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Mind-Body Interventions for Gastrointestinal Conditions

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 6010 Executive Blvd., Suite 300, Rockville, MD 20852.

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Structured Abstract

Objectives. The objective of this evidence report was to conduct a search of the literature on the use of all mind-body therapies for the treatment of health conditions and, on the basis of that search, to choose either a condition or a mind-body modality for a comprehensive review. The health condition chosen, based on the results of an initial search, was gastrointestinal problems. The specific questions addressed in this project were: (1) What mind-body therapies have been used in the literature, for which body systems/conditions, and using what kind of research design? (2) What is the efficacy of mind-body therapies for the treatment of gastrointestinal problems?

Search strategy. A research librarian performed an initial database search of MEDLINE[®], HealthSTAR, EMBASE[®], Allied and Complementary Medicine[™], MANTIS[™], PsycINFO[®], Social Science Citation Index[®], two files of Science Citation Index[®], and CINAHL[®]. We used “mind/body relations (metaphysics)” and “mind body therapies” as the MeSH term and a set of synonyms for mind-body. A more focused search was conducted for gastrointestinal health problems and mind-body.

Selection criteria. The literature search was confined to those mind-body therapies currently recognized as such by the National Center for Complementary and Alternative Medicine (NCCAM). In the initial search, all studies focusing on mind-body therapies were included. Those studies that focused on gastrointestinal (GI) problems were then identified. The mind-body therapies documented in the literature for treating GI problems included: behavioral therapy, biofeedback, cognitive therapy, guided imagery, hypnosis, placebo, relaxation therapy, and multimodal therapy.

Data collection and analysis. All titles, abstracts, or articles were reviewed by two independent reviewers and entered into a database. The titles/or abstracts/or articles were analyzed and synthesized into a descriptive report. Particular attention was paid to the mind-body modality used, the target body systems/conditions, the outcomes measured, and the type of study design used. An in-depth analysis was conducted on those studies that focused on GI conditions. We identified 53 GI studies that included a concurrent comparison group. Because of the clinical heterogeneity of these trials, however, we did not conduct a meta-analysis. Instead, a qualitative synthesis was conducted.

Main results. In the search of mind-body studies, the most common body systems/conditions for which mind-body therapy literature was found are: neuropsychiatric; head/ear, nose, and throat (head/ENT); gastrointestinal; circulatory; and musculoskeletal. Regarding therapies, the most common ones for which published studies were found were: biofeedback, hypnosis, relaxation, behavioral, and cognitive. For GI conditions, the most commonly studied mind-body therapy was biofeedback (n = 22), and the most commonly studied conditions were irritable bowel syndrome (n = 15), followed by fecal incontinence/encopresis (n = 11). Studies with a comparison group were reviewed for biofeedback (n = 17), hypnosis (n = 8), relaxation therapy (n = 8), behavioral therapy (n = 8), multimodal therapy (n = 4), cognitive therapy (n = 4), guided imagery (n = 2), and placebo (n = 1).

Eleven of the biofeedback studies had a no biofeedback comparison group, and two reported a significant benefit from biofeedback. These studies were of adults with fecal incontinence and nausea/vomiting following chemotherapy. In the remaining nine biofeedback trials, seven of which were on children, biofeedback was not reported to have any benefit. There were seven studies of hypnosis that had a no hypnosis comparison group, six of which reported a significant benefit (for irritable bowel syndrome, two studies; nausea/vomiting, two studies; duodenal ulcer, one study; and ulcerative colitis, one study). Six of the eight relaxation-therapy controlled trials reported a significant benefit for irritable bowel syndrome (two studies), nausea/vomiting (two studies), ulcer (one study), and GI distress (one study). For the eight studies in behavioral therapy, six studies with a no behavioral therapy comparison group reported a significant benefit for encopresis (one study), nausea/vomiting (two studies), irritable bowel syndrome (two studies), and abdominal pain (one study). In cognitive therapy, four studies, all with a no cognitive therapy comparison group, reported a significant benefit. These were for irritable bowel (three studies) and ulcer (one study). In guided imagery therapy, one out of two studies with a no imagery comparison group reported a significant benefit. In placebo therapy there was only a single study. Four studies using a multimodal intervention, which does not enable a conclusion about individual therapies, were also reviewed.

