scales of the interviews). Using these criteria for diagnostic agreement, we calculated kappa scores and obtained values of κ=.66 for all 83 patient interviews and κ=.70 for the interviews of the final 65 patients.

TREATMENT INTEGRITY

Intervention checklists were adapted from our earlier studies to assess treatment integrity. The checklists closely followed the treatment manuals, including the structure of the session and the information to be presented and discussed. Treatment integrity was assessed by a research assistant who listened to audiotapes of all sessions for 4 randomly selected participants in each condition. The assistant rated the therapist's interventions against the intervention checklist and noted whether every item was properly addressed. Treatment integrity was 90.1% in the CBT condition and 93.1% in the AR condition.

SHORT-TERM OUTCOME: CBT, AR, AND WL

Table 1 presents means and standard deviations on the outcome measures at pretest and posttest in each condition. Seven (7) participants did not complete the first 12 weeks of the study; 2 dropped out of CBT and 5 dropped out of AR (there were no dropouts in the WL condition). Missing posttest data were replaced with pretest scores. Thus, the data presented in Table 1 (and the pretest to posttest analyses) are based on the intent-to-treat sample.

We conducted preliminary analyses on a wide range of variables to see if participants in the three conditions were comparable at intake. No between-group differences were found for demographic variables (age, sex, ethnic origin, years of education, and employment status), clinical variables (duration of GAD, number of comorbid conditions, medication status, and previous psychotherapy), or outcome variables (CSR, PSWQ, WAQ-Som, STAI-T, and BDI-II). Pretest to posttest analyses were therefore conducted without controlling for these variables.

Given that we were interested in comparing each treatment condition to WL (see Hypothesis 1), we ran two sets of analyses, the first comparing CBT to WL and the second comparing AR to WL. We ran 2 Group×2 Time analyses of variance (ANOVAs) for each of the first five measures, and a between-subjects ANOVA for the CGI-I. For each set of analyses, Bonferroni corrections were applied and significance levels were adjusted to $p<.008$. The first set of analyses revealed that CBT was superior to WL on four measures: CSR, $F(1, 41)=24.67$, $p<.001$, partial $\eta^2=.38$; PSWQ, $F(1, 41)=25.30$, $p<.001$, partial $\eta^2=.38$; WAQ-Som, $F(1, 40)= 8.87$, $p=.005$, partial $\eta^2=.18$; and CGI-I, $F(1, 41)= 13.87$, $p=.001$, partial $\eta^2=.25$. In the second set of analyses, AR was superior to WL on one measure: CSR, $F(1, 40)=8.27$, $p=.006$, partial $\eta^2=.17$. Thus, relative to WL, although both treatments led to greater change on overall severity of GAD, only CBT led to greater change on pathological worry, somatic symptoms of GAD, and global clinical improvement. Finally, compared to WL, neither treatment led to superior outcomes on trait anxiety or depressive symptoms from pretest to posttest.

We also used one-way within-subjects ANOVAs to test for changes in each outcome measure within each experimental condition and found significant decreases on every measure in the CBT and AR conditions, as well as significant decreases on two measures (CSR, WAQ-Som) in the WL condition. Table 2 presents pretest to posttest effect sizes.

SHORT-TERM OUTCOME: CBT AND AR

Following a 12-week delay, wait-listed participants were randomly allocated to one of the two treatment conditions, which yielded a final CBT sample of n=33 and a final AR sample of n=31 (one participant dropped out after the post wait-list assessment). Preliminary analyses were carried out to ensure that participants in the two treatment conditions were comparable at pretreatment. Again, we observed no between-group differences for demographic, clinical, and outcome variables. Furthermore, all participants completed the measures of treatment credibility and expectancy (CES-GAD), treatment motivation (NML) and therapist characteristics (TRS) after the third treatment session. In the CBT condition, mean scores were 24.78 (SD = 2.86) for the CES-GAD, 67.78 (SD=6.07) for the NML, and 59.62 (SD=10.84) for the TRS. Participants in the AR condition had mean scores of 23.38 (SD=3.41) for the CES-GAD, 66.68 (SD = 6.50) for the NML, and 59.83 (SD=12.33) for the TRS. One-way ANOVAs revealed no significant between-group differences on any of the measures of common therapy factors. Thus, pretest to posttreatment analyses comparing the active treatment conditions did not control for demographic, clinical and outcome variables, as well as common therapy factors.

