

Efficacy of a Cognitive—Behavioral Treatment for Generalized Anxiety Disorder Evaluation in a Controlled Clinical Trial

Robert Ladouceur

École de Psychologie Université Laval

Michel J. Dugas

Department of Psychology Concordia University

Mark H. Freeston

Centre de Recherche Fernad-Seguin

Eliane Léger

École de Psychologie Université Laval

Fabien Gagnon

Center Hospitalier Université Laval

Nicole Thibodeau

Center Hospitalier Université Laval

ABSTRACT

Recent advances in the understanding of worry have led to the development of treatments for generalized anxiety disorder (GAD). The present study tested a GAD treatment that targeted intolerance of uncertainty, erroneous beliefs about worry, poor problem orientation, and cognitive avoidance. Twenty-six primary GAD patients were randomly allocated to a treatment condition ($n = 14$) or a delayed treatment control condition ($n = 12$). Self-report, clinician, and significant other ratings assessed GAD and associated symptoms. The results show that the treatment led to statistically and clinically significant change at posttest and that gains were maintained at 6- and 12-month follow-ups. Furthermore, 20 of 26 participants (77%) no longer met GAD diagnostic criteria following treatment. With regard to the treatment's underlying model, the results show that intolerance of uncertainty significantly decreased over treatment and that gains were maintained at both follow-ups. Although nonspecific factors were not significant predictors of treatment outcome, their role in the treatment of GAD requires further investigation.

Since the inclusion of generalized anxiety disorder (GAD) in the *Diagnostic and Statistical Manual of Mental Disorders* (3rd ed. [DSM—III] ; [American Psychiatric Association \[APA\], 1980](#)), its diagnostic criteria have undergone sweeping changes. In 1987, the main diagnostic criteria for GAD in the *DSM—III—R* ([APA, 1987](#)) ceased to be a series of somatic symptoms and became the presence of excessive worry. Seven years later, following a period of intense research on worry, the *DSM—IV* ([APA, 1994](#)) retained excessive worry as the hallmark of GAD, and this has led to improved identification and, in some cases, improved treatment outcomes (see [Dugas & Ladouceur, 1998](#), for a review).

Borkovec and his collaborators have underscored that anxiety involves a process of interacting subsystems (e.g., cognitive, physiological, affective, and behavioral; see [Borkovec & Costello, 1993](#) ; [Borkovec & Newman, 1999](#)). In other words, changes in one subsystem may lead to changes in the others. Thus, if people decrease their level of worry, which is first and foremost a cognitive phenomenon, this should lead to changes in their physiological responding, their subjective level of

affect, and their worry-related behaviors. Given the recent advances in our understanding of worry, it may be possible to design a treatment intervention for GAD that exclusively focuses on worry to lead to changes in all interacting subsystems. For instance, if people with GAD learn to control their worry, they may find that their somatic symptoms decrease accordingly (i.e., restlessness, frequent fatigue, difficulty concentrating, irritability, muscle tension, and sleep disturbance). By intensively focussing on worry, a key feature of the cognitive subsystem, rather than attempting to target many interacting subsystems, a cognitive—behavioral intervention may lead to clinically significant change in the cognitive as well as other subsystems. The most obvious implication of this reasoning is that a potentially effective treatment for GAD could draw on recent applied research to target worry in a highly specific fashion. The second implication is that relaxation training, which represents one of the most common treatment components for GAD (see [Barlow, Rapee, & Brown, 1992](#) ; [Borkovec & Costello, 1993](#)), would not be applied. The present study tests such a treatment package.

The main goal of the proposed treatment is of course to decrease the tendency to worry and eliminate GAD. To do so, the intervention targets the four components of our GAD worry model: intolerance of uncertainty, erroneous beliefs about worry, poor problem orientation, and cognitive avoidance (see [Dugas, Gagnon, Ladouceur, & Freeston, 1998](#) , for a detailed description of the model). First, the treatment stresses the importance of dealing with uncertainty in everyday life. Applied research has shown that GAD patients have a lower threshold for uncertainty than do other anxiety disorder patients and nonclinical individuals ([Ladouceur et al., 1999](#)). Other research teams have also shown that nonclinical high worriers have difficulty dealing with uncertainty in problem-solving situations ([Metzger, Miller, Cohen, Sofka, & Borkovec, 1990](#) ; [Tallis, Eysenck, & Mathews, 1991](#)). Finally, experimental manipulations of intolerance of uncertainty in nonclinical participants lead to changes in their level of worry, with increased intolerance of uncertainty leading to greater worry ([Ladouceur, Gosselin, & Dugas, in press](#)).

Second, the treatment attempts to correct erroneous beliefs about worry. Compared with moderate worriers, nonclinical high worriers believe that worry is useful because it helps prevent negative outcomes from occurring and minimizes the negative effects (e.g., feelings of guilt or shame) if these outcomes should occur ([Freeston, Rhéaume, Letarte, Dugas, & Ladouceur, 1994](#)). Nonclinical high worriers also believe that worry is more useful because it motivates them, prepares them for the worst, and distracts them from emotional topics ([Borkovec & Roemer, 1995](#)). Another independent study has shown that individuals with high levels of worry believe that worrying helps analytical thinking ([Davey, Tallis, & Capuzzo, 1996](#)). Finally, compared with nonclinical study participants, GAD patients report that worrying is more effective to avoid negative outcomes and promote positive ones ([Ladouceur et al., 1999](#)).

The treatment also targets poor problem orientation. A growing body of evidence shows that high levels of worry are related to poor problem orientation (i.e., the person's cognitive set when faced with a problem) and unrelated to knowledge of problem-solving skills per se ([Dugas, Freeston, & Ladouceur, 1997](#) ; [Dugas, Letarte, Rhéaume, Freeston, & Ladouceur, 1995](#)). Further, GAD patients have poorer problem orientation than do other anxiety disorder patients and nonclinical participants ([Ladouceur et al., 1999](#)). This last study also found that GAD patients have similar knowledge of problem-solving skills to the other two groups. So clearly, GAD patients appear to possess adequate knowledge of problem-solving skills but they may have difficulty actually solving their problems because of a tendency to react to them in a nonproductive way. These reactions (e.g., poor problem orientation) include seeing the problem as a threat to be avoided rather than a challenge to be met and having poor confidence in one's problem-solving ability.

