

Chapter 2

GAD Treatment Research*

Of all the anxiety disorders, GAD is considered the most difficult to treat effectively (Brown, Barlow, & Liebowitz 1994). Early psychosocial interventions for anxiety disorders utilized exposure techniques, such as systematic desensitization for the treatment of phobic behavior. However, the phenomenology of GAD proved too diffuse for the application of early exposure-based treatments (Borkovec & Whisman 1996). Therefore, early GAD treatment research included anxiety management strategies targeting somatic anxiety symptoms. Relaxation training provided clients with new and effective coping responses for use whenever anxiety cues were detected. Indeed, relaxation training remains one of the standard components in cognitive-behavioral treatment for GAD today. Later GAD treatments incorporated cognitive therapy strategies targeting inflated perceptions of threat as well as imaginal exposure to internal and external anxiety cues for the purpose of coping rehearsal. Such cognitive-behavioral treatment packages have been evaluated in numerous controlled psychotherapy outcome research trials. Although GAD remains the most difficult to treat anxiety disorder, cognitive-behavioral therapy (CBT) consistently produces significant therapeutic change that persists over time. Furthermore, CBT appears superior to no treatment and to nondirective counseling.

This chapter provides a concise review of the extant GAD psychotherapy outcome research conducted over the past 23 years. Since the earliest empirical investigations of this nature in the mid 1980's, comprehensive psychosocial treatment packages addressing the various cognitive, behavioral, and psychological features of GAD have been developed and tested. Current state-of-the-art CBT for GAD continues to receive empirical support. However, these treatments do not produce clinically meaningful change for as many clients as seen in the cognitive-behavioral treatment of other anxiety disorders. Four comprehensive literature reviews and meta-analytic studies will be described (Borkovec & Whisman 1996; Gould, Otto, Pollack, & Yap 1997; Borkovec & Ruscio 2001; Gould, Safren, Washington, & Otto 2004). More recent investigations of GAD treatment effects not captured in these reviews will be presented as well. Finally, therapy outcome research examining the treatment of GAD among older adults will be discussed.

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Initial GAD Psychotherapy Outcome Research

Several controlled therapy trials examining the efficacy of psychosocial treatments for GAD were conducted during the mid 1980's and early 1990's. In 1996, Borkovec and Whisman conducted a comprehensive review of these and other early investigations of GAD psychotherapy effects. They reported that weak experimental methodology at that time left the results of many investigations difficult to interpret. As a result, Borkovec and Whisman applied strict methodological criteria to each investigation and only included those believed to yield interpretable results. Many methodological factors were considered, including: the method of diagnosis, the use of blind assessors, whether medication use was controlled, counterbalancing of therapists, use of written protocol manuals, assessment of treatment adherence, measurement of treatment expectancy and credibility, attrition rates, and the length of follow-up periods. Eleven controlled outcome investigations meeting the minimal methodological standards set by the authors were included. Twelve other studies were excluded, largely because of limitations in diagnostic assessment procedures and/or ambiguities in diagnostic inclusion criteria.

Study Characteristics

Of the eleven investigations reviewed by Borkovec and Whisman (1996), GAD diagnosis was established with Diagnostic and Statistical Manual (DSM) criteria in seven of the eleven projects, Research Diagnostic Criteria (RDC) were applied in two studies, and an additional two studies used both methods. Blind assessors were involved in seven of the studies, but were not included in two. Blind assessment was considered not applicable in an additional two studies. For investigations in which medication use was applicable, patient medication usage was balanced in two investigations, left unchecked in one study, and unknown in four studies. To minimize any effects specific to the therapist, rather than the treatment, the authors examined whether each investigation counterbalanced therapists across therapy conditions. Only two studies employed this approach. Five investigations did not counterbalance therapists, and this methodological design feature either was not applicable or was not mentioned in four studies. Treatment adherence and client expectancies of treatment were both assessed in seven of the eleven studies. Of the entire list of eleven investigations, attrition rates ranged from 0% to 37.5% with a mean of 11.2%. Final follow-up assessments were conducted an average of 11.2 months after the end of treatment.

Sample Characteristics and Treatment Features

The mean age of the clients who participated in these eleven studies was 36 years, consisting of 383 women (65.1%) and 205 men (34.9%). The average duration of GAD symptoms was 5.5 years. Four studies included clients who were concurrently

maintained on a fixed dosage of medication. Among these four studies, 40.4% of clients were taking psychoactive medication. With regard to treatment, the average number of sessions was 10.3 with a range from 4 to 18. Treatment sessions were on average 64.1 min in length but ranged from 40 to 120 min. An average of 5.5 therapists provided treatment, but the number of therapists ranged from 2 to 16. The types of therapists varied and included professional clinicians, a mix of clinicians and graduate students, graduate students only, and, in the case of one investigation, psychiatric nurses.