Conclusions. There are limited data to support the efficacy of relaxation therapy, behavioral therapy, cognitive therapy and guided imagery as therapy for certain gastrointestinal conditions. There is no evidence to support the efficacy of biofeedback for children with gastrointestinal conditions, while for adults the evidence is mixed. The studies of hypnosis are limited by methodologic problems and no conclusions can be drawn.

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Summary

Overview

The objective of this evidence report was to search the literature on the use of mind-body therapies for the treatment of health conditions and, on the basis of this search, to choose either a condition or mind-body modality for a comprehensive review. A broad search of mind-body therapies showed that there were sufficient studies regarding their use for gastrointestinal (GI) conditions to warrant a detailed review. GI conditions pose a significant health problem, and they can be challenging to manage. They also have been the focus of mind-body interventions, including: behavioral therapy, biofeedback, cognitive therapy, guided imagery, hypnosis, meditation, placebo therapy used as an intervention, relaxation therapy, and multimodal therapy. However, no studies of meditation were found that used a comparative treatment design. Therefore, this report reviews the use of behavioral therapy, biofeedback, cognitive therapy, guided imagery, hypnosis, placebo therapy, relaxation therapy, and multimodal therapy for the treatment of GI conditions.

Reporting the Evidence

The purpose of this work is to identify those mind-body therapies that have empirical support of efficacy. Such information can be used to help health care providers care for patients with GI conditions and to identify future research needs. The specific questions addressed in this report are:

- (1) *What mind-body therapies have been reported in the literature, for which body systems/conditions, and using what kind of research design?*
- (2) *What is the efficacy of mind-body therapies for the treatment of gastrointestinal conditions?*

An initial broad search of the mind-body literature yielded 2460 titles, of which 690 were judged possibly relevant to our investigation based on the use of a short screening form. This form screened for source of the article, subject, language, focus, body system, outcomes, modalities used, human/animal subjects, and study type. To answer our first major research question and to describe the basic characteristics of the published mind-body literature, we assessed these accepted articles for their target body systems or health conditions, for the mind-body modalities used, and for the study design. To answer our second research question, we further assessed this abridged group of articles and identified 53 studies of GI conditions that included a mind-body therapy in a trial. These studies provided evidence regarding the efficacy of mind-body therapies for the treatment of GI conditions.

Methodology

A panel of technical experts representing diverse disciplines was established to advise us throughout the course of our research.

We searched the literature using the following online databases: MEDLINE[®], HealthSTAR, EMBASE[®], PsycINFO[®], Allied and Complementary Medicine[™], MANTIS[™], *Psychological Abstracts*, Social Science Citation Index[®], two files of Science Citation Index[®], and CINAHL[®].

We used the following MeSH terms: mind/body metaphysics, mind body therapies, mind/body medicine, mind/body wellness, bodymind medicine, mind/body therapies, psychosomatics/psychosomatic/psychosomatic medicine, wisdom of the body, self healing, placebo, healing force of nature, healing consciousness, biopsychosocial, psychoneuroimmunology¹, and wellness. We further restricted the search by including terms for selected mind-body modalities as defined by the National Center for Complementary and Alternative Medicine (NCCAM) plus terms that would identify research reporting any outcomes.

There was no language restriction. Additional articles were identified from citations of articles, particularly review articles, and citations suggested by external reviewers. All titles, abstracts, and articles were reviewed by two reviewers, whose disagreements were resolved by consensus.

We collected data on the articles generated by this search regarding body system, mind-body modality, and study design with a screening form developed for this purpose. We used titles, abstracts, and/or articles to collect this information. We analyzed these data, reported on the general characteristics of the field of mind-body research, and used this analysis to inform our selection of a topic for a focused review.

We then conducted a focused literature search on mind-body therapies specifically for the treatment of GI conditions, searching the same databases used for the earlier search. In addition to the mind-body search terms, we also used the more general “outcomes” terms for GI conditions. We collected data for these new articles using the same review technique employed in the initial search.