The final treatment target is cognitive avoidance. Most of the work on the avoidance function of worry has been carried out by Borkovec and his colleagues. They have shown that worry is mostly made up of

verbal—linguistic cognitive activity, which may suppress fear-related mental imagery ([Borkovec & Inz, 1990](#)). The avoidance of mental imagery appears to lead to an inhibition of the sympathetic autonomic system, which may in turn negatively reinforce worry ([Borkovec & Hu, 1990](#) ; [Borkovec, Lyonfields, Wiser, & Deihl, 1993](#)). Because it is associated with avoidance of mental imagery and resulting physiological activation, worry may interfere with emotional processing. This intriguing possibility has received support from two recent studies (see [Butler, Wells, & Dewick, 1995](#) ; [Wells & Papageorgiou, 1995](#)).

The present treatment has an additional innovative feature. Worries are broken down into one of two types: (a) worries about situations that are amenable to problem solving, and (b) worries about situations (that often do not yet exist) that are not amenable to problem solving. This distinction is crucial because attempting to solve problems that cannot be resolved (or may never occur) may actually lead to increases in worry (see [Dugas, Freeston, et al., 1998](#)). Considering the research findings on the avoidance function of worry, cognitive exposure appears to be ideally suited to tackle the second type of worries (i.e., those concerned with situations that cannot be solved through instrumental means).

The main goal of this study was to assess the efficacy of a cognitive—behavioral treatment for GAD that exclusively targets GAD worry. The main hypothesis was that the treatment program would lead to statistically and clinically significant change in GAD and associated symptoms. We tested this hypothesis by comparing a treatment condition to a wait-list condition. The second hypothesis predicted that treatment gains would be maintained at 6- and 12-month follow-ups. Maintenance of treatment gains was assessed by combining both groups of participants.

Method

Participants and Procedure

Following the publication of an article describing our work on GAD in a local newspaper, 99 individuals contacted our treatment center between May 1995 and March 1996. All callers were first screened by telephone with a structured telephone interview developed for this and other related studies (i.e., [Dugas, Freeston, et al., 1998](#) ; [Ladouceur et al., 1999](#)). The telephone interview was used to eliminate individuals who clearly did not have GAD and would not benefit from the treatment being offered. The 42 remaining participants were then invited to our clinic for a structured diagnostic interview, the Anxiety Disorders Interview Schedule for *DSM—IV* (ADIS; [Brown, Di Nardo, & Barlow 1994](#)). The interview was tape-recorded and a second clinician listened to the recording to assess diagnostic reliability. If both clinicians did not agree that GAD was the most severe psychological disorder, we held a case conference with other members of our research team to arrive at a consensus. If disagreement persisted, the participant was excluded from the study. Entry criteria consisted of (a) a primary diagnosis of GAD, (b) no change in medication type or dose during the 8 weeks before treatment, (c) willingness to keep medication status stable while participating in the study (i.e., no change in medication type or increase in dose), (d) no evidence of suicidal intent, (e) no evidence of current substance abuse, and (f) no evidence of current or past schizophrenia, bipolar disorder, or organic mental disorder. Of 42 interviewed participants, 5 were excluded from the study because they did not have GAD and 4 were excluded because GAD was not their most severe disorder. The 31 remaining participants were offered a place in the treatment program; 26 accepted and completed the assessment protocol. The final sample ($n = 26$) was made up of 20 women and 6 men, all of whom were French-speaking Caucasians. They had a mean age of 39.7 years ($SD = 10.8$) and an average of 15.2 years of education. Additional (comorbid) diagnoses were specific phobia ($n = 16$), social phobia ($n = 12$), panic disorder with agoraphobia ($n = 3$), panic disorder without agoraphobia ($n = 3$), major depressive disorder ($n = 1$), obsessive—compulsive disorder ($n = 1$), and trichotillomania ($n = 1$). At

intake, 9 participants were taking medication; four were taking both anxiolytics and antidepressants and 5 were taking only anxiolytics. Retrospective reports revealed a mean duration of GAD of 15.6 years ($SD = 13.3$). Finally, 20 of 26 participants reported having already consulted a mental health professional for emotional problems.

Measures Outcome measures.

The ADIS-IV ([Brown, Di Nardo, & Barlow, 1994](#)) thoroughly assesses all anxiety disorders and screens for mood disorders, somatoform disorders, psychoactive substance use disorders, psychotic disorders, and medical problems. The interview yields information on the presence of Axis I disorders with severity ratings on a 9-point Likert scale. In the present study, an independent clinician administered the ADIS-IV at all measurement times. The Penn State Worry Questionnaire (PSWQ; [Meyer, Miller, Metzger, & Borkovec, 1990](#)) has 16 items that measure a trait-like tendency to worry. The French translation of the PSWQ is unifactorial, has high internal consistency ($\alpha = .91$), excellent test—retest reliability ($r = .81$) and convergent validity with other measures of worry and anxiety ([Ladouceur et al., 1992](#)). The Worry and Anxiety Questionnaire (WAQ; [Dugas, Freeston, Lachance, Provencher, & Ladouceur, 1995](#)) contains 11 items about *DSM-IV* diagnostic criteria for GAD. The WAQ shows good convergent and discriminant validity as well as satisfactory test—retest reliability ([Dugas, Freeston, et al., 1995](#)). To complement the measure of worry (PSWQ), only the 6 GAD somatic symptom items from the WAQ were retained for this study (i.e., restlessness or feeling keyed up or on edge, frequent fatigue, difficulty concentrating or mind going blank, irritability, muscle tension, and sleep disturbance).

The Beck Anxiety Inventory (BAI; [Beck, Epstein, Brown, & Steer, 1988](#)) is a 21-item state anxiety scale measuring the intensity of cognitive, affective, and somatic anxious symptoms experienced during the past week. Like the English version, the French translation shows excellent metric properties ([Freeston, Ladouceur, Thibodeau, Gagnon, & Rhéaume, 1994](#)). The Beck Depression Inventory (BDI; [Beck, Rush, Shaw, & Emery, 1979](#)) consists of 21 items covering the principal depressive symptoms. Again, the French translation has excellent metric properties ([Bourque & Beaudette, 1982](#)). Finally, the Significant Other Rating Scale (SORS) was developed for this study to measure GAD and related symptoms as assessed by someone close to the participant. The questionnaire includes 12 items that are rated on a 9-point Likert scale (0—8). The items ask about GAD symptoms (worry, somatic symptoms, mood, satisfaction with life, etc.).