Treatment Outcome Results

Borkovec and Whisman (1996) first examined within-group results reported in the eleven reviewed investigations. Each active psychosocial treatment produced significant improvement pre to post treatment on all outcome measures. These active psychosocial treatments included cognitive-behavior therapy, anxiety management training, cognitive therapy alone, behavior therapy alone, and applied relaxation. Nonspecific control conditions, including nondirective counseling, psychosocial placebo, pill placebo, and diazepam, yielded significant changes on fewer measures than the active treatments. No-treatment control conditions (six studies) did not result in changes over time, suggesting that spontaneous remission did not account for the effects observed in the other conditions. Furthermore, two investigations (Butler, Fennell, Robson, & Gelder 1991; Barlow, Rapee, & Brown 1992) reported decreased psychoactive medication use among active treatment condition participants. Therapy gains associated with behavioral and cognitive-behavioral interventions maintained at follow-up on most measures, and in two studies, further improvement on some measures was reported. Improvements resulting from nonspecific therapy conditions were shorter-lived, with most of these clients experiencing some degree of relapse by the follow-up assessment. Treatment gains resulting from placebo conditions also tended not to persist. Borkovec and Whisman concluded that improvement of GAD is unlikely to occur without treatment and that improvements associated with the active psychosocial interventions could not be attributed only to nonspecific factors.

Active psychosocial interventions were compared to control conditions directly with between-group statistical comparisons. In all of the six investigations including a no-treatment condition, the active psychosocial treatment resulted in greater improvement than the no-treatment condition on all or most measures. Results from studies comparing cognitive-behavioral or behavioral therapies to nonspecific control conditions were less clear. Generally these comparisons revealed that active cognitive-behavioral or behavioral interventions were superior to nonspecific control conditions on some measures. While these results certainly were promising, Borkovec and Whisman (1996) cautioned that strong between-group effects were not found often. Across all treatment conditions, CBT did produce the largest degree of change on measures of anxiety and depression when calculated within-group

effect sizes were compared in a meta-analysis. Effect sizes associated with CBT interventions also were significantly larger than those associated with all other psychosocial interventions. When CBT was examined in terms of clinically significant change (a return to within one standard deviation of the mean of the normal population), 75% of the studies reported long-term maintenance or gains toward achieving clinically significant change. However, four of six investigations comparing active treatment conditions to each other (Barlow et al. 1992; White, Keenan, & Brooks 1992; Borkovec & Costello 1993; Borkovec & Mathews 1988) found no between-group differences when comparing: 1) cognitive therapy to applied relaxation, 2) cognitive therapy alone to behavior therapy alone to CBT, 3) applied relaxation to applied relaxation plus cognitive therapy and self-control desensitization, and 4) cognitive therapy plus relaxation to self-control desensitization plus relaxation to non-directive therapy plus relaxation. Two of the six studies did find some significant group differences. Butler et al. (1991) found that CBT was superior to behavior therapy alone on some measures, and Borkovec, Mathews, Chambers, Ebrahimi, et al. (1987) found that cognitive therapy plus relaxation was superior to non-directive therapy plus relaxation on some measures. Borkovec and Whisman concluded that these last two studies may suggest a potential incremental effect for cognitive therapy when combined with other behavioral interventions such as relaxation training.

Summary of Preliminary Research Findings

According to the review conducted by Borkovec and Whisman (1996), CBT interventions yielded larger within-group effect sizes and greater clinically significant change, both at the end of treatment and over a one-year follow-up period, than other psychosocial treatments for GAD. CBT was also associated with lower dropout rates and larger reductions in psychoactive medication use during and after treatment. Borkovec and Whisman concluded that the combination of cognitive therapy, behavior therapy and relaxation techniques, and self-control desensitization, consisting of imaginal exposure and coping rehearsal procedures, is most likely to produce long-term improvement in both the somatic and cognitive features of GAD. Indeed, updated procedures for each of these recommended therapy components are provided in this book. However, a variety of empirical questions remain. Which of these treatment components are most important? In combination they appear to work, but are all components needed to achieve desired therapeutic change? Are all therapy components equally essential, or are some components more effective than others? Clarifying the role of nonspecific factors and isolating the specific effects of individual treatment components both would enhance our understanding of why cognitive-behavioral GAD treatment works.

Cognitive-Behavioral and Pharmacological Treatment Research

The review and meta-analysis conducted by Borkovec and Whisman (1996) included investigations of psychosocial treatment effects only. Around that same time, Gould et al. (1997) conducted a meta-analytic review of controlled trials including both CBT and pharmacotherapy treatment for GAD. This review was much broader in scope, examining 35 investigations. A total of 61 individual treatment comparisons were available from research conducted between 1974 and 1996. Thus, this was the first meta-analysis comparing CBT to pharmacological interventions for GAD. Gould et al. included both published and unpublished “in press” research projects in their meta-analytic investigation.