We selected all studies identified in either the initial or the focused search that studied GI conditions using a controlled study design with a concurrent comparison group. This yielded 53 GI studies that were then reviewed in-depth. However, because of the clinical heterogeneity of these trials, we did not conduct a meta-analysis. Instead, a qualitative analysis was conducted on these studies.

Findings

- The five most common body systems/conditions for which mind-body therapy literature was found are: neuropsychiatric; head/ear, nose, and throat (head/ENT); GI; circulatory; and musculoskeletal.
- The trials that exist on GI conditions are seriously limited by methods problems (small sample sizes, lack of randomization, and clinical heterogeneity).
- The greatest number of trials of a mind-body therapy for GI conditions in trials was biofeedback (n = 17).

¹ Psychoneuroimmunology is such a vast field in its own right that we confined our focus to those articles that either specifically indicate a mind-body therapy or indicate a specific diagnosis with psychoneuroimmunology.

- There are fewer controlled trials in the GI studies that assess other mind-body therapies: hypnosis (n = 8), relaxation (n = 8), behavioral therapy (n = 8), multimodal therapy (n = 4), cognitive therapy (n = 4), imagery (n = 2), and placebo (n = 1).
- The most commonly studied GI conditions were irritable bowel syndrome (n = 15), fecal incontinence/encopresis (n = 11), constipation (n = 10), vomiting (n = 8), nausea (n = 7), and abdominal pain (n = 5).
- There is no evidence to support the efficacy of biofeedback therapy for children.
- There is limited evidence (i.e., at least one trial whose quality score characterized it as “good” that reported statistically significant benefits and the majority of other studies also report statistically significant benefits) to support the efficacy of the following mind-body therapies:
 - > Behavioral
 - > Cognitive
 - > Guided imagery
 - > Relaxation
- The methodological shortcomings of studies reporting beneficial effects of hypnosis preclude drawing conclusions about its efficacy.
- Results are mixed regarding the use of biofeedback in adults.

Future Research

Future mind-body research needs to be better designed and implemented. Studies need to enroll adequate numbers of well-defined, clinically homogeneous populations, and they need to compare the mind-body therapy both to other potentially effective therapies and to a convincing control. They should employ randomization, use blinding where feasible, and measure outcomes that are meaningful to patients and that can be reliably assessed. Ultimately, only those studies with a control group for comparative analysis can address the question of the efficacy of mind-body therapies. A more focused research program might overcome the problem of too few studies found on too many GI conditions and variable patient populations.

Evidence Report

Chapter 1. Introduction

Purpose

This evidence report details the methodology, results, and conclusions of a literature search on the use of mind-body therapies for the treatment of gastrointestinal (GI) conditions. The mind-body therapies documented in the literature included: behavioral therapy, biofeedback, cognitive therapy, guided imagery, hypnosis, meditation, placebo therapy, and relaxation therapy. The purpose of this work is to identify those therapies that have empirical support of efficacy. Such information can be used to help health care providers care for GI conditions and to identify future research needs. The specific questions addressed in this report are:

- (1) *What mind-body therapies have been reported in the literature, for which body systems/conditions, and using what kind of research design?*
- (2) *What is the efficacy of mind-body therapies for the treatment of gastrointestinal conditions?*

Scope of Work

The work initially involved a survey of the literature on mind-body research for clinical conditions. From this initial review we were able to identify the number of studies done on given conditions, the therapy used, and the probable type of study design utilized. Following discussions with our expert advisory panel and with the agencies funding and administering the project (National Center for Complementary and Alternative Medicine [NCCAM]; Agency for Healthcare Research and Quality [AHRQ]), the focus was narrowed to the use of mind-body therapies for gastrointestinal conditions. This decision was based on the expectation that the quantity and quality of the evidence would be sufficient to support a systematic review.