Two-way repeated measures ANOVAs comparing the treatment conditions from pretreatment to posttreatment were carried out on each outcome measure (with the exception of the CGI-I). For each measure, we found significant within-group effects (with improvements on all variables), nonsignificant between-group effects, and nonsignificant Group×Time interactions. A one-way ANOVA comparing both treatment conditions at posttreatment revealed a significant between-group difference on the CGI-I, $F(1, 62)=6.05$, $p<.05$, partial $\eta^2 =.09$, with participants in the CBT condition showing greater improvement than those in the AR condition. Thus, although analyses involving measures of specific symptoms suggested that the treatment conditions led to similar change, ratings of global improvement suggested that CBT resulted in greater positive change than did AR.

LONG-TERM OUTCOME

Means and standard deviations on the outcome measures at all measurement times in the treatment conditions are presented in Table 3. Long-term outcomes were assessed by conducting growth curve analyses. Specifically, we used the multilevel modeling program Hierarchical Linear Modeling (HLM 6.04; Raudenbush, Bryk, & Congdon, 2005) to compute growth curves for each participant. The effect of time was assessed using participants' scores at posttreatment, and at 6-, 12-, and 24-month follow-ups. Separate analyses were conducted for each of the study measures.

To test Hypothesis 2 (that CBT would be superior to AR over follow-up), we calculated and contrasted the slopes for each measure from posttreatment to 2-year follow-up in both conditions. All between-group comparisons of slopes revealed nonsignificant findings. To test Hypothesis 3 (that CBT, and not AR, would lead to continued progress over follow-up), we compared the slope for each measure in each condition with a slope of zero (a slope of zero denotes no change over time). In the CBT condition, the slopes for three measures were significantly different from a slope of zero: the PSWQ slope, coefficient = −1.98, $t(30) = -3.99$, $p<.001$; the STAI-T slope, coefficient=−1.33, $t(30)=-2.64$, $p<.05$; and the CGI-I

slope, coefficient=−.14, $t(30)=-2.28$, $p<.05$. For each of these three measures, the results point to continued improvement over the 2 years following the end of treatment for CBT participants. In the AR condition, none of the slopes were significantly different from a slope of zero.

DIAGNOSTIC REMISSION

In line with current recommendations on the use the ADIS-IV, diagnostic remission was defined as having a Clinician's Severity Rating of 3 or less for GAD. In the CBT condition, remission rates for GAD were 70% at posttreatment, 76% at 6-month follow-up, 84% at 12-month follow-up, and 77% at 24-month follow-up. In the AR condition, remission rates for GAD were 55% at posttreatment, 70% at 6-month follow-up, 68% at 12-month follow-up, and 61% at 24-month follow-up. Chi-square tests comparing remission rates in both conditions revealed nonsignificant results at every time point.

In terms of additional diagnoses, we used HLM to assess change over time from pretreatment to 2-year follow-up in the number of additional diagnoses in each treatment condition. The CBT and AR slopes were not significantly different from each other, suggesting that the number of additional diagnoses was not differentially impacted by the treatment conditions. Furthermore, in both CBT and AR, the slopes for number of additional diagnoses were not significantly different from a slope of 0, indicating that the number of diagnoses was unaffected by each of the treatment conditions.

MEDICATION

Medication use was scored as a dichotomous variable (0=*no medication use*; 1=*medication use*) at each study time point. In the CBT condition, percentages of participants taking anxiolytic or antidepressant medication were 58% at pretreatment, 52% at posttreatment, 46% at 6-month follow-up, 45% at 12-month follow-up, and 36% at 24-month follow-up. In the AR condition, percentages were 58% at pretreatment, 50% at posttreatment, 57% at 6-month follow-up, 67% at 12-month follow-up, and 46% at 24-month follow-up. Change in medication status was assessed by using HLM to examine medication use from pretreatment to 24-month follow-up in each treatment condition. When the slopes for the treatment conditions were compared, they were not significantly different. Finally, in both AR and CBT, the slopes for medication use were not significantly different from a slope of 0, suggesting that use of medication was unaffected by each of the treatments.

Discussion

The current study compared the efficacy of CBT and AR for generalized anxiety disorder. The study also included a wait-list control condition to confirm each treatment's efficacy. The first hypothesis (that both treatments would be superior to wait-list at posttest) received partial support. Although the data supported the superiority of CBT over WL, they offered only limited support for the superiority of AR over WL. The second hypothesis (that CBT would be superior to AR over follow-up) was not supported, whereas the third hypothesis (that only CBT would lead to continued progress over follow-up) was supported. In the following paragraphs, we discuss the implications of these findings.