Inclusion Criteria and Methodological Considerations

Gould et al. (1997) limited their analysis to investigations with a control group so they could compute a precise between-group effect size for each intervention. Acceptable control conditions included no treatment, wait list, or pill/psychological placebo. Participants either met DSM diagnostic criteria for GAD or would have met those criteria had they been applied to the sample. Randomization of participants to condition was not set as a specific inclusion criterion, but this methodological characteristic was typical among the investigations included. Concurrent medication use was not an exclusion criterion, but rather was considered a variable of interest.

CBT Outcome Results

Each treatment condition was classified as either cognitive-behavioral or pharmacological. Cognitive-behavioral treatments included cognitive restructuring, situational exposure, imaginal exposure, interoceptive exposure, systematic desensitization, relaxation training, relaxation with biofeedback, anxiety management training, or any combination thereof. The mean effect size (ES) across all CBT interventions was 0.70 for anxiety measures and 0.77 for symptoms of depression, both of which were statistically significant when compared to no treatment. According to Cohen (1988), an ES of 0.2 is considered a small effect, an ES of 0.5 reflects a medium-sized effect, and an ES of 0.8 is a large effect. The effect size calculated when cognitive therapy interventions were examined alone, based on three studies, was 0.59. For behavior therapy alone, also based on three studies, the calculated effect size was 0.51. Cognitive and behavioral strategies were combined in eight investigations, resulting in a CBT treatment package effect size of 0.91. When used as independent treatment strategies, anxiety management training and relaxation

training had effect sizes of 0.91 and 0.64 respectively. Relaxation with biofeedback had the lowest effect size of 0.34 and was significantly lower than combined CBT strategies. The mean attrition rate for CBT studies was 10.6%. With regard to treatment format, there were no statistical differences between the effect sizes of group interventions (0.66) versus individual interventions (0.81). No differences were found with regard to length of treatment, as CBT treatments ranged from 4 to 15 hours of intervention with a mean of 9.5 clinical hours.

Pharmacotherapy Outcome Results

Pharmacological interventions included all drugs that had been approved by the United States Food and Drug Administration for the treatment of GAD as well as agents that had not received such approval but were commonly prescribed for GAD. The 24 trials selected for meta-analysis included thirty-nine separate interventions, and all twenty-four investigations utilized pill placebo control conditions. The active pharmacotherapy interventions yielded an overall effect size of 0.60 for symptoms of anxiety and an overall effect size of 0.46 for depressive symptoms. The associated attrition rate was 15.2%. Interventions employing benzodiazepines were the most common, included in 23 of the studies. When examined in isolation, these medications produced an overall effect size of 0.70 and a 13.1% drop-out rate. Investigations using diazepam specifically were the second most common type of pharmacologic investigation, represented by eleven studies. This intervention produced the largest effect size (0.76) but also the highest dropout rate (16.9%) of the benzodiazepine class. Trials examining Lorazepam, Alprazolam, Bromazepam, and buspirone yielded effect sizes of 0.66, 0.44, 0.61, 0.39 respectively, with dropout rates ranging from 8% to 16.8%. Antidepressant medications were examined in three studies, resulting in an effect size of 0.57 and one-third of participants (33.5%) dropping out of treatment.

Comparisons Between CBT and Pharmacological Treatments

When the overarching intervention categories of CBT (ES = 0.70) and pharmacotherapy (ES = 0.60) were compared, no significant differences in anxiety symptom reduction were found between the two treatment modalities. In addition, no differences in attrition rates were found (10.6% for CBT, 15.2% for pharmacotherapy). However, Gould et al. (1997) found that CBT interventions (ES = 0.77) were superior to pharmacological interventions (ES = 0.46) in the reduction of depressive symptomatology, although only three of the pharmacology trials measured depression. Gould and colleagues warned that the effect sizes associated with CBT inadvertently may have been inflated by the use of control groups that were less stringent than the pill placebo control groups found in pharmacology trials.

Nevertheless, CBT interventions were associated with maintenance of treatment gains at least 6 months later. Long-term effects of the pharmacological interventions often were not examined, although some evidence of lost treatment gains following discontinuation of diazepam was found. Additional concerns might be raised for medication treatment of women during their childbearing years, as the effects of these agents on the fetus are unknown. Interestingly, over 60% of the patients included in this meta-analytic review were women.

