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Psychosocial Treatment of Anxiety Disorders

Guest Editors–Edna B. Foa, PhD, and Martin E. Franklin, PhD

CME Mount Sinai
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Time for wakefulness

PROVIGIL® (modafinil) TABLETS
BRIEF SUMMARY: Consult Package Insert for Complete Prescribing Information
INDICATIONS and USAGE: To improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.
CONTRAINDICATIONS: Known hypersensitivity to PROVIGIL
PRECAUTIONS: ***General:*** Patients should be cautioned about operating an automobile or other hazardous machinery until they are reasonably certain that PROVIGIL therapy will not adversely affect their ability to engage in such activities.
Cardiovascular System: In clinical studies of PROVIGIL, signs and symptoms including chest pain, palpitations, dyspnea, and transient ischemic T-wave changes on ECG were observed in 3 subjects in association with mitral valve prolapse or left ventricular hypertrophy. It is recommended that PROVIGIL tablets not be used in patients with a history of left ventricular hypertrophy or ischemic ECG changes, chest pain, arrhythmia or other clinically significant manifestations of mitral valve prolapse in association with CNS stimulant use. Patients with a recent history of MI or unstable angina should be treated with caution. Periodic monitoring of hypertensive patients taking PROVIGIL may be appropriate.
Central Nervous System: Caution should be exercised when PROVIGIL is given to patients with a history of psychosis.
Patients with Severe Renal Impairment: Treatment with PROVIGIL resulted in much higher exposure to its inactive metabolite, modafinil acid, but not PROVIGIL itself.
Patients with Severe Hepatic Impairment: PROVIGIL should be administered at a reduced dose because its clearance is decreased.
Patients Using Contraceptives: The effectiveness of steroidal contraceptives may be reduced when used with PROVIGIL and for 1 month after discontinuation. Alternative or concomitant methods of contraception are recommended during and for 1 month after treatment.
Information for Patients: Physicians are advised to discuss the following with patients taking PROVIGIL:
Pregnancy: Animal studies to assess the effects of PROVIGIL on reproduction and the developing fetus were not conducted so as to ensure a comprehensive evaluation of the potential of PROVIGIL to adversely affect fertility, or cause embryolethality or teratogenicity. Patients should notify their physician if they become pregnant or intend to become pregnant during therapy. They should be cautioned of the potential increased risk of pregnancy when using steroidal contraceptives (including depot or implantable contraceptives) with PROVIGIL and for 1 month after discontinuation. ***Nursing:*** Patients should notify their physician if they are breast feeding. ***Concomitant Medication:*** Patients should inform their physician if they are taking or plan to take any prescription or over-the-counter drugs, because of the potential for drug interactions. ***Alcohol:*** It is prudent to avoid alcohol while taking PROVIGIL. ***Allergic Reactions:*** Patients should notify their physician if they develop a rash, hives, or a related allergic phenomenon.
Drug Interactions: ***CNS Active Drugs:*** In a single-dose study, coadministration of PROVIGIL 200 mg with *methylphenidate* 40 mg delayed the absorption of PROVIGIL by approximately 1 hour. The coadministration of a single dose of *clomipramine* 50 mg with PROVIGIL 200 mg/day did not affect the pharmacokinetics of either drug. One incident of increased levels of *clomipramine* and its active metabolite desmethylclomipramine has been reported. In a single-dose study with PROVIGIL (50, 100 or 200 mg) and *triazolam* 0.25 mg, no clinically important alterations in the safety profile of either drug were noted. In the absence of interaction studies with *monoamine oxidase (MAO) inhibitors*, caution should be exercised.
Potential Interactions with Drugs That Inhibit, Induce, or Are Metabolized by Cytochrome P-450 Isoenzymes and Other Hepatic Enzymes: Chronic dosing of PROVIGIL 400 mg/day resulted in ~20% mean decrease in PROVIGIL plasma trough concentration suggesting that PROVIGIL may have caused induction of its metabolism. Coadministration of potent inducers of CYP3A4 (eg, carbamazepine, phenobarbital, rifampin) or inhibitors of CYP3A4 (eg, ketoconazole, itraconazole) could alter the levels of PROVIGIL. Caution needs to be exercised when PROVIGIL is coadministered with drugs that depend on hepatic enzymes for their clearance; some dosage adjustment may be required. Potentially relevant *in vivo* effects of PROVIGIL based on *in vitro* data are:
A slight induction of CYP1A2 and CYP2B6 in a concentration-dependent manner has been observed.
A modest induction of CYP3A4 in a concentration-dependent manner may result in lower levels of CYP3A4 substrates (eg, cyclosporine, steroidal contraceptives, theophylline).