Process measure.

The Intolerance of Uncertainty Scale (IUS; [Freeston, Rhéaume, et al., 1994](#)) measures intolerance of uncertainty, the main component of the underlying GAD model. The questionnaire is composed of 27 items relating to uncertainty, emotional and behavioral reactions to ambiguous situations, the consequences of uncertainty, and attempts to control future events. The IUS has excellent internal consistency ($\alpha = .91$; [Freeston et al., 1994](#)), and good test—retest reliability over 5 weeks ($r = .78$; [Dugas, Freeston, & Ladouceur, 1997](#)).

Measures of nonspecific factors.

The Therapist Rating Scale ([Williams & Chambless, 1990](#)), which was translated and adapted for this study, measures participant perceptions of the therapist. The instrument assesses the following therapist characteristics on a 7-point Likert scale ranging from 1 to 7: caring/involved, modeling self-confidence, unconditionally accepting, challenging, explicit, and willing to be known. A translated and adapted version of the Credibility and Expectancy Scale ([Borkovec & Nau, 1972](#)) was used to assess the

credibility of the treatment and participant expectations of therapeutic change (see [Freeston et al., 1997](#)). This version of the scale contains 7 items rated on a 5-point scale ranging from 1 to 5. The Nijmegen Motivation List ([Keijsers, Hoogduin, & Schaap, 1994](#)) was translated and adapted for the present study to assess treatment motivation. The scale contains 17 items rated on a 5-point scale ranging from 1 to 5.

Experimental Design

We chose a wait-list control group design to allow all participants to receive the treatment package and provide statistical power for certain analyses (e.g., maintenance of treatment gains). Participants were randomly allocated to either the treatment ($n = 14$) or wait-list ($n = 12$) condition. There were no dropouts in either group.

Therapists

The four therapists were licensed psychologists trained in cognitive—behavior therapy. Eliane Léger, a psychologist with 3 years experience, treated 8 participants in the treatment group and all 12 wait-list participants. Michel J. Dugas, an advanced doctoral student with 10 years clinical experience; Mark H. Freeston, a post-doctoral researcher with 4 years clinical experience; and a doctoral student with 2 years clinical experience each provided treatment to 2 participants each in the treatment group. The first three therapists all had experience delivering treatment within experimental protocols. The last therapist and Mark H. Freeston also shared responsibility for training and supervision. A session-by-session treatment manual¹ was prepared and used to train all therapists.

Therapy Conditions

Patients in the wait-list condition were told that treatment would begin 16 weeks after their initial assessment. During the waiting period, they were telephoned once a month to monitor their state and provide a minimal amount of support. No treatment interventions were administered during the 16-week waiting period.

The treatment consisted of 16 one-hour therapy sessions conducted weekly. Average treatment duration for all patients was 15.8 sessions. The treatment consisted of (a) presentation of treatment rationale, (b) awareness training, (c) correction of erroneous beliefs about worry, (d) problem-orientation training, and (e) cognitive exposure.

Presentation of treatment rationale.

In the first session, the therapist presented the treatment rationale; that is, that one's perception of uncertainty is an important source of worry and anxiety. The therapist explained that because uncertainty is pervasive in everyday life, the treatment's goal is not to eliminate uncertainty, but rather to help participants recognize it, accept it, and develop coping strategies when faced with uncertain situations.

Awareness training.

During this phase, patients were asked to stop what they were doing at predetermined times of the day (3 to 4 times a day) and record their immediate worries in a notepad. They were also asked to note if each worrisome situation was directly modifiable (amenable to problem solving). Awareness training lasted 2 to 3 sessions, depending on the needs of each patient.

Correction of erroneous beliefs about worry.

In this treatment phase, patients identified their beliefs about worry (i.e. "my worries about my child's health are useful because if something should happen to her, at least I wouldn't be taken by surprise") and listed the advantages and disadvantages of holding these beliefs. Next, the therapist used various cognitive and behavioral techniques to help patients reevaluate the actual usefulness of worry. The therapist also stressed that correcting erroneous beliefs about worry helps increase tolerance of uncertainty because one learns to deal with the uncertainty of future events rather than trying to control them by using worry. It should be noted that only beliefs about the positive consequences of worrying were targeted during this treatment phase, as these beliefs may lead to the reinforcement of worrying.

Problem-orientation training.

Problem-orientation training was used for worries that were amenable to problem solving. Because intolerance of uncertainty may lead to excessive preoccupation with the minor details of the problem situation, the therapist helped patients stay focused on the problem and identify all key elements of the problem situation while not paying undue attention to related minor details. Once patients identified the key elements, they were encouraged to proceed with the problem-solving process even if they were unsure of its outcome beforehand (thus targeting both poor problem orientation and intolerance of uncertainty).

Cognitive exposure.

Worries about situations that were not amenable to problem solving were treated with cognitive exposure. Most of these worries concerned highly remote events, either in time or probability. First, patients described the worrisome image, which was recorded on a looped tape for repeated exposure. They were then exposed to the image using a Walkman® tape recorder (Sony Electronics, Inc., Tokyo, Japan) while using covert response prevention (the proscription of all voluntary activity used to neutralize the image). Cognitive exposure also helped decrease intolerance of uncertainty by changing the meaning given to threatening future events.

Relapse Prevention

All patients received a written relapse prevention guide that presented a summary of the strategies used for each type of worry. The guide was individualized by the patients as a homework assignment before the last therapy session by answering questions about their own manifestations of intolerance of uncertainty, erroneous beliefs about worry, poor problem orientation, and cognitive avoidance.

Follow-Up Assessment

Follow-up assessments were carried out 6 and 12 months after treatment. Participants completed all self-report measures and were assessed by an independent clinician using the ADIS-IV.

Treatment Integrity

Treatment integrity was assessed by a graduate student who listened to a recording of three sessions for each participant (randomly chosen) and rated the therapist's interventions against a standardized treatment intervention checklist (see [Dugas & Ladouceur, in press](#)). The checklist contained a list of treatment interventions that were consistent with the therapy protocol (e.g., cognitive reevaluation of the usefulness of worrying, problem orientation training, and cognitive exposure) and a separate list of

interventions that were not (e.g., thought stopping, stimulus control, distraction from worries, and passive listening). For all 26 participants combined, treatment integrity reached 99% (i.e. the therapists adhered to the treatment protocol 99% of the time). Passive listening was the only intervention used by the therapists that was not indicated by the treatment protocol.