Mind-Body Defined

Mainstream mind-body medicine, as defined by Chiaramonte (1997, p. 788), is “based on the premise that mental or emotional processes (the mind) can affect physiologic function (the body).” Lazar (1996) elaborates on this point further, saying that mind-body medicine is an integrative discipline that examines the relationship between psychological states and psychological interventions and between physiology and pathophysiological processes. On the other hand, most practitioners of complementary and alternative medicine (CAM)—which takes a different approach to mind-body medicine—hold that the mind’s impact on the body is not unidirectional; rather, there is an integrated process in which both mind and body affect each other (Achterberg, Dossey, Gordon et al., 1992).

A number of studies have implicated the mind as being the cause of or contributing to several disease states, including cardiovascular disease, pain (both acute and chronic), cancer, and gastrointestinal disorders (Meersin, 1994; Rosenman et al., 1964; Stuart et al., 1987; Williams et al., 1980; Caudill et al., 1991; Whitehead and Schuster, 1985; Whitehead, 1992;

Greer, 1991; Levy et al., 1987). Although there is sufficient evidence to support a relationship between the mind (mental/cognitive/emotional functions) and the physical body, our scientific understanding of the intricate details of how the two interrelate remains unclear. As a scientific pursuit, mind-body medicine tries to elucidate this relationship with the aim of harnessing it to treat and prevent disease. Its treatment methods thus use the mind to alter physiology in order to promote health and include relaxation exercises, meditation, and hypnosis. Psychosomatic medicine can also be considered a form of mind-body medicine; likewise, psychoneuroimmunology, which is the investigation of pathways via hormones, neuropeptides, and cytokines that connect the mind and body.

There are some important differences between the mainstream approach and the CAM approach to mind-body medicine. Mainstream mind-body research attempts to isolate the specific outcomes of specified mind-body therapies such as meditation. CAM, however, goes one step further and frames mind-body medicine within the context of the human factors in healing, such as “closeness, caring, compassion, and empathy between the therapist and patient” (Achterberg, Dossey, Gordon et al., 1992). These different approaches to mind-body medicine also give rise to differences in what constitutes a successful outcome for treatment. With mainstream medicine, the looked-for outcomes are the same as for any clinical research: the diminution or eradication (curing) of a disease state and the promotion of health. With CAM, the outcome may not involve eradication of the disease but simply a “profound sense of psychological or spiritual well-being and wholeness” (Achterberg, Dossey, Gordon et al., 1992, p. 4)—that is, healing as opposed to curing. These differences can be summed up by saying that mainstream mind-body medicine is more focused on *treatment* (i.e., objective outcomes), while CAM is more focused on *care* (i.e., process). Most of the studies reviewed in this report focused on treatment.

Review Scope

After discussions with NCCAM and AHRQ, we decided to confine our review to those modalities recognized by NCCAM as mind-body. They include art therapy, biofeedback, counseling, dance therapy, guided imagery, humor therapy, hypnotherapy, meditation, music therapy, prayer therapy, psychotherapy, relaxation therapy, support groups, and yoga. NCCAM defines these therapies as techniques that “involve exploring the mind’s ability to affect the body. This is based on traditional principles on how the mind and body are interlinked.” We further restricted our review to those therapies that involve a clinical intervention with some form of mind-body therapy. They include relaxation, meditation, imagery/visualization, hypnosis, and biofeedback. Since both psychoneuroimmunology and psychotherapy are disciplines in their own right and have extensive bodies of literature, they have also been included in this review, but only if they specifically identify a mind-body therapy as specified by NCCAM. Moreover, NCCAM also wished to exclude from this review pain as the primary or only outcome measure for biofeedback.

It should be kept in mind that a complicating factor in defining the therapies discussed here is that they are so often used together. Biofeedback can be used as an adjunct to other therapies; hypnosis makes extensive use of relaxation methods to achieve the trance state; relaxation, in turn, uses meditation to achieve its goals; and virtually all of these modalities use some form of imagery. Cognitive therapy and behavioral therapy have even fused into a single intervention—cognitive-behavioral therapy.

Mind-Body Modalities

In our review of the literature, the following mind-body therapies were identified as having controlled trials, either by themselves or in combination.