SHORT-TERM OUTCOMES

CBT was superior to WL on 4 of 6 outcomes: overall severity of GAD, pathological worry, somatic symptoms of GAD, and global clinical improvement. However, CBT was not superior to WL in terms of pretest to posttest change on trait anxiety and depressive symptoms. Consequently, this study did not replicate earlier findings showing that the same CBT protocol was superior to WL on general anxiety and depressive symptoms (Dugas et al., 2003; Ladouceur et al., 2000). The different measures used in the studies (the previous studies used the Beck Anxiety Inventory and the BDI, whereas this study used the STAI-T and the BDI-II) may have contributed to the inconsistent findings. In particular, the STAI-T, which some authors consider to be a measure of negative affect (e.g., Bieling et al., 1998; Watson & Clark, 1984), may be less sensitive to change than the BAI, which is primarily a measure of somatic anxiety (see Cox, Cohen, Direnfeld, & Swinson, 1996; Keedwell & Snaith, 1996). Overall, however, the data from the current study lend further support to the efficacy of CBT, in particular with regards to the symptoms of GAD and global improvement.

AR was superior to WL on only one outcome, namely overall severity of GAD as assessed by the CSR of the ADIS-IV. Thus, the data offered limited support for the superiority of AR over WL in terms of short-term improvement. At first glance, these findings appear to be at odds with previous studies (e.g., Barlow et al., 1992; Borkovec & Costello, 1993) that clearly support the efficacy of AR for the treatment of GAD. However, one must keep in mind that wait-listed participants made substantial improvements in the current study, more than what is typically observed in the treatment literature on GAD. For example, the WL condition generated a mean effect size of partial η^2 =.18 for all pretest to posttest assessments, as well as significant improvements on two measures (overall severity of GAD and somatic symptoms of GAD). Thus, although we did not find strong support for the superiority of AR over WL, it appears that the assessment of the short-term efficacy of AR (and CBT) was biased by the unusually large gains made by the wait-listed participants.

When CBT and AR were directly compared in terms of pretreatment to posttreatment change, only one significant finding emerged: CBT was superior in terms of global clinical improvement. It is somewhat surprising that CBT did not lead to statistically greater change in worry (as assessed by the PSWQ), which is not directly addressed by AR. One possible explanation for this result is that GAD, like other anxiety disorders, involves a process of interacting cognitive, physiological, affective, and behavioral systems (Beck & Clark, 1997; Borkovec et al., 2002), which implies that change in one system typically leads to changes in others. Consequently, although AR may have initially generated changes in somatic symptoms such as muscle tension, these initial changes may have subsequently led to changes in worry. The finding that AR did not generate greater change than CBT on somatic symptoms (as assessed by the WAQ-Som) may also be accounted for by the notion of interacting systems.

LONG-TERM OUTCOMES

When we compared the long-term outcomes of participants in the CBT and AR conditions, we found no significant between-group differences. These findings are somewhat at odds

with those of Borkovec and Costello (1993), who found evidence for the superiority of CBT over AR at 12-month follow-up. One could argue that studies with larger samples sizes would help clarify the long-term outcomes associated with CBT and AR. Of course, one could also argue that the current study's sample size (n=33 for CBT; n=31 for AR) and follow-up strategy (3 assessments over 2 years) should be sufficient to detect patterns that have practical implications for clinical practice. Either way, one thing seems clear: in terms of direct comparisons, the findings suggest that the treatments tested in the current study lead to similar short- and long-term outcomes.

When the slopes of participants in the CBT condition were compared to a slope of 0 (no change), the results revealed that treated participants made further progress during the follow-up phase of the study. Specifically, further gains were noted on the measures of pathological worry, trait anxiety, and global clinical improvement. It is noteworthy that a previous study (Dugas et al., 2003) also found that this CBT protocol led to further decreases in worry in the 2 years following treatment termination. Thus, it appears that the CBT protocol tested in the current study helps patients with GAD to significantly decrease their level of worry over the course of treatment *and* continue to decrease their worry following treatment termination. It may be that recognizing, accepting, and dealing with uncertainty is a complex task that requires exposure to a wide variety of uncertainty-inducing situations over an extended period of time. Consequently, although patients begin to change their uncertainty-related beliefs, appraisals, and behaviors over the course of therapy, this multifaceted change process may very well continue following treatment termination as the individual is faced with a broad array of new and challenging situations.