Results

Preliminary Analyses

As mentioned above, the participants were randomly allocated to one of two groups: treatment ($n = 14$) and wait-list control ($n = 12$). At intake, no between-group differences were found for sociodemographic (age, sex, level of education, employment, and relationship status) and clinical variables (comorbid conditions, medication, duration of GAD, and previous consultations). Further, there were no between-group differences on 5 of 6 outcome measures (ADIS-IV Severity scale, PSWQ, WAQ Somatic scale, BAI, and BDI). However, a significant result (no Bonferroni correction) emerged for the SORS, $F(1, 24) = 4.61, p < .05$. Significant others rated participants in the treatment group ($M = 55.29, SD = 11.72$) as being more distressed than did significant others of those in the control group ($M = 44.30, SD = 14.39$).

Posttreatment Improvement Treatment versus wait-list.

A two-way repeated measures multivariate analysis of variance (MANOVA; Group \times Time) on outcome measures revealed a significant Group \times Time interaction, $F(6, 19) = 8.10, p < .05$. A modified Bonferroni correction (see [Simes, 1986](#)) was applied to all univariate analyses of treatment effects. Two-way repeated measures analyses of variance (ANOVAs) then showed significant interactions for all outcome measures: ADIS-IV Severity scale, $F(1, 24) = 35.04, p < .05$; PSWQ, $F(1, 24) = 33.31, p < .05$; WAQ Somatic scale, $F(1, 24) = 12.59, p < .05$; BAI, $F(1, 24) = 7.30, p < .05$; BDI, $F(1, 24) = 4.47, p < .05$; and SORS, $F(1, 23) = 4.89, p < .05$. We used simple main effects tests to measure differences between the two groups at posttest (following treatment or wait-list). The results showed that posttest scores were significantly lower in the treatment group on the ADIS-IV Severity scale, $F(1, 24) = 27.33, p < .05$; the PSWQ, $F(1, 24) = 27.24, p < .05$; the BAI, $F(1, 24) = 4.33, p < .05$; and the BDI, $F(1, 24) = 15.09, p < .05$. Finally, within-group repeated measures ANOVAs revealed significant decreases on all measures in the treatment group ($p < .05$) and on none of the measures in the control group. Given the between-group difference on the SORS at pretest, all appropriate analyses were rerun with SORS pretest scores entered as a covariate. The results were unchanged and therefore will not be presented here. Pretest and posttest scores for the treatment and wait-list groups are presented in [Table 1](#).

Total sample.

The 12 participants in the control condition were offered the same treatment following the 4-month waiting period. Postwait-list results were used as their pretreatment scores. All participants in the wait-list condition started and completed treatment. Thus the following analyses are based on the total sample of 26 participants. Missing data at 6- and 12-month follow-ups (data for 3 and 4 participants respectively) were replaced by endpoint scores (the last available score). A two-way MANOVA (Group \times Time) revealed no group or interaction effects. Further, two-way ANOVAs on each measure revealed no interaction effects. Thus, one-way analyses of variance are reported below.

A repeated measures MANOVA showed a significant time effect, $F(6, 20) = 27.29, p < .05$. Follow-up ANOVAs revealed significant decreases on all measures: ADIS-IV Severity scale, $F(1, 25) = 130.30, p$

< .05; PSWQ, $F(1, 25) = 79.78, p < .05$; WAQ Somatic scale, $F(1, 25) = 52.52, p < .05$; BAI, $F(1, 25) = 27.27, p < .05$; BDI, $F(1, 25) = 28.54, p < .05$; and SORS, $F(1, 25) = 19.12, p < .05$. Effect size (Cohen's d), from pre- to posttest, was also calculated for each measure: ADIS-IV Severity scale, $d = 3.19$; PSWQ, $d = 2.38$; WAQ Somatic scale, $d = 1.58$; BAI, $d = 0.87$; BDI, $d = 1.11$; and SORS, $d = 0.89$. We assessed maintenance of treatment gains in two ways. First, repeated measures ANOVAs (two per variable) comparing pretreatment and follow-up scores revealed significant decreases on all measures from pretreatment to both 6- and 12-month follow-ups. Second, repeated measures ANOVAs (two per variable) comparing posttreatment and follow-up scores found no significant differences on all but one measure from posttreatment to 6-month follow-up (BAI, $F(1, 25) = 10.01, p < .05$) and no significant differences on all measures from posttreatment to 12-month follow-up. [Table 2](#) presents scores for all participants at pretreatment, posttreatment, and 6- and 12-month follow-ups.

Clinically Significant Change

Given the importance of evaluating the clinical significance of change (see [Kendall, Marrs-Garcia, Nath, & Sheldrick, 1999](#)), we assessed it in two ways. First, treatment response was defined by a 20% change in pretreatment scores. Second, endstate functioning was defined by a score that was within one standard deviation of the mean of normative samples. When norms were unavailable, we used a face-valid level of meaningful change to determine endstate functioning. For the GAD residual symptom score on the ADIS-IV, a score of 3 or less on the 9-point scale was considered to reflect a meaningful endstate score. For the SORS, a score of 36 or less (an average of 3 on each 9-point scale item) was defined as meaningful change. Missing data were again replaced by endpoint scores. For each participant, responder status and endstate functioning were determined as follows: criteria reached on 0 to 1 measures was low, on 2 to 4 measures was moderate, and on 5 to 6 measures was high. [Table 3](#) presents the frequency and percentage of participants in each category of responder status and endstate functioning at posttest, 6-month follow-up, and 12-month follow-up. It should be noted that on the measure of trait worry, the PSWQ, the percentage of participants scoring within one standard deviation of the mean of normative samples was 81% at posttest, 73% at 6-month follow-up, and 69% at 12-month follow-up. In addition, at posttreatment and 6- and 12-month follow-ups, 20 of 26 patients (77%) no longer met GAD diagnostic criteria.