Behavioral Therapy

Behavioral therapy uses behavior modification for the treatment of health problems. It makes a distinction between disease and illness, the latter referring to the *sick role*, that is, the socially determined behaviors that go with a disease and which may be as debilitating as the disease. Thus, therapy is focused on changing the sick role behaviors. A behavioral therapy known as *systematic desensitization*, introduced by Wolpe (1958), has become one of the most common treatments of phobias. Other examples of behavioral therapy include aversion therapy (Panconesi, Gallassi, Sarti et al., 1999) as well as the development of problem-solving skills, stress inoculation (Beck and Fernandez, 1998), social skills training, marital therapy, and reinforcement (Bowers and Clum, 1988).

The expected outcome of behavioral therapy is documented changes in actual behavior (Lipsey and Wilson, 1993). Frequently, behavioral therapy is focused on behavioral risk factors, such as smoking, that are thought to be causally related to illness (Garrick and Loewenstein, 1989). A clean definition of behavioral therapy is complicated by the fact that it is frequently combined with cognitive approaches and will include relaxation and biofeedback.

Biofeedback

Biofeedback provides information to a patient about a targeted physiologic process that enables the individual to control that process (Wald, 1981) through mental activity (Stamatiadis and Polimeneas, 1997). Consequently, the patient gains voluntary control over processes that may not be consciously monitored. A form of psychophysiological self-regulation (Green and Shellenberger, 1999), biofeedback usually provides a patient with visual or auditory signals that can supply information about minute physiologic changes and the intensity of functions. These signals also give instant feedback to the patient on their efforts to control or alter the target function. Biofeedback has been used to teach muscle control and to modify autonomic dysfunction associated with blood pressure, pulmonary, and vascular disease (van der Plas, Benninga, Buller et al., 1996). Biofeedback is frequently used as an adjunct to other therapies. For at least one author (Olson, 1995), biofeedback excludes physiological self-regulation that does not use external instrumentation and feedback (such as relaxation therapy, hypnosis, meditation, and imagery).

Schwartz and Schwartz (1993) describe five different types of biofeedback:

- (1) Electromyographic (EMG) biofeedback—measures muscle tension.
- (2) Thermal biofeedback—measures temperature of skin.
- (3) Electrodermal activity (EDA)—measures minute changes in sweat activity..
- (4) Finger pulse—measures pulse rate and force.
- (5) Breathing—measures breathing rate, volume, rhythm, and location (chest vs. abdomen).

Cognitive Therapy

Cognitive therapy is based on the principles of cognitive psychology. Cognition refers to people's thoughts—in particular, to the way people think about their illness—which can have a profound effect on their physical state. Cognitive therapy involves such techniques as cognitive preparation and cognitive reframing through the use of cognitive self-statements (Beck and Fernandez, 1998). It is most frequently combined with behavioral therapy—and as such often identified as cognitive-behavioral therapy (CBT)—but it is also combined with relaxation and guided imagery.

An example of cognitive therapy might involve a patient identifying triggers for anger, using cognitive training to redefine the triggers, and then practicing this cognitively until the response becomes automatic. These techniques lead to a cognitive reappraisal or restructuring of how a patient thinks about the problem and, it is hoped, about the negative behavior. This therapy is based on the premise that behavior is rooted in a person's cognitive appraisal (i.e., one's definition) of events. Once the meaning of an event has been established, it becomes associated with an emotional reaction and a behavior (Schrodt and Tasman, 1999). Cognitive changes are seen as necessary for behavioral changes. Assessing risk and benefits and then initiating an action, for example, would constitute cognitive activity. By identifying the cognitive schema by which an individual gives meaning to an event, the therapy can attempt to alter the cognition. For example, to view illness fatalistically lessens the concept of self-efficacy; that is, the ability to act on things and change outcomes, a quality needed for illness prevention. Much of cognitive therapy involves enhancing the patient's ability to monitor his or her thinking and to develop alternative ways of thinking about an issue.