Recent GAD Treatment Outcome Meta-Analysis Results

Both research groups described above recently updated their reviews, including newer investigations published since the mid 1990's. Borkovec and Ruscio (2001) re-analyzed controlled GAD psychotherapy outcome investigation results, comparing CBT treatment packages to individual cognitive and behavioral components as well as to no-treatment and nonspecific control conditions. In 2004, Gould and colleagues conducted a new meta-analysis containing only those investigations which included some form of cognitive-behavioral treatment. Both of these recent meta-analytic investigations provided a more sophisticated and complete picture of CBT effects in the treatment of GAD.

Updated Psychotherapy Outcome Meta-Analytic Review Results

Borkovec and Ruscio (2001) conducted a meta-analytic review of 13 controlled clinical trials of CBT for GAD. They selected the same eleven investigations included in the earlier Borkovec and Whisman (1996) review and added two clinical trials conducted since the original review. Many rigorous methodological characteristics of these 13 investigations were identified. Eight of the thirteen studies included diagnostic reliability checks, and three of these eight further included independent diagnostic interviews for every client to exclude false positive cases. Further methodological considerations such as blind assessors, balancing therapist caseload to prevent therapist effects (8 studies), strict treatment protocols (9 studies), and protocol adherence checks (8 studies) were also reported. Additionally, nine of the thirteen studies assessed nonspecific factors, including client perceptions of treatment credibility and outcome expectancies. Six of the studies reviewed allowed clients with concurrent medication use to participate, but most required clients to maintain their current dosage throughout the treatment period. Participants were, on average, in their late thirties, and approximately two-thirds were women. The average duration of GAD symptoms was 7 years. Treatment involved an average of 10.6 therapy sessions, and session length averaged 69 min.

Borkovec and Ruscio (2001) classified each of the treatment conditions into four groups: CBT package interventions, cognitive therapy only or behavior therapy

only, pill placebo or non-cognitive/behavioral alternative treatment (e.g., psychodynamic therapy, nondirective counseling/supportive listening, pharmacotherapy), and waiting-list or no treatment. As expected, CBT conditions produced the largest within-group effect sizes on both anxiety and depression measures. The next largest effect sizes were found for the alternative treatments, followed by the single-component cognitive or behavioral treatments. Not surprisingly, waiting-list and no treatment conditions did not produce changes over time. Unlike the previous Borkovec and Whisman (1996) review, Borkovec and Ruscio also calculated between-group effect sizes so that the effects of CBT could be contrasted with control condition effects. This meta-analysis revealed that CBT package treatments were superior to no treatment in all investigations (mean ES = 1.09 on anxiety measures post-treatment, mean ES = 0.92 on depression measures post-treatment). CBT also appeared superior to nonspecific or alternative treatment conditions post-treatment in 82% of the studies that examined this comparison (mean ES = 0.71 for anxiety, mean ES = 0.66 for depression). Finally, CBT outperformed cognitive therapy and behavior therapy single components in 20% of comparisons at post-treatment assessment (mean ES = 0.26 for both anxiety and depression measures separately). Fortunately, all 13 investigations reviewed included follow-up assessments, either 6 months or 12 months after treatment ended. Clinical improvements associated with active treatments were consistently maintained, or improved upon, at follow-up. Between-group effect sizes calculated with follow-up assessment data changed in opposing directions, depending on which treatments were selected for comparison. CBT appeared even more superior to cognitive or behavior therapy single component treatments at follow-up (mean ES = 0.54 for anxiety measures and mean ES = 0.45 for depression measures) than at post-treatment. However, effects sizes were lower at follow-up than at post-treatment when CBT was compared to placebo and alternative control treatments (mean ES = 0.30 for anxiety and mean ES = 0.21 for depression). Borkovec and Ruscio suggested that these effect size reductions may have been due to the fact that clients assigned to placebo conditions were more likely to seek additional treatment between post-treatment and follow-up assessment.

Updated CBT Meta-Analytic Review Results

Most recently, Gould et al. (2004) conducted a meta-analysis using similar methods to their original 1997 meta-analytic review. However, this updated review contained only 16 investigations because Gould and colleagues selected only those studies which included some form of cognitive-behavioral treatment. Thirteen of these investigations were included in their 1997 meta-analysis, and Gould et al. identified three additional studies conducted since their original review. Similar to the results of their previous meta-analysis, Gould et al. (2004) found a mean ES for all forms of CBT of 0.73 for anxiety measures and 0.77 for depression measures. Both of these effect size statistics were statistically significant when compared against the null hypothesis

predicting no increase in efficacy relative to the control conditions. When types of CBT interventions were examined further, CBT package treatments yielded a mean ES on anxiety measures of 0.90 and anxiety management training resulted in an average anxiety ES of 0.91. Relaxation training alone produced a mean ES of 0.64, cognitive therapy alone produced an average ES of 0.59, and interventions consisting of only behavior therapy techniques yielded a mean effect size of 0.51. Relaxation training combined with biofeedback produced a relatively small mean ES of 0.34. Two of the reviewed studies also included the pharmacological treatment diazepam, resulting in an average ES of 0.41 when compared to a pill placebo. CBT in these two studies produced a mean effect size of 1.26 when compared to pill placebo. Furthermore, the combination of CBT and diazepam greatly enhanced the effects of diazepam alone, but only appeared to increase the effects of CBT alone slightly.