Additional Diagnoses

The mean number of additional diagnoses at intake was 1.62 (1.64 in the treatment condition and 1.58 in the control condition). A two-way ANOVA comparing participants in the treatment and wait-list conditions showed a significant difference on the number of additional diagnoses from pre- to posttest, $F(1, 24) = 5.86, p < .05$. At posttest, participants in the treatment condition had 0.42 additional diagnoses ($SD = 0.76$), whereas those in the control condition had 1.33 ($SD = 1.23$). When all participants were combined, a one-way ANOVA examining change from pretreatment to posttreatment revealed a significant change in additional diagnoses, $F(1, 25) = 18.33, p < .05$. The mean number of additional diagnoses decreased from 1.50 ($SD = 1.10$) at pretreatment to 0.65 ($SD = 1.06$) at posttreatment. Further, one-way ANOVAs investigating change from posttreatment to 6- and 12-month follow-ups showed no change in the number of additional diagnoses, thereby revealing maintenance of treatment generalization. The mean number of additional diagnoses at 6- and 12-month follow-ups were 0.54 ($SD = 0.72$) and 0.59 ($SD = 0.80$), respectively.

Medication

At pretreatment, 9 participants were taking medication. Of the 4 participants who were taking both anxiolytics and antidepressants, 2 had eliminated their anxiolytics at follow-ups and 2 continued to take both types of medication. Of the 5 participants who were taking only anxiolytics at pretreatment, all 5

continued to take their anxiolytics at posttreatment and follow-ups. Finally, 1 participant who was not taking medication at pretreatment began taking antidepressant medication at follow-ups. Thus, medication remained relatively stable over the treatment and follow-up period.

Intolerance of Uncertainty

Treatment process was investigated by examining changes in scores on the IUS. A two-way repeated measures ANOVA on IUS scores revealed a significant Group \times Time interaction, $F(1, 24) = 19.46, p < .05$. Changes in intolerance of uncertainty for the total sample, once wait-list participants had received treatment, were then examined. As expected, a one-way ANOVA revealed a significant change in IUS scores over treatment, $F(1, 25) = 46.81, p < .05$. Finally, maintenance of change in intolerance of uncertainty was assessed in two ways. First, one-way repeated measures ANOVAs revealed that IUS scores significantly decreased from pretreatment to both 6- and 12-month follow-ups. Second, one-way repeated measured ANOVAs showed that IUS scores remained unchanged from posttreatment to both 6- and 12-month follow-ups. Mean IUS scores for the total sample were 87.08 ($SD = 21.08$) at pretreatment, 52.73 ($SD = 16.13$) at posttreatment, 56.73 ($SD = 21.86$) at 6-month follow-up, and 54.96 ($SD = 20.09$) at 12-month follow-up.

Therapeutic Relationship, Treatment Credibility, and Motivation to Change

The therapeutic relationship, treatment credibility, and motivation to change were assessed following the third therapy session. Mean scores on the Therapist Rating Scale ($M = 144.70, SD = 13.02$) and the Credibility and Expectancy Scale ($M = 25.17, SD = 2.55$) indicated that participants rated therapist characteristics and treatment rationale as satisfactory. Further, the mean score on the Nijmegen Motivation List ($M = 70.64, SD = 6.94$) suggested that participants were highly motivated for therapy. The three measures were correlated with pre- to posttreatment change scores on all six outcome measures and the results showed that none of the correlations reached the level of statistical significance.

Discussion

The first hypothesis, which stated that the treatment program would lead to statistically and clinically significant change in GAD and associated symptoms, was confirmed. As expected, the cognitive—behavioral treatment was effective for decreasing self-reported worry, somatic symptoms, general anxiety, and depression. It is noteworthy that from pre- to posttreatment, there was a statistically significant decrease on all six measures in the treatment group and on none of the measures in the control group. Further, for all 26 participants, mean posttreatment scores are well within the nonclinical range on all measures (see [Table 1](#)). Investigation of clinically significant change revealed a similar pattern. At posttreatment, the majority of participants were in the high responder (65%) and high endstate functioning (62%) categories. Moreover, 77% of participants no longer met diagnostic criteria for GAD. Although these numbers could certainly be improved on, they are quite similar to those reported in recent studies of empirically supported treatments for GAD ([Barlow et al., 1992](#); [Borkovec & Costello, 1993](#)). In fact, the percentage of participants having reached high endstate functioning at posttreatment in the present study is superior to those previously reported. But given that the specific criteria for determining endstate functioning were different in these studies, caution is advised in making such direct comparisons.

The second hypothesis, that is, that treatment gains would be maintained at 6- and 12-month follow-ups, was also confirmed. At both follow-ups, change from pretreatment scores remained statistically significant on all six measures. Further, posttreatment to follow-up comparisons revealed that scores on only one measure, the BAI, significantly increased from posttreatment to 6-month follow-up. However,

means scores on the BAI decreased at 12-month follow-up and there was no longer a significant difference with posttreatment scores. Again, scores on all measures 1 year following treatment were well within the nonclinical range. Of particular interest was the mean score of 46.27 ($SD = 12.70$) on the PSWQ, a clear indication that the tendency to worry was no longer in the range of scores typically found in GAD patients ($M = 68.11$, $SD = 9.59$; [Brown, Antony, & Barlow, 1992](#)).

Assessment of responder status and endstate functioning also indicated that, overall, treatment gains were maintained at both follow-ups. One year following treatment, 62% and 58% of participants continued to meet criteria for high responder status and high endstate functioning, respectively. Furthermore, the percentage of participants no longer meeting GAD diagnostic criteria remained unchanged since posttreatment (i.e., 77%). Again these numbers are comparable to those obtained in recent studies using similar criteria. However, it should be noted that there was a slight increase in the percentage of participants considered to have low responder status and low endstate functioning in the year following treatment. But these percentages remained very low (8% in both cases) and represent only 2 of the 26 participants. Considering that maintenance of treatment gains is clearly a central issue in the treatment of GAD, these results are all the more encouraging.

Given that GAD often presents with other disorders (see [Sanderson, Di Nardo, Rapee, & Barlow, 1990](#); [Wittchen, Zhao, Kessler, & Eaton, 1994](#)), the effect of GAD treatment on comorbid conditions is an important clinical issue. In the present study, the number of comorbid disorders statistically decreased from pretreatment ($M = 1.50$) to posttreatment ($M = 0.65$) and this decrease was maintained at 6-month ($M = 0.54$) and 12-month follow-ups ($M = 0.59$). These findings indicate that effectively treating GAD has beneficial effects above and beyond the specific symptom of clusters that make up GAD. Some authors have suggested that GAD may represent a basic anxiety disorder that acts as a vulnerability factor for other mood and anxiety disorders (see [Barlow, 1988](#); [Rapee, 1991](#)). If this turns out to be the case, then it may be that effective GAD treatments lead to considerable generalization of treatment gains, such as remission of other comorbid mood and anxiety disorders. This intriguing possibility certainly merits further study.