An apparent concentration-related suppression of expression of CYP2C9 activity may result in higher levels of CYP2C9 substrates (eg, warfarin, phenytoin).
A reversible inhibition of CYP2C19 may result in higher levels of CYP2C19 substrates (eg, diazepam, propranolol, phenytoin, S-mephenytoin).
In some patients deficient in CYP2D6, the amount of metabolism via CYP2C19 may be substantially larger. Co-therapy with PROVIGIL may increase levels of some tricyclic antidepressants (eg, clomipramine, desipramine).
Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis: The highest dose studied in carcinogenesis studies represents 1.5 times (mouse) or 3 times (rat) the maximum recommended human daily dose of 200 mg on a mg/m^2 basis. There was no evidence of tumorigenesis associated with PROVIGIL administration in these studies, but because the mouse study used an inadequate high dose below that representative of a maximum tolerated dose, the carcinogenic potential in that species has not been fully evaluated. ***Mutagenesis:*** There was no evidence of mutagenic or clastogenic potential of PROVIGIL. ***Impairment of Fertility:*** When PROVIGIL was administered orally to male and female rats prior to and throughout mating and gestation at up to 100 mg/kg/day (4.8 times the maximum recommended daily dose of 200 mg on a mg/m^2 basis) no effects on fertility were seen. This study did not use sufficiently high doses or large enough sample size to adequately assess effects on fertility.
Pregnancy: Pregnancy Category C: Embryotoxicity was observed in the absence of maternal toxicity when rats received oral PROVIGIL throughout the period of organogenesis. At 200 mg/kg/day (10 times the maximum recommended daily human dose of 200 mg on a mg/m^2 basis) there was an increase in resorption, hydronephrosis, and skeletal variations. The no-effect dose for these effects was 100 mg/kg/day (5 times the maximum recommended daily human dose on a mg/m^2 basis). When rabbits received oral PROVIGIL throughout organogenesis at doses up to 100 mg/kg/day (10 times the maximum recommended daily human dose on a mg/m^2 basis), no embryotoxicity was seen. Neither of these studies, however, used optimal doses for the evaluation of embryotoxicity. Although a threshold dose for embryotoxicity has been identified, the full spectrum of potential toxic effects on the fetus has not been characterized. When rats were dosed throughout gestation and lactation at doses up to 200 mg/kg/day, no developmental toxicity was noted post-natally in the offspring. There are no adequate and well-controlled trials with PROVIGIL in pregnant women. PROVIGIL should be used during pregnancy only if the potential benefit outweighs the potential risk.
Labor and Delivery: The effect of PROVIGIL on labor and delivery in humans has not been systematically investigated. Seven normal births occurred in patients who had received PROVIGIL during pregnancy.
Nursing Mothers: It is not known whether PROVIGIL or its metabolite are excreted in human milk. Caution should be exercised when PROVIGIL is administered to a nursing woman.
PEDIATRIC USE: Safely and effectiveness in individuals below 16 years of age have not been established.
GERIATRIC USE: Safety and effectiveness in individuals above 65 years of age have not been established.
ADVERSE REACTIONS: PROVIGIL has been evaluated for safety in over 2200 subjects, of whom more than 900 subjects with narcolepsy or narcolepsy/hypersomnia were given at least 1 dose of PROVIGIL. In controlled clinical trials, PROVIGIL was well tolerated, and most adverse experiences were mild to moderate. The most commonly observed adverse events (≥5%) associated with the use of PROVIGIL more frequently than placebo-treated patients in controlled US and foreign studies were headache, infection, nausea, nervousness, anxiety, and insomnia. In US controlled trials, 5% of the 369 patients who received PROVIGIL discontinued due to an adverse experience. The most frequent (≥1%) reasons for discontinuation that occurred at a higher rate for PROVIGIL than placebo patients were headache (1%), nausea (1%), depression (1%) and nervousness (1%). The incidence of adverse experiences that occurred in narcolepsy patients at a rate of ≥1% and were more frequent in patients treated with PROVIGIL than in placebo patients in US controlled trials are listed below. Consult full prescribing information on adverse events.
Body as a whole: Headache,[1] chest pain, neck pain, chills, rigid neck, fever/chills
Digestive: Nausea,[1] diarrhea,[1] dry mouth,[1] anorexia,[1] abnormal liver function,[2] vomiting, mouth ulcer, gingivitis, thirst
Respiratory system: Rhinitis,[1] pharyngitis,[1] lung disorder, dyspnea, asthma, epistaxis
Nervous system: Nervousness,[1] dizziness, depression, anxiety, cataplexy, insomnia, paresthesia, dyskinesia,[3] hypertonia, confusion, amnesia, emotional lability, ataxia, tremor
Cardiovascular: Hypotension, hypertension, vasodilation, arrhythmia, syncope