When the long-term outcomes of participants in AR were contrasted with a no-change condition (a slope of 0), no significant findings emerged. In other words, participants treated with AR maintained their treatment gains over the 2-year follow-up on every outcome. In fact, for every measure, the follow-up slope was a negative one, suggesting that a larger sample would not have revealed a pattern of relapse—in fact, a larger sample may have exposed further progress following treatment. At the very least, the data suggest that AR leads to the maintenance of treatment gains following treatment, which is in line with previous clinical trials of AR for GAD (e.g., Arntz, 2003; Barlow et al., 1992; Borkovec & Costello, 1993; Öst & Breitholz, 2000).

Overall, the results of the current study can be interpreted in different ways. On the one hand, direct comparisons of CBT and AR revealed only one significant finding: CBT led to greater change in global clinical improvement from pretreatment to posttreatment. All other direct comparisons of CBT and AR indicated that the treatments produce similar short- and long-term outcomes. Thus, in terms of direct comparisons, the weight of the evidence indicates that CBT and AR are equivalent. On the other hand, CBT was superior to WL on 4 of 6 outcomes whereas AR was superior to WL on only 1 outcome. In addition, CBT led to continued improvement on 3 outcomes over follow-up whereas AR did not lead to continued improvement following treatment. Thus, comparisons of each treatment with another point of reference (either waiting list or no change over follow-up) provide greater support for the efficacy of CBT than AR. Perhaps the most appropriate interpretation for the overall pattern of findings is that CBT and AR lead to outcomes that are more similar than different. Given

the well-documented efficacy of AR in the treatment of GAD (Chambless et al., 1998; Chambless & Ollendick, 2001), this conclusion is not entirely surprising.

One implication of the current findings is that the CBT protocol may need to be revised to more fully meet the needs of individuals with GAD. In particular, recent data suggest that a greater focus on the interaction between intolerance of uncertainty and fear of anxiety (Buhr & Dugas, 2009) may be beneficial. As discussed elsewhere (Dugas & Koerner, 2005; Koerner & Dugas, 2006), GAD may be characterized by conflicting cognitive-motivational states resulting from high levels of intolerance of uncertainty and fear of anxiety. Specifically, intolerance of uncertainty may promote the use of approach behaviors to attain a sense of certainty, and fear of anxiety may promote the use of avoidance strategies to inhibit the experience of anxious arousal. By directly addressing these conflicting cognitive-motivational states, we may be able to increase the efficacy of treatment.

This study had a number of limitations; the first being that allegiance effects may have biased the comparison of the treatment conditions. Considering that the CBT protocol was initially developed by the first author (Dugas & Ladouceur, 2000), we may have unwittingly favored CBT over AR in some way. A second limitation of the study is that a single therapist treated 61 of 65 participants. Because one therapist treated almost all participants, we cannot assess the extent to which the findings reflect the specific treatments as opposed to the characteristics of the therapist. Relatedly, we did not assess the competency of the therapist, which is a notable limitation of the study (ideally, treatment studies should assess both integrity and competency). Had we used more therapists, and measured competency in addition to integrity, the utility and generalizability of the findings would have been greater.

A third limitation relates to the reliability of the diagnoses. Because the ADIS-IV was only administered to patients having received a diagnosis of GAD on the MINI, the results of the ADIS-IV could have been influenced by demand characteristics. Likewise, given that the assessors were aware that a severity score difference of at least 2 points on the CSR of the ADIS-IV was required for inclusion in the study, the frequency of such an occurrence may have increased. A final limitation of note is the relatively small sample size. Although the size of the sample was larger than all but one previous study comparing CBT and AR (Barlow et al., 1992, had the same number of participants), a larger sample would have nonetheless been helpful for some analyses.

In summary, the results of the present study indicate that CBT and AR are efficacious treatments for GAD. The findings also suggest that although both treatments produce similar outcomes, only CBT appears to lead to continued improvement following treatment termination. Nonetheless, one thing seems clear: given that treatments developed specifically for GAD lead to full remission in only about half to two-thirds of patients (Fisher, 2006), much work remains to be done.