Gould and colleagues concluded that CBT package treatments seem to produce the strongest treatment effects and may offer some advantage over single component cognitive or behavioral treatments. However, the clinical significance associated with such statistically significant findings is more difficult to ascertain. One of the earlier investigations reviewed (Butler et al. 1991) found that only 32% of clients who received CBT and 16% of clients who received behavior therapy met criteria for high end-state functioning. On the other hand, the more recent Ladouceur, Dugas, Freeston, Léger, et al. (2000) investigation found that 77% of participants no longer met GAD diagnostic criteria after CBT treatment ended. Furthermore, 62% of clients met additional high end-state functioning criteria. Most treatment gains were maintained at 6-month and at 12-month follow-up. The CBT intervention developed by Ladouceur and colleagues targeted core cognitive features including intolerance of uncertainty, worry beliefs, poor problem-solving orientation, and cognitive avoidance, and this particular CBT protocol also appears effective when delivered in a group format (Dugas, Ladouceur, Léger, Freeston, et al. 2003). In short, while various CBT treatments are likely to lead to clinical improvement, clients receiving these treatments do not always experience full recovery.

Additional GAD Treatment Research

A few recent GAD psychotherapy outcome investigations were not captured in the meta-analytic reviews described above. In their most recent randomized controlled trial of CBT, Borkovec and colleagues compared their full CBT package treatment to its two individual components (Borkovec, Newman, Pincus, & Lytle 2002). Öst and Breitholtz (2000) compared applied relaxation to cognitive therapy using a randomized design, but found little evidence that one treatment component was superior to the other. Arntz (2003) conducted a similar investigation and found similar results. However, methodological limitations leave some of the results obtained from these component control investigations difficult to interpret. Newer forms of treatment attempt to improve outcomes for individuals suffering from GAD further, and preliminary research on these new treatment developments are promising.

Component Analysis of CBT for GAD

In their most recent investigation, Borkovec and colleagues (2002) randomly assigned treatment-seeking participants diagnosed with GAD to one of three therapy conditions: cognitive therapy alone, applied relaxation with self-control desensitization, and a CBT package treatment including all of these components. A total of 76 clients received 14 weeks of individual therapy and were followed for a two-year follow-up period. All three therapy conditions produced strong therapeutic effects, but no group differences were found immediately following treatment or at any of the follow-up assessment periods. In addition, approximately half of these clients met stringent criteria for high end-state functioning at the end of treatment, many of whom maintained these gains over the two-year follow-up period. For example, over 56% of clients who received the full CBT package treatment met high end-state functioning criteria following treatment and 6 months later. This figure dropped to 43% 1 year after treatment and to 38% 2 years after treatment. Results from a measure of interpersonal problems suggested that interpersonal behavior may be an important additional treatment target for individuals with GAD. Neither CBT nor its individual components appeared to improve interpersonal functioning.

Borkovec and colleagues concluded that while CBT provides clinically significant benefit to many clients, further treatment development beyond the intrapersonally-oriented CBT approach is needed. Borkovec, Newman, and Castonguay (2003) have since integrated interpersonal and experiential therapy components into their current CBT for GAD. Preliminary research results for their newly developed “interpersonal/emotional processing” (I/EP) treatment for GAD are encouraging (Newman, Castonguay, Borkovec, & Molnar 2004). In an open trial, 18 clients meeting GAD criteria were treated with 15 sessions of this integrative treatment. Results suggested that interpersonal treatment components can be added to CBT successfully while maintaining therapeutic alliance and therapist credibility. Within-group effect sizes for treatment outcome were slightly larger than those found for traditional CBT. Currently, a large clinical trial is underway to examine the efficacy of this treatment further.

Comparisons Between Applied Relaxation and Cognitive Therapy

Öst and Breitholtz (2000) randomly assigned 36 treatment-seeking clients diagnosed with GAD to either applied relaxation or cognitive therapy treatment conditions. Clients received twelve sessions of individual therapy and were re-assessed following treatment and at one-year follow-up. Both treatments resulted in large clinical improvements that were maintained, and sometimes even furthered, 1 year later. No group differences on any of the outcome measures were found, perhaps because of the small sample size. Sixty-two percent of the cognitive therapy group met clinically significant change criteria post-treatment. By the 1-year follow-up period, this figure dropped to 56%. Among applied relaxation group participants, 53% met clinical significance criteria following treatment, and this figure increased to 67% at the follow-up assessment.