Hemic/Lymphatic: Eosinophilia
Special senses: Amblyopia, abnormal vision
Metabolic/Nutritional: Hyperglycemia, albuminuria
Musculo-skeletal: Joint disorder
Skin/Appendages: Herpes simplex, dry skin
Urogenital: Abnormal urine, urinary retention, abnormal ejaculation[4]
[1]Incidence ≥5%,[2] Elevated liver enzymes,[3] Oro-facial dyskinesias,[4] Incidence adjusted for gender.
Dose Dependency: In US trials, the only adverse experience more frequent (≥5% difference) with PROVIGIL 400 mg/day than PROVIGIL 200 mg/day and placebo was headache.
Vital Signs Changes: There were no consistent effects or patterns of change in vital signs for patients treated with PROVIGIL in the US trials.
Weight Changes: There were no clinically significant differences in body weight change in patients treated with PROVIGIL compared to placebo.
Laboratory Changes: Mean plasma levels of gamma-glutamyl transferase (GGT) were higher following administration of PROVIGIL but not placebo. Few subjects (1%) had GGT elevations outside the normal range. Shift to higher, but not clinically significantly abnormal, GGT values appeared to increase with time on PROVIGIL. No differences were apparent in alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, total protein, albumin, or total bilirubin. There were more elevated eosinophil counts with PROVIGIL than placebo in US studies; the differences were not clinically significant.
ECG Changes: No treatment-emergent pattern of ECG abnormalities was found in US studies following administration of PROVIGIL.
Postmarketing Reports
In addition to the adverse events observed during clinical trials, the following adverse events have been identified during post-approval use of PROVIGIL in clinical practice. Because these adverse events are reported voluntarily from a population of uncertain size, reliable estimates of their frequency cannot be made.
Hematologic: Agranulocytosis
Central Nervous System: Symptoms of psychosis, symptoms of mania
DRUG ABUSE and DEPENDENCE: Abuse Potential and Dependence: In addition to wakefulness-promoting effect and increased locomotor activity in animals, in humans, PROVIGIL produces psychoactive and euphoric effects, alterations in mood, perception, thinking, and feelings typical of other CNS stimulants. *In vitro,* PROVIGIL binds to the dopamine reuptake site and causes an increase in extracellular dopamine but no increase in dopamine release. PROVIGIL is reinforcing, as evidenced by its self-administration in monkeys previously trained to self-administer cocaine. In some studies PROVIGIL was also partially discriminated as stimulant-like. Physicians should follow patients closely, especially those with a history of drug and/or stimulant (eg, methylphenidate, amphetamine, or cocaine) abuse. Patients should be observed for signs of misuse or abuse (eg, incrementation of doses or drug-seeking behavior). In individuals experienced with drugs of abuse, PROVIGIL produced psychoactive and euphoric effects and feelings consistent with other scheduled CNS stimulants (methylphenidate). Patients should be observed for signs of misuse or abuse.
Withdrawal: Following 9 weeks of PROVIGIL use in 1 US trial, no specific symptoms of withdrawal were observed during 14 days of observation, although sleepiness returned in narcoleptic patients.
OVERDOSAGE: Human Experience: A total of 151 doses of ≥1000 mg/day (5 times the maximum recommended daily dose) have been recorded for 32 individuals. Doses of 4500 mg and 4000 mg were taken intentionally by 2 patients participating in foreign depression studies. In both cases, adverse experiences observed were limited, expected, and not life-threatening, and patients recovered fully by the following day. The adverse experiences included excitation or agitation, insomnia, and slight or moderate elevations in hemodynamic parameters. In neither of these cases nor in others with doses ≥1000 mg/day, including experience with up to 21 consecutive days of dosing at 1200 mg/day, were any unexpected effects or specific organ toxicities observed. Other observed high-dose effects in clinical studies have included anxiety, irritability, aggressiveness, confusion, nervousness, tremor, palpitations, sleep disturbances, nausea, diarrhea, and decreased prothrombin time. **Overdose Management:** No specific antidote to the toxic effects of PROVIGIL overdose has been identified. Overdoses should be managed with primarily supportive care, including cardiovascular monitoring. Emesis or gastric lavage should be considered. There are no data suggesting that dialysis or urinary acidification or alkalinization enhance drug elimination. The physician should consider contacting a poison-control center on the treatment of any overdose.
Manufactured for: **Cephalon, Inc.,** West Chester, PA 19380
For more information about PROVIGIL, please call Cephalon Professional Services at 1-800-896-5855 or visit our Website at **www.PROVIGIL.com.**