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Table 1

Means and Standard Deviations on Outcome Measures in Each Experimental Condition at Pretest and Posttest

Measure and condition	Pretest (*N*=65)		Posttest (*N*=65)	
	M	***SD***	***M***	***SD***
CSR				
CBT	5.78	1.04	1.61	2.21
AR	5.36	1.26	2.55	2.58
WL	5.90	1.25	4.78	2.07
PSWQ				
CBT	61.65	8.27	51.13	9.87
AR	58.01	5.51	52.16	8.04
WL	57.34	9.78	58.80	9.13
WAQ-Som				
CBT	21.13	4.07	17.74	4.45
AR	20.82	5.48	17.91	4.81
WL	22.42	3.17	21.45	3.65
STAI-T				
CBT	53.04	7.30	46.35	7.99
AR	52.23	7.15	46.95	8.42
WL	52.06	9.62	48.98	8.68
BDI-II				
CBT	15.36	8.20	8.83	6.63
AR	16.65	9.27	10.27	8.99
WL	13.70	7.72	11.20	7.26
CGI-I				
CBT	-	-	2.35	0.94
AR	-	-	2.77	1.02
WL	-*	-	3.35	0.81

Note. CSR=Clinician's Severity Rating from the Anxiety Disorders Interview Schedule for DSM-IV; CBT=cognitive-behavioral therapy; AR=applied relaxation; WL=waiting list; PSWQ=Penn State Worry Questionnaire; WAQ-Som=Worry and Anxiety Questionnaire, Somatic subscale; STAI-T=State-Trait Anxiety Inventory, Trait version; BDI-II=Beck Depression Inventory II; CGI-I=Clinical Global Impression, Improvement subscale.

* CGI-I scores cannot be calculated until the second assessment.

Table 2

Pretest to Posttest Effect Sizes (Partial η^2) in the CBT, AR, and WL Conditions

Measures	CBT	AR	WL
CSR	0.76	0.62	0.39
PSWQ	0.74	0.34	0.03
WAQ-Som	0.61	0.37	0.23
STAI-T	0.55	0.36	0.16
BDI-II	0.55	0.49	0.10

Note. CBT=cognitive-behavioral therapy; AR=applied relaxation; WL= waiting list; CSR= Clinician's Severity Rating from the Anxiety Disorders Interview Schedule for DSM-IV; PSWQ=Penn State Worry Questionnaire; WAQ-Som = Worry and Anxiety Questionnaire, Somatic subscale; STAI-T=State-Trait Anxiety Inventory, Trait version; BDI-II=Beck Depression Inventory II.

Table 3

Means and Standard Deviations on Outcome Measures in the Treatment Conditions at Pretest, Posttest, and Follow-ups

Measure and condition	Pretest (*n*=64)		Posttest (*n*=64)		6 months (*n*=50)		12 months (*n*=50)		24 months (*n*=42)	
	M	***SD***	***M***	***SD***	***M***	***SD***	***M***	***SD***	***M***	***SD***
CSR										
CBT	5.44	1.21	1.73	2.23	1.33	1.86	1.00	1.60	1.21	1.75
AR	5.16	1.81	2.55	2.55	1.43	1.88	1.57	1.91	1.21	2.08
PSWQ										
CBT	60.76	8.88	50.79	10.24	48.70	10.33	45.83	8.67	45.30	8.01
AR	58.20	6.48	51.21	7.90	49.09	7.49	46.74	8.61	48.17	11.72
WAQ-Som										
CBT	21.06	4.02	17.36	5.03	15.63	4.12	14.90	4.99	15.63	4.84
AR	21.00	4.83	17.94	4.40	18.22	4.78	15.89	4.03	15.77	5.17
STAI-T										
CBT	51.06	7.87	45.45	9.11	43.30	9.68	41.38	8.79	41.93	9.29
AR	51.94	7.90	46.03	9.75	45.52	9.10	43.16	8.39	43.54	9.39
BDI-II										
CBT	13.67	7.91	8.70	6.89	7.81	7.45	6.52	5.27	6.81	5.59
AR	15.07	9.08	9.71	8.74	8.00	6.90	6.74	7.83	6.46	5.47
CGI-I										
CBT	-	-	2.24	0.90	1.96	0.76	1.69	0.97	1.75	0.84
AR	-*	-	2.84	1.04	2.04	1.11	2.10	0.83	1.93	1.21

Note. CSR=Clinician's Severity Rating from the Anxiety Disorders Interview Schedule for DSM-IV; CBT=cognitive-behavioral therapy; AR=applied relaxation; PSWQ=Penn State Worry Questionnaire; WAQ-Som=Worry and Anxiety Questionnaire, Somatic subscale; STAI-T=State-Trait Anxiety Inventory, Trait version; BDI-II=Beck Depression Inventory II; CGI-I=Clinical Global Impression, Improvement subscale.

*CGI-I scores cannot be calculated until the second assessment.