In a second study of this nature, Arntz (2003) randomly assigned 45 clients diagnosed with GAD to twelve sessions of either applied relaxation or cognitive therapy treatment. As expected, both treatments yielded improvements on clinical variables including measures of trait anxiety, fear, and depression. Between-group analyses demonstrated greater improvement for the applied relaxation group following treatment, but the two groups were equivalent at 6-month follow-up. At that time, 53% of clients who received applied relaxation and 55% of clients who received cognitive therapy had obtained clinically significant recovery.

Summary of Recent Research Findings and Future Directions

Results from these three investigations further support the efficacy of CBT, both as a package treatment and when broken down into its separate components. These results did not provide additional support for the combination of multiple cognitive and behavioral treatment components. However, important methodological factors should be considered when interpreting these results. Psychotherapy outcome research trials tend to involve relatively small sample sizes. This limitation may not allow for sufficient statistical power to detect small incremental effects of each therapy component. Indeed, Borkovec et al. (2002) argued that the lack of group differences found in their investigation may be attributed to the strength of the therapeutic effects generated by each therapy component condition. The more powerful meta-analytic statistical procedures utilized by Borkovec and Ruscio (2001) and by Gould et al. (2004) addressed this limitation. Results from both of those investigations did provide empirical support for the combination of therapy components seen in CBT package treatments. Despite significant advances in GAD treatment development, a large minority of clients do not reach high levels of end-state functioning. Further treatment development targeting additional clinical features, such as problematic interpersonal behavior patterns, may increase the efficacy of GAD treatment even more.

Newer psychosocial treatments for GAD have departed from traditional CBT procedures, and preliminary research support for these treatments has become available. For example, a Supportive-Expressive psychodynamic therapy developed specifically for GAD targets cognition and behavior surrounding interpersonal themes such as obtaining love, security, stability, or protection from others (Crits-Christoph, Crits-Christoph, Wolf-Palacio, Fichter, & Rudick 1995). This psychotherapy research group tested the effects of their treatment in an open trial investigation (Crits-Christoph, Connolly, Azarian, Crits-Christoph, & Shappell 1996). A total of 26 treatment-seeking clients diagnosed with GAD were included. Therapists were trained according to a treatment manual, and therapists successfully adhered to this therapy protocol with competence and fidelity. Clients demonstrated significant improvement on measures of anxiety, worry, depression, and interpersonal problems.

A meta-cognitive treatment for GAD recently received empirical support from an open trial as well. Wells and King (2005) provided this newly developed therapy to ten clients meeting DSM-IV diagnostic criteria for GAD. Clients attended a

range of three to twelve sessions targeting meta-cognitive factors such as counter-productive thought control strategies and negative beliefs about worry itself. Significant improvements following treatment were reported for all clients, and these improvements were maintained at 6- and 12- month follow-up for nine of the ten clients. In a final open trial conducted by Roemer and Orsillo (2007), sixteen clients diagnosed with GAD completed sixteen sessions of individual acceptance-based behavior therapy. This treatment integrated mindfulness training (Segal, Williams, & Teasdale 2002), Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, & Wilson 1999) and Dialectical Behavior Therapy (DBT; Linehan 1993) into an existing CBT treatment protocol based on the work of Borkovec and colleagues (2002). Significant improvements were found on a clinician-rated GAD symptom severity measure as well as self-report measures of anxiety, depression, experiential avoidance, and quality of life. Successful case study results were reported following Emotion Regulation Therapy (ERT; Mennin 2004), an integrative treatment that teaches clients adaptive emotion regulation skills and guides clients toward confrontation of core issues with experiential therapy techniques. Thus, a number of new treatments for GAD expand upon the traditional cognitive-behavioral approach. Additional information about the efficacy of these new interventions will become available as further treatment outcome research is conducted.

GAD Treatment for Older Adults

Unfortunately, much of GAD outcome research just described cannot be generalized readily to individuals outside the ages of 18–65. Not only were the majority of outcome measures originally developed for people ages 18–65, but anxiety can, and often does, present differently in child, adolescent, adult, and elderly populations (Alwahhabi 2003). Generalized anxiety disorder is one of the most frequent diagnoses among individuals over age 65, and GAD is three times more common than major depression in this age group (Blazer 1997; Beekman, Bremmer, Deeg, van Balkom, et al. 1998). Nearly half of elderly persons meeting diagnostic criteria for GAD developed the disorder later in life, but for those with an earlier symptom onset, a more severe course is typical (Le Roux, Gatz, & Wetherell 2005). Notable advances have been made in the areas of GAD treatment development and outcome research for elderly adults, although less empirical research targeting this special population is currently available.