PROVIGIL® (MODAFINIL) C-IV Tablets

Cephalon

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Author Guidelines

Introduction

CNS Spectrums is an *Index Medicus* journal that publishes original scientific literature and reviews on a wide variety of neuroscientific topics of interest to the clinician. *CNS Spectrums* will publish 12 issues in 2003. As the immense prevalence of comorbid diseases among patients seen by psychiatrists and neurologists increases, these physicians will jointly diagnose and treat the neuropsychiatrically ill. Our mission is to provide these physicians with an editorial package that will enhance and increase their understanding of neuropsychiatry; therefore, manuscripts that address crossover issues germane to neurology and psychiatry will be given immediate priority.

Scope of Manuscripts

CNS Spectrums will consider the following types of articles for publication:

Original Research: Original Research present methodologically sound original data.

Reviews: Reviews are **comprehensive** articles that summarize and synthesize the literature on various topics in a scholarly and clinically relevant fashion. Suitable topics include mood disorders, schizophrenia and related disorders, personality disorders, substance-use disorders, anxiety disorders, neuroscience, psychosocial aspects of psychiatry, child psychiatry, geriatric psychiatry, and other topics of interest to clinicians. Original flowcharts designed to aid the clinician in diagnosis and treatment will be considered for publication in reviews and are encouraged.

Case Reports: Single or multiple case reports will be considered for publication.

Letters to the Editor: Letters will be considered for publication.

Manuscript Submission

General information: Two copies of the manuscript with a letter on the author's letterhead should be submitted to Jack M. Gorman, Editor (or, in Europe, to Joseph Zohar, International Editor), c/o MBL Communications, 333 Hudson Street, 7th Floor, New York, NY 10013; (F) 212.328.0600. Authors are also required to submit their manuscripts on computer disk in Microsoft Word format. Disks should be labeled with the word processing program, title of paper, and lead author's name. Accepted manuscripts and letters will be edited for clarity and style.

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Peer review: Authors must provide five names of particularly qualified potential reviewers with no conflict of interest in reviewing the work. Contact information, including complete address, phone, fax numbers, E-mail address, and affiliations, should be included. The corresponding author will be notified by the editors when a decision regarding acceptance has been made. Peer review is anonymous.

Manuscript Preparation

Length: Reviews and Original Research should not exceed 5,000 words (excluding References). Letters should not exceed 1,500 words. Single Case Reports should not exceed 3,750 words and may be submitted with a photograph, if applicable. Diagnostic/treatment algorithms (see Reviews) should contain an extensive introduction, flowchart or series of graphs that fill 8–12 journal pages, and a concise summary.