The present findings also show that a cognitive—behavioral treatment that exclusively targets excessive worry can lead to statistical and clinical change in GAD somatic symptoms. Although these somatic symptoms were not directly targeted by a treatment intervention such as progressive muscular relaxation, means scores on the Somatic scale of the WAQ went from 32.85 at pretreatment to 19.96 at posttreatment. Further, these gains were maintained at both follow-ups. This finding suggests that it may not be necessary to include general anxiety reduction techniques when treating most individuals with GAD. By intensively focussing on worry, the key feature of the GAD cognitive subsystem, the present treatment led to change in the GAD physiological subsystem. Having said this, it may be that some GAD patients (i.e., those with a predominantly somatic profile) require general anxiety reduction techniques. But this does not appear to be the case for most individuals with GAD.

This study is the first to show, in a randomized group-comparison design, that a cognitive—behavioral treatment that targets intolerance of uncertainty, erroneous beliefs about worry, poor problem orientation, and cognitive avoidance is effective for treating GAD and has beneficial effects on comorbid conditions. The results of this study also show that the treatment leads to a significant decrease in intolerance of uncertainty, which is maintained at 6- and 12-month follow-ups. However, no mediational analyses were undertaken in this study to test the conjecture that reduced intolerance of uncertainty mediates the impact of the treatment on GAD symptoms. It should be underscored, nonetheless, that a previous study used time series analyses to show that changes in intolerance of uncertainty preceded changes in time spent worrying for 3 of 4 GAD patients over the course of treatment ([Dugas & Ladouceur, in press](#)). Although this latter finding requires replication with a larger sample, it does suggest that changes in intolerance of uncertainty may mediate changes in worry during

the treatment of GAD.

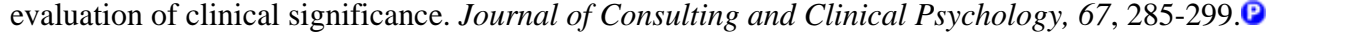

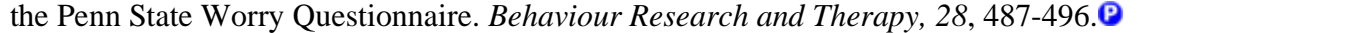

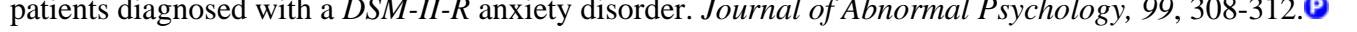


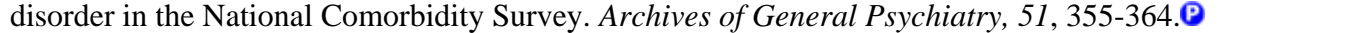
A number of limitations of the present study should be noted. First, interrater agreement of diagnosis was obtained by having a second clinician listen to an audiotaped recording of the original diagnostic interview. Although this method is certainly better than not requiring a check on the diagnosis, the administration of two independent diagnostic interviews remains the most rigorous method for establishing diagnostic reliability. A second limitation concerns the assessment of nonspecific therapy factors. Although participant reports of therapist characteristics, treatment credibility, and therapy motivation did not emerge as significant predictors of treatment outcome, further research is necessary before concluding that nonspecific factors do not make an important contribution to successful treatment outcomes with the treatment tested in this study. To properly address this issue, future researchers could use an equally credible alternative treatment or provide a detailed analysis of the relationship between changes in specific factors (the processes posited by the underlying model), nonspecific factors, and GAD symptoms.

In spite of these limitations, the results of this study are consistent with the notion that the package based on specific theory-driven components accounts for the extent of therapeutic change and maintenance of gains observed in this study (especially because the use of medication remained relatively stable over treatment and follow-ups). Recall that worry is highly related to intolerance of uncertainty ([Dugas et al., 1997](#) ; [Tallis et al., 1991](#)), erroneous beliefs about worry ([Davey et al., 1996](#) ; [Freeston et al., 1994](#)), poor problem orientation ([Dugas, Letarte, et al., 1995](#) ; [1997](#)), and cognitive avoidance ([Borkovec & Hu, 1990](#) ; [Borkovec & Inz, 1990](#)). At an informal level, participants reported that distinguishing between two types of worry (those that are amenable to problem solving and those that are not) was extremely useful in helping them "feel in control" of their worries and understand how to handle each specific worry. Not trying to solve a problem that does not yet exist certainly seems like a worthwhile endeavor for those who suffer from excessive worry.

References

- American Psychiatric Association. (1980). *Diagnostic and statistical manual of mental disorders* ((3rd ed.). Washington, DC: Author.)
- American Psychiatric Association. (1987). *Diagnostic and statistical manual of mental disorders* ((3rd ed., rev.). Washington, DC: Author.)
- American Psychiatric Association. (1994). *Diagnostic and statistical manual of mental disorders* ((4th ed.). Washington, DC: Author.)
- Barlow, D. H. (1988). *Anxiety and its disorders: The nature and treatment of anxiety and panic*. (New York: Guilford Press)
- Barlow, D. H., Rapee, R. M. & Brown, T. A. (1992). Behavioral treatment of generalized anxiety disorder. *Behavior Therapy*, *23*, 551-570. [P](#)
- Beck, A. T., Epstein, N., Brown, G. & Steer, R. A. (1988). An inventory for measuring clinical anxiety: Psychometric properties. *Journal of Consulting and Clinical Psychology*, *56*, 893-897. [P](#)
- Beck, A. T., Rush, A. J., Shaw, B. F. & Emery, G. (1979). *Cognitive therapy of depression*. (New York: Guilford Press)
- Borkovec, T. D. & Costello, E. (1993). Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. *Journal of Consulting and Clinical Psychology*, *61*, 611-619. [P](#)
- Borkovec, T. D. & Hu, S. (1990). The effect of worry on cardiovascular response to phobic imagery. *Behaviour Research and Therapy*, *28*, 69-73. [P](#)
- Borkovec, T. D. & Inz, J. (1990). The nature of worry in generalized anxiety disorder: A predominance of thought activity. *Behaviour Research and Therapy*, *28*, 153-158. [P](#)