Early Psychotherapy Outcome Research

Early controlled clinical trials examined the efficacy of CBT for anxiety symptoms among the elderly in the absence of diagnostic assessment. In their review of this literature, Stanley and Novy (2000) found consistent empirical support for the use of CBT treatments, particularly relaxation training, among older community volunteer

participants with various anxiety-related complaints. For example, Scogin, Rickard, Keith, Wilson, and McElreath (1992) compared four sessions of progressive relaxation training to an imaginal relaxation procedure. A wait-list control group was included as well. The sample consisted of 71 participants in their late sixties endorsing elevated subjective anxiety. Both relaxation conditions produced significant reductions in state anxiety levels compared to the wait-list control condition, and these gains were maintained at least 1 year following treatment (Rickard, Scogin, & Keith 1994). The attrition rate, however, was 24%, as only 54 of the original 71 participants completed treatment.

GAD Psychotherapy Outcome Research

A few controlled therapy trials since have been conducted with older participants diagnosed with GAD. In the first investigation of this nature (Stanley, Beck, & Glassco 1996), adults aged 55–81 received either CBT or a nondirective supportive therapy control treatment. Each treatment consisted of 14 weekly small group therapy sessions. Both therapy conditions produced significant changes on self-report as well as clinician-administered measures, and therapy gains were largely maintained or improved at 6-month follow-up. However, group differences on outcome measures were not found.

In a replication and extension of their initial outcome trial, Stanley and colleagues randomized 80 older adults (age 60 or over) to group-administered CBT or a minimal contact control condition (Stanley, Beck, Novy, Averill, et al. 2003). Results from both treatment completer and intent-to-treat analyses demonstrated that clients who received CBT experienced greater improvement across a variety of outcome measures compared to the control group. Although therapy gains were maintained at one-year follow-up and 45% of clients who received CBT were classified as treatment responders, clients did not return to normative levels of functioning.

In a third randomized psychotherapy outcome investigation of CBT for late-life GAD (Wetherell, Gatz, & Craske 2003), group-administered CBT was compared to a structured discussion control therapy as well as to a wait-list control group. Both therapies proved superior to the wait-list control condition, but no differences between the two therapy conditions were found by 6-month follow-up. However, only CBT produced large effect sizes following treatment (average $ES = 0.79$), whereas the discussion control group therapy yielded only small to medium-sized effects ($ES = 0.36$).

In each of these three investigations, the CBT protocol used was based on a cognitive-behavioral treatment for GAD developed for younger adults (e.g., Craske, Barlow, & O'Leary 1992) with only slight modifications for older adults. However, treatment was conducted in a small group format. Group treatment may be ideal for this population given that older adults frequently experience losses in their social networks (Wetherell, Hopko, Diefenbach, Averill, et al. 2005). Although group CBT treatments generally appear effective for older adults suffering from GAD, the

impact of such treatments may be significantly reduced among clients facing concurrent medical problems (Radley, Redston, Bates, Pontefract, & Lindesay 1997). Individual CBT also may be effective for older adults diagnosed with GAD. In a single-case experimental multiple-baseline design, Ladouceur and colleagues treated eight adults (age 60–71) diagnosed with GAD using an adapted version of their CBT protocol (Ladouceur, Léger, Dugas, & Freeston 2004). Seven of the eight participants improved significantly by the end of treatment, and these gains were maintained at six and 12-month follow-up.

Other Treatment-Related Research

Researchers also have identified specific variables that may be related to positive treatment response among older adults (Wetherell et al. 2005). Data from the three psychotherapy outcome projects described above were pooled and analyzed for investigation of outcome predictors (Stanley et al. 1996, 2003; Wetherell et al. 2003), resulting in a total sample of 65 adults with a mean age of 67 years. All three of these projects utilized the same treatment manual and inclusion/exclusion criteria. Demographic, clinical, treatment, and outcome variables were similar across all three projects. The CBT intervention was delivered in a group format and included psychoeducation, relaxation strategies, imaginal exposure, cognitive restructuring, and behavior modification. Results suggested that initial GAD severity, the presence of co-morbid conditions, and degree of engagement in homework exercises predicted treatment-related improvement in GAD severity, especially at 6-month follow-up.

Blazer (1997) suggested that in addition to standard CBT components, clinicians should consider including memory training when treating the elderly. Memory training is an intervention designed to improve memory or to adapt to existing memory difficulties (Yesavage, Sheikh, Tanke, & Hill 1988). Indeed, some research supports the modification of traditional CBT procedures when treating elderly clients. In a series of studies, Mohlman, Gorenstein, Kleber, De Jesus, et al. (2003) examined the effects of an individual CBT treatment specifically suited to older adults. This treatment included memory and learning aids, homework reminders, and weekly review sessions. Both standard CBT and enhanced CBT treatments resulted in decreased GAD frequency and severity. However, the enhanced CBT produced reductions on a broader variety of outcome measures than the standard CBT. Furthermore, the enhanced CBT produced greater effect sizes than the standard CBT when each active treatment was compared to a wait list control condition. Fifty percent of clients treated with standard CBT no longer met diagnostic criteria at the end of treatment, whereas 86% of clients who received the enhanced CBT no longer met criteria. Another modified CBT protocol was designed to accommodate sensory and cognitive challenges that are often present for older clients (Stanley, Hopko, Diefenbach, Bourland, et al. 2003). In a small pilot investigation, clients who received this modified CBT treatment showed statistically significant improvement when compared to clients in a treatment-as-usual control group.