Please note: If your article is **Original Research,** it should be formatted as: Abstract (100–200 words); Introduction, Materials/Methods; Results; Discussion; Conclusion; References (numbered and comprehensive list).

Spacing: One space should be left after commas and periods. Manuscripts should be double-spaced.

Abstract: Authors must provide a brief abstract.

Focus/Talking Points: Please provide three to six points that dictate the main focus of the manuscript, similar to teaching objectives, in bulleted format. These take-home points should clearly illustrate what you are trying to convey in the article.

References: American Medical Association style. See the following examples:

1. Jones J. Necrotizing Candida esophagitis. *JAMA.* 1980;244:2190-2191.
2. Stryer L. *Biochemistry.* 2nd ed. San Francisco, Calif: WH Freeman Co; 1980:559-596.

Continuing Medical Education: Authors must submit four multiple-choice questions (two Type A and two Type K), with answers.

Copyright: Materials are accepted for exclusive publication in *CNS Spectrums* and become the property of *CNS Spectrums.* Permission to reproduce material must be obtained from the publisher.

Disclosure of Commercial Interests

Authors must include a statement about all forms of support, including grant and drug company support. Such information may, at the editor's discretion, be shared with reviewers. If the article is accepted for publication, the editors will consult with the authors as to whether this information should be included in the published paper.

Submission Checklist

- ☐ Original manuscript plus one copy, with cover letter on author's letterhead
- ☐ Copies of permission letters to reproduce previously published and unpublished material
- ☐ A brief abstract of the article
- ☐ Four CME multiple-choice questions with answers
- ☐ Three to six focus points
- ☐ Disk labeled with the word processing program, title of paper, and lead author's name
- ☐ Names and addresses of two potential reviewers

Time for wakefulness

A unique wake-promoting agent

PROVIGIL promotes daytime wakefulness, improving patients' ability to participate in daily activities—with no effect on nighttime sleep.[1-3]

Long-term safety

The long-term safety profile of PROVIGIL has been demonstrated for up to 136 weeks.[4]

PROVIGIL was generally well tolerated. Most frequently reported adverse events in clinical trials were headache, nausea, nervousness, anxiety, infection, and insomnia. Most adverse events were mild to moderate. PROVIGIL may interact with drugs that inhibit, induce, or are metabolized by cytochrome P450 isoenzymes.

Dosing

Recommended dose for PROVIGIL is 200 mg taken orally once daily in the morning. Both PROVIGIL doses, 200 mg and 400 mg QD, were effective.

PROVIGIL is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy.

References: 1. PROVIGIL full prescribing information. **2.** US Modafinil in Narcolepsy Multicenter Study Group. Randomized trial of modafinil for the treatment of pathological somnolence in narcolepsy. *Ann Neurol*. 1998;43:88-97. **3.** US Modafinil in Narcolepsy Multicenter Study Group. Randomized trial of modafinil as a treatment for the excessive daytime somnolence of narcolepsy. *Neurology*. 2000;54:1166-1175. **4.** Data on file, Cephalon, Inc.

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Tablets

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EDITORIAL MISSION

CNS Spectrums' *editorial mission is to address relevant neuropsychiatric topics, including the prevalence of comorbid diseases among patients, and original research and reports that emphasize the profound diagnostic and physiologic connections made within the neurologic and psychiatric fields. The journal's goal is to serve as a resource to psychiatrists and neurologists seeking to understand and treat disturbances of cognition, emotion, and behavior as a direct consequence of central nervous system disease, illness, or trauma.*

POSTTRAUMATIC STRESS DISORDER IN VICTIMS OF CHILD SEXUAL ABUSE AND THE EFFICACY OF COGNITIVE-BEHAVIORAL THERAPY

page 340

"In order to explore which of the subscales contributed to the group differences, the MANOVAs were repeated for the constituent subscales of the Trauma and Self factors. The Trauma factor includes intrusive experiences, defensive avoidance, dissociation, and impaired self-reference. These subscales were subjected to a repeated measures MANOVA, which resulted in a significant assessment period effect, $F_{(8,444)}$=24.9, Pillai's trace=.62, P=.000, but no interaction and only a trend for a group main effect (P=.07)."