- Borkovec, T. D., Lyonfields, J. D., Wisner, S. L. & Deihl, L. (1993). The role of worrisome thinking in the suppression of cardiovascular response to phobic imagery. *Behaviour Research and Therapy*, *31*, 321-324. [P](#)
- Borkovec, T. D. & Nau, S. D. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, *3*, 257-260. [P](#)
- Borkovec, T. D. & Newman, M. G. (1999). Worry and generalized anxiety disorder. (In A. S. Bellack & M. Hersen (Series Eds.) & P. Salkovskis (Vol. Ed.), *Comprehensive clinical psychology: Vol. 4. Adults: Clinical formulation and treatment* (pp. 439—459). Oxford: Elsevier Science.)
- Borkovec, T. D. & Roemer, L. (1995). Perceived functions of worry among generalized anxiety disorder subjects: Distraction from more emotionally distressing topics? *Journal of Behavior Therapy and Experimental Psychiatry*, *26*, 25-30. [P](#)
- Bourque, P. & Beaudette, D. (1982). Etude psychométrique du questionnaire de dépression de Beck auprès d'un échantillon d'étudiants universitaires francophones [Psychometric study of the Beck Depression Inventory with French-Canadian university students]. *Revue Canadienne des Sciences de Comportement*, *14*, 211-218.
- Brown, T. A., Antony, M. M. & Barlow, D. H. (1992). Psychometric properties of the Penn State Worry Questionnaire in a clinical anxiety disorders sample. *Behaviour Research and Therapy*, *30*, 33-37. [P](#)
- Brown, T. A., Di Nardo, P. A. & Barlow, D. H. (1994). *Anxiety Disorders Interview Schedule for DSM-IV*. (Albany, New York: Graywind Publications.)
- Butler, G., Wells, A. & Dewick, H. (1995). Differential effects of worry and imagery after exposure to a stressful stimulus: A pilot study. *Behavioural and Cognitive Psychotherapy*, *23*, 45-56. [P](#)
- Davey, G. C. L., Tallis, F. & Capuzzo, N. (1996). Beliefs about the consequences of worrying. *Cognitive Therapy and Research*, *5*, 499-520. [P](#)
- Dugas, M. J., Freeston, M. H., Lachance, S., Provencher, M. & Ladouceur, R. (1995, July). *The Worry and Anxiety Questionnaire: Initial validation in non-clinical and clinical samples*. (Paper presented at the World Congress of Behavioural and Cognitive Therapies, Copenhagen, Denmark.)
- Dugas, M. J., Freeston, M. H. & Ladouceur, R. (1997). Intolerance of uncertainty and problem orientation in worry. *Cognitive Therapy and Research*, *21*, 593-606. [P](#)
- Dugas, M. J., Freeston, M. H., Ladouceur, R., Rhéaume, J., Provencher, M. D. & Boisvert, J.-M. (1998). Worry themes in primary GAD, secondary GAD and other anxiety disorders. *Journal of Anxiety Disorders*, *12*, 253-261. [P](#)
- Dugas, M. J., Gagnon, F., Ladouceur, R. & Freeston, M. H. (1998). Generalized anxiety disorder: A preliminary test of a conceptual model. *Behaviour Research and Therapy*, *36*, 215-226. [P](#)
- Dugas, M. J. & Ladouceur, R. (1998). Analysis and treatment of generalized anxiety disorder. (In V. E. Caballo (Ed.), *International handbook of cognitive—behavioural treatments of psychological disorders* (pp. 197—225). Oxford, England: Pergamon Press.)
- Dugas, M. J. & Ladouceur, R. (in press). Treatment of GAD: Targeting intolerance of uncertainty in two types of worry. *Behavior Modification*, ,
- Dugas, M. J., Letarte, H., Rhéaume, J., Freeston, M. H. & Ladouceur, R. (1995). Worry and problem solving: Evidence of a specific relationship. *Cognitive Therapy and Research*, *19*, 109-120. [P](#)
- Freeston, M. H., Ladouceur, R., Gagnon, F., Thibodeau, N., Rhéaume, J., Letarte, H. & Bujold, A. (1997). Cognitive—behavioral treatment of obsessive thoughts: A controlled study. *Journal of Consulting and Clinical Psychology*, *65*, 405-413. [P](#)
- Freeston, M. H., Ladouceur, R., Thibodeau, N., Gagnon, F. & Rhéaume, J. (1994). L'inventaire d'anxiété de Beck: Propriétés psychométriques d'une traduction française [The Beck Anxiety Inventory: Psychometric properties of a French translation]. *L'Encéphale*, *20*, 47-55.
- Freeston, M. H., Rhéaume, J., Letarte, H., Dugas, M. J. & Ladouceur, R. (1994). Why do people worry? *Personality and Individual Differences*, *17*, 791-802. [P](#)
- Keijsers, G. P. J., Hoogduin, C. A. L. & Schaap, C. P. D. R. (1994). Predictors of treatment outcome in the behavioural treatment of obsessive—compulsive disorder. *British Journal of Psychiatry*, *165*, 781-786. [P](#)