Guided Imagery

The most common form of imagery used in therapy is *guided imagery*, where a patient is asked to deliberately focus on a particular image to either “relax, manage stress, or alleviate a specific symptom” (Sobel and Ornstein, 1996). Key to this therapy is that the patient is in control of the image and can redirect it. The image does not have to be physiologically true, as in the case of a cancer patient imagining being free of cancer, or even real in the sense that the patient has or would ever experience what the image depicts. Imagery may be just simple visualization or sensory perceptions such as smell, touch, and sound (Rossman and Bresler, 2000). Although imagery uses the conscious mind, it may also be utilized to tap into the unconscious or less conscious mind.

Hypnosis

It is difficult to define hypnosis partly because it “remains exceedingly vague and continues to be used in contradictory ways by different investigators” (Spanos, 1991, p. 644). Furthermore, the term *hypnotherapy* has been applied to a wide range of therapies. Hypnosis is characterized by an “artificially induced state” of mind (Benson, 1989) and increased suggestibility, and it usually includes suggestion of relaxation and drowsiness. Hypnosis may be either self-induced or brought on by the therapist. The psychological state associated with hypnosis is referred to as a *trance state* (Spanos, 1991). This is a “waking state in which the subject's attention is detached

from his immediate environment and is absorbed by inner experiences such as feelings, thoughts and imagery” (Heap, 1996, p. 515).

Achieving the trance state, referred to as *hypnotic induction*, is often accomplished through a series of exercises, such as relaxation exercises, eye closure, induced drowsiness, etc. While in the trance state, the patient is thought to be more responsive to suggestions made by the therapist or, in the case of self-hypnosis, to self-direction. Suggestions may take effect immediately or at some later time. Hypnosis may also cause involuntary changes in perception, memory, and mood, and these changes have both biological and behavioral consequences (Wickramasekera, 1999). Those successfully hypnotized show distinct EMG patterns, and some individuals may be able to recall data not easily accessed by the conscious mind (Saichek, 2000).

In general, there are two major groups of therapists that employ hypnosis. The *authoritarian hypnotist* imposes both the trance state and the resolution of a problem on the patient using prepared inductions (Saichek, 2000). The *Erickson hypnotist* does not believe the trance state alone will create changes and does not seek to impose changes on the patient; instead, the patient retains the power and the resources to solve his or her problems.

For most of its history, hypnosis has been surrounded with controversies and disputes. For some writers there is no scientific definition of hypnosis that would distinguish it from a “relaxed but aware state” (Logue and Edwards, 1998). Hypnosis is clearly related to relaxation exercises and makes extensive use of imagery.

Meditation

Harvard’s Herbert Benson, M. D., was the first to report the physical effects of meditation (Benson, Beary, et al., 1974). He observed that after 20 minutes of meditation, a participant’s heart rate, breathing rate, blood pressure, and oxygen consumption decreased, while skin resistance increased and blood flow was altered. For some adherents, meditation therapy is a technique for emptying the mind; for others, it is “the intentional self-regulation of attention, a systematic focus on particular aspects of inner or outer experience” (Astin, Shapiro, and Schwartz, 2000, p. 73). Meditation often involves arresting “awareness in the present moment without struggle or wandering” (Baime, 1999).

There are two general forms of concentration methods. The first *focuses the mind* on a specific thing or act, such as breathing and posture, as exemplified by yoga. The second is known as “mindfulness practices,” a meditation technique that *empties the mind*. Attention is not restricted to any one object or act “but rather attends to any and all sensations, perceptions, cognitions, and emotions as they arise moment to moment in the field of awareness” (Astin, Shapiro, and Schwartz, 2000, p. 73). Mindfulness meditation is achieved in a variety of ways, but it usually involves intense concentration on such things as breathing or on a mantra, which is a sound repeated over and over (Vickers and Zollman, 1999). Mindfulness meditation has its origins in Buddhist meditation and was introduced into the medical setting in 1979 by Jon Kabat-Zinn, founder of the Stress Reduction Clinic at the University of Massachusetts Medical Center (Kabat-Zinn, 1993; 1996). The goal of this technique is to have the participant become more aware, more in touch with what is happening within one’s body and mind in the present moment. This modality has been used to treat anxiety (Kabat-Zinn, Massion, Kristeller et al., 1992) and pain (Kabat-Zinn, Lipworth, and Burney, 1985).