TESTING LONG-TERM EFFECTS OF EXPOSURE AND RITUAL PREVENTION AND MEDICATION TREATMENTS FOR OBSESSIVE-COMPULSIVE DISORDER

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"We conducted a one-way MANOVA on follow-up measures using data from the medication-free patients. This analysis revealed a significant effect of treatment group (based on Wilk's λ) $F_{(12,50)}$=2.00, P<.05. Univariate ANOVA revealed a significant main effect of treatment on assessor-rated fear ($F_{(2,33)}$=6.61, P<.005), assessor-rated ritual ($F_{(2,34)}$=7.75, P<.005), and Y-BOCS compulsions ($F_{(2,33)}$=6.25, P<.01). A trend in the same direction was found for Y-BOCS obsessions (P<.09). There were no differences in assessor-rated avoidance or HAM-D scores. Post hoc analyses using the Student-Newman-Keuls test indicated that for Y-BOCS compulsions and assessor-rated rituals, the EX/RP and EX/RP-plus-medication groups were rated as significantly less severe than the SRI-only group. In the case of assessor-rated fear, the EX/RP plus medication group was rated as less severe than either the EX/RP-alone or medication-alone groups, which did not differ from one another. ANOVA comparing follow-up scores of patients on medications (15 patients originally treated with an SRI alone and 9 treated with EX/RP plus medication) failed to demonstrate group differences."

TREATMENT COMPONENTS, TREATMENT VARIATIONS, AND OUTCOMES IN PANIC DISORDER

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"The apparent ability of CBT to confer longer-term advantages with brief treatment is a central strength of the approach for efficacy estimates. Certainly, this perspective is supported by the overall performance of patients as assessed in meta-analytic studies. It is also supported by direct analysis of costs of and outcome in a specialty anxiety clinic offering treatment with either CBT or psychopharmacology specialists. Consistent with the controlled treatment-outcome literature, Otto and colleagues found that clinic treatment by these specialists resulted in approximately equal outcome. Examination of the costs of the treatments indicated that individual CBT was somewhat more costly than pharmacotherapy during the acute 4-month treatment phase, but then quickly makes up its initial costs over follow-up, so that by 1 year it was found to be roughly half as costly as pharmacotherapy. Group treatment provided a more extreme example, with cost savings relative to pharmacotherapy starting in the acute treatment phase and extending forward, so that it was less than 25% of the costs of pharmacotherapy by the end of the 1-year study."

THE PRESENT STATUS AND POSSIBLE NEW DEVELOPMENTS IN TREATING SOCIAL ANXIETY DISORDER

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"Exposure exercises are most effective when patients' psychological engagement in the feared situation is maximized, that is, when they pay full attention to the situation and allow the inevitable rush of anxiety and arousal to occur. However, anxious patients may try to distract themselves from the feared situation as it unfolds, or their tendency to focus attention on the threatening aspects of the situation may prevent them from attending to what is actually happening. Therefore, instructions to maintain focus on the feared situation are an important component of, and increase the efficacy of, exposure techniques."

INTEGRATING THERAPIES FOR THE TREATMENT OF GENERALIZED ANXIETY DISORDER

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"Within individual studies, CBT has been found superior to waiting-list no-treatment conditions in all seven investigations that have employed this control condition. Between-group effect sizes have averaged 1.09 at post-therapy among such studies. Although no follow-up data for comparison are available on no-treatment conditions due to patients receiving therapy at the end of the post-assessment period, CBT conditions have routinely maintained or increased their degree of improvement at the 6-month or 12-month follow-up assessments commonly reported in these investigations. CBT also has been found superior to the various conditions controlling for nonspecific factors in 9 out of 11 such comparisons at posttherapy and 7 out of 9 comparisons at follow-up. Between-group effect sizes in these latter studies have averaged 0.71 at post-therapy and 0.30 at follow-up. Less clarity has emerged from comparisons of CBT to one or more of its therapy components. CBT superiority has been found in only 2 out of 11 such comparisons at posttherapy and 3 out of 8 comparisons at follow-up." CNS

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Feature Articles

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