- Kendall, P. C., Marrs-Garcia, A., Nath, S. R. & Sheldrick, R. C. (1999). Normative comparisons for the evaluation of clinical significance. *Journal of Consulting and Clinical Psychology, 67*, 285-299. 
- Ladouceur, R., Dugas, M. J., Freeston, M. H., Rhéaume, J., Blais, F., Gagnon, F., Thibodeau, N. & Boisvert, J.-M. (1999). Specificity of generalized anxiety disorder symptoms and processes. *Behavioral Therapy, 30*, 191-207.
- Ladouceur, R., Freeston, M. H., Dumont, J., Letarte, H., Rhéaume, J., Thibodeau, N. & Gagnon, F. (1992, June). *The Penn State Worry Questionnaire: Psychometric properties of a French translation*. (Paper presented at the Annual Convention of the Canadian Psychological Association, Québec, Canada.)
- Ladouceur, R., Gosselin, P. & Dugas, M. J. (in press). Experimental manipulation of intolerance of uncertainty: A study of a theoretical model of worry. *Behaviour Research and Therapy, ,*
- Metzger, R. L., Miller, M. L., Cohen, M., Sofka, M. & Borkovec, T. D. (1990). Worry changes decision making: The effect of negative thoughts on cognitive processing. *Journal of Clinical Psychology, 46*, 78-88. 
- Meyer, T. J., Miller, M. L., Metzger, R. L. & Borkovec, T. D. (1990). Development and validation of the Penn State Worry Questionnaire. *Behaviour Research and Therapy, 28*, 487-496. 
- Rapee, R. M. (1991). Generalized anxiety disorder: A review of clinical features and theoretical concepts. *Clinical Psychology Review, 11*, 419-440. 
- Sanderson, W. C., Di Nardo, P. A., Rapee, R. M. & Barlow, D. H. (1990). Syndrome comorbidity in patients diagnosed with a *DSM-II-R* anxiety disorder. *Journal of Abnormal Psychology, 99*, 308-312. 
- Simes, R. J. (1986). An improved Bonferroni procedure for multiple tests of significance. *Biometrika, 73*, 751-754.
- Tallis, F., Eysenck, M. H. & Mathews, A. (1991). Elevated evidence requirements and worry. *Personality and Individual Differences, 12*, 21-27. 
- Wells, A. & Papageorgiou, C. (1995). Worry and the incubation of intrusive images following stress. *Behaviour Research and Therapy, 33*, 579-583. 
- Williams, K. E. & Chambless, D. L. (1990). The relationship between therapist characteristics and outcome of in vivo exposure treatment for agoraphobia. *Behavior Therapy, 21*, 111-116.
- Wittchen, H. U., Zhao, S., Kessler, R. C. & Eaton, W. W. (1994). *DSM-III-R* generalized anxiety disorder in the National Comorbidity Survey. *Archives of General Psychiatry, 51*, 355-364. 

1

Treatment manuals can be obtained from Michel J. Dugas, Department of Psychology, Concordia University, 7141 Sherbrook Street West, Montreal, Quebec, Canada H4B 1R6. Electronic mail requests may be sent to dugas@vax2.concordia.ca.

This study was funded by the Medical Research Council of Canada and the Fonds de la Recherche en Santé du Québec.

We thank Martin D. Provencher for serving as a therapist in the study, and Frédéric Langlois and Jean-Marie Boisvert for their help in carrying out this study.

Correspondence may be addressed to Robert Ladouceur, École de Psychologie, Université Laval, Québec, Canada, G1K 7P4.

Electronic mail may be sent to robert.ladouceur@psy.ulaval.ca

Received: May 7, 1999

Revised: March 13, 2000

Accepted: April 10, 2000

Table 1. Means and Standard Deviations on Outcome Measures at Pretest and Posttest for the Treatment (n = 14) and Wait-List (n = 12) Groups

Table 1
Means and Standard Deviations on Outcome Measures at Pretest and Posttest for the Treatment (n = 14) and Wait-List (n = 12) Groups

Variable and group	Pretest		Posttest	
	M	SD	M	SD
ADIS-IV*				
Treatment	8.36	0.74	2.64	1.55
Waiting-list	5.92	0.80	5.67	1.37
PSWQ				
Treatment	65.86	8.96	45.64	9.96
Waiting-list	59.25	7.44	64.58	8.27
WAQ†				
Treatment	35.29	7.83	22.00	11.38
Waiting-list	31.75	7.06	30.00	7.78
BAI				
Treatment	16.54	10.53	7.02	6.50
Waiting-list	14.33	5.85	12.18	6.08
BDI				
Treatment	15.76	10.66	5.43	6.42
Waiting-list	18.33	8.31	16.83	8.54
SORS				
Treatment	55.28	11.72	35.63	10.64
Waiting-list	44.30	14.39	39.23	15.93

Note. ADIS-IV = Anxiety Disorders Interview Schedule; PSWQ = Penn State Worry Questionnaire; WAQ = Worry and Anxiety Questionnaire; BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; SORS = Significant Other Rating Scale.

*Symptom Severity scale.
†Anxiety scale.

Table 2. Means and Standard Deviations on Outcome Measures at Pretreatment, Posttreatment, and 6- and 12-Month Follow-Ups for All Participants (N = 26)

Table 2
Means and Standard Deviations on Outcome Measures at Pretreatment, Posttreatment, and 6- and 12-Month Follow-Ups for All Participants (N = 26)

Variable	Pretreatment		Posttreatment		6 months		12 months	
	M	SD	M	SD	M	SD	M	SD
ADIS-IV*	8.08	1.11	2.80	1.29	3.02	1.75	2.80	1.18
PSWQ	62.27	8.10	49.08	8.75	46.20	9.28	46.20	8.25
WAQ†	32.69	8.14	19.19	8.40	17.20	10.25	16.25	8.25
BAI	16.15	10.00	6.07	5.44	6.15	7.07	6.07	6.07
BDI	16.20	10.11	6.17	5.76	6.10	7.13	6.10	6.10
SORS	47.27	10.00	30.12	9.17	30.08	9.20	28.69	8.69

Note. ADIS-IV = Anxiety Disorders Interview Schedule; PSWQ = Penn State Worry Questionnaire; WAQ = Worry and Anxiety Questionnaire; BAI = Beck Anxiety Inventory; BDI = Beck Depression Inventory; SORS = Significant Other Rating Scale.

*Symptom Severity Scale.
†Anxiety scale.

Table 3. Frequencies and Percentages of Participants (N = 26) in Each Category of Responder Status and Endstate Functioning at Posttest, 6-Month Follow-Up, and 12-Month Follow-Up

Table 3
Frequencies and Percentages of Participants (N = 26) in Each Category of Responder Status and Endstate Functioning at Posttest, 6-Month Follow-Up, and 12-Month Follow-Up

No. of measures	Responder status		Endstate functioning	
	Frequency	%	Frequency	%
Posttest				
0-1	0	0	1	4
2-4	9	35	9	35
5-6	17	65	16	62
6-month follow-up				
0-1	3	12	2	8
2-4	9	33	11	42
5-6	14	54	13	50
12-month follow-up				
0-1	2	8	2	8
2-4	8	31	9	35
5-6	16	62	15	58

Note. At posttest, 14 participants (54%) met criteria for both high responder status and high endstate functioning. At 6-month follow-up, 12 participants (46%) met criteria for both high responder status and high endstate functioning. At 12-month follow-up, 14 participants (54%) met criteria for both high responder status and high endstate functioning. 0-1 = low; 2-4 = moderate; and 5-6 = high.