Mindfulness meditation is one of several recognized forms of meditation; another is transcendental meditation. Practically all forms induce a state of deep relaxation (Baime, 1999).

Although meditation was historically associated with religious or spiritual movements, this is no longer always the case.

Placebo Therapy

A placebo is defined as an inert or innocuous treatment that works not because of the therapy itself but because of its suggestive effect. It is considered a mind-body modality, but with some distinct differences. Placebo therapy depends on the power of a patient's belief that the therapy will be effective (Goleman and Gurin, 1993). The fact that placebos work at all is strong evidence in favor of mind-body therapies, particularly when the outcome measures are not subjective, for example, urinary flow rate or blood glucose levels. However, placebo poses another challenge for mind-body therapies: the extent to which they provide any effect beyond that provided by placebo.

Mind-body therapy attempts to harness the same forces that make placebos work. The difference is that placebos are generally considered to have nonspecific effects. For researchers, the placebo effect is viewed as experimental static (Goleman and Gurin, 1993), a form of background noise. It can simply result from the impact of the therapeutic encounter; from the interpersonal relationship between the patient and the practitioner (Bowers and Clum, 1988); or from the patient's awareness of being in a clinical situation (Garcia-Alonso, Guallar, Bakke et al., 1998). The distinction between other kinds of mind-body therapies and placebo, therefore, is that the former intend a specific result, the latter a nonspecific one. However, both interventions rely on the same mechanism—the mind—for effect.

Placebo can be considered in two distinct ways. First, it can be seen as something inherently present in all interventions and the result simply of an intervention being made (similar to the Hawthorne effect whereby observing behavior causes the behavior to change). Second, placebo can be used intentionally as a therapy when, for example, a practitioner gives a patient an inert substance known to the practitioner but not to the patient. This is the classic *sugar pill* that results in a surprisingly large number of recoveries, usually around 30 percent, for a wide range of conditions (Goleman and Gurin, 1993). In this review, we focused on placebo in the second sense; that is, as a deliberate mind-body intervention.

Relaxation Therapy

The object of relaxation therapy is to help the patient enter a relaxed state through the use of specified techniques, such as imaging, breathing exercises, biofeedback, and yoga. Relaxation is primarily directed at muscles, either muscles in general or a specific set of muscles. It may also be achieved by inducing physical sensations, such as warmth, in different parts of the body (Vickers and Zollman, 1999).

Relaxation therapy takes advantage of the body's natural relaxation response, which is the opposite of the fight-or-flight response that causes stress (Sobel and Ornstein, 1996). By refocusing the mind, an individual can induce the relaxation response and trigger physiological changes, including slower heart rate, slower breathing, lower blood pressure, and lower metabolism, as well as muscle relaxation (Sobel and Ornstein, 1996).

Chapter 2. Methodology

We synthesize evidence from the scientific literature on the effectiveness of mind-body therapies for gastrointestinal conditions using the evidence review and synthesis methods of the Southern California Evidence-based Practice Center. This is one of the designated centers established by the Agency for Healthcare Research and Quality for the systematic review of literature on the evidence for benefits and harms of health care interventions. The project staff collaborated with the National Center for Complementary and Alternative Medicine, the project officer at AHRQ, and a group of technical experts representing diverse disciplines.

Scope of Work

Our literature review process consisted of the following steps:

- Identify sources of evidence in the literature.
- Conduct a search of the mind-body literature to identify topic areas with sufficient publications to support a detailed review.
- Conduct a focused literature search on mind-body treatments for one topic with sufficient literature, in this case, for gastrointestinal conditions.
- Assess the search strategy for completeness.
- Evaluate potential evidence for methodological quality and relevance.
- Extract study-level variables and results from studies meeting methodologic and clinical criteria.
- Synthesize the results.
- Submit the results to technical experts for review.
- Incorporate the reviewers' comments into the report.

Objectives

We conducted a literature search of the field of mind-body research to establish the distribution of studies using mind-body interventions. These studies were then evaluated to determine if there was a sufficient body of literature in any one combination of disease and/or mind-body modality to enable a comprehensive systematic review. The mind-body topic was selected after extensive discussions with our panel of technical