Older adults taking anxiolytic medication for their anxiety symptoms may benefit from the combination of CBT and a medical management for medication taper intervention. Gorenstein, Kleber, Mohlman, De Jesus, et al. (2005) developed this intervention with the aim of reducing anxiety symptoms as well as anxiolytic medication dependence. Older adults who completed this combination intervention experienced greater improvements on psychological measures than clients randomized to a medical management only condition, and some of these gains were maintained at 6-month follow-up. Both client groups significantly reduced their medication usage. Gorenstein and colleagues concluded that CBT appears to alleviate anxiety symptoms, even as clients take steps to reduce anxiolytic medication.

A final possible treatment modification when working with elderly clients involves conducting treatment in the client's home. This option allows clients who are disabled or unable to travel access to treatment. Barrowclough, King, Colville, Russell et al. (2001) compared a standard CBT delivered in the home to a supportive counseling and empathetic listening control treatment. Fifty-five patients with a mean age of 72 meeting diagnostic criteria for GAD, panic disorder, social phobia, or anxiety disorder NOS were treated with 16 1-hour individual sessions. Clients in the CBT condition improved significantly more than clients randomized to the supportive counseling condition on measures of anxiety and depression immediately after treatment and at 1-year follow-up.

Taken together, these empirical research results suggest that older adults with GAD may benefit from a cognitive-behavioral treatment approach and that modifications to standard CBT protocols may increase the efficacy of these treatments further. Future efforts to improve CBT outcomes for older adults are certainly needed, however, as many older clients remain within the clinical range on psychopathology measures at the conclusion of treatment.

Chapter Summary

Many randomized controlled clinical trials have examined the efficacy of CBT for GAD over the past couple of decades. In their 1996 review, Borkovec and Whisman concluded that cognitive-behavioral treatments consistently produce significant therapeutic gains which typically are maintained at follow-up. The results of a meta-analysis conducted by Gould and colleagues (1997) suggested that CBT and pharmacotherapy yield roughly equivalent outcomes in the short term, but only the benefits associated with CBT maintain through follow-up periods. An updated meta-analysis of GAD psychotherapy outcome research (Borkovec & Ruscio 2001) further found that CBT consistently proved superior to no treatment and to nonspecific control conditions. CBT sometimes outperformed single cognitive or behavioral component treatments. In their updated meta-analysis of CBT for GAD research, Gould and colleagues (2004) also reported that CBT package treatments seem to produce the strongest treatment effects and may offer some advantage over single component cognitive or behavioral treatments. However, the clinical significance

associated with such statistically significant findings is difficult to ascertain, and many clients with GAD experience some benefit from CBT without returning to high levels of end-state functioning.

More recent treatment research (Borkovec et al. 2002) identified additional clinical problems associated with GAD that might be targeted in future psychotherapy protocols. This research group has integrated experiential and interpersonal therapy techniques into their traditional CBT for GAD with promising results (Newman et al. 2004). An interpersonally-oriented brief psychodynamic treatment (Crits-Christoph et al. 1996), a meta-cognitive therapy (Wells & King 2005), and an acceptance-based behavior therapy (Roemer & Orsillo 2007) also are gaining preliminary empirical support.

Most GAD treatment research was conducted with adult samples in the 18–65 age range. However, a growing interest in the nature and treatment of GAD among older adults has emerged. A few psychotherapy outcome investigations support the use of CBT protocols in the treatment of older adults. These outcomes might be further improved with slight modifications such as memory training, learning aids, homework reminders, weekly review sessions, and delivery of therapy sessions in the home.

Despite its limitations, CBT remains the psychosocial intervention for GAD with the greatest amount of empirical support. The combination of psychoeducation, applied relaxation training, cognitive therapy, and behavioral and imaginal exposure treatment components consistently has helped individuals suffering from this difficult to treat anxiety disorder. Nevertheless, additional treatment development efforts are needed to improve the efficacy of psychotherapy for GAD further. The forthcoming chapters of this book explain each of these cognitive-behavioral procedures in great detail, largely based upon the CBT for GAD developed by Borkovec and colleagues (2002). Additional suggestions for the integration of adjunct therapy techniques that may enhance the efficacy of traditional CBT are provided throughout these chapters as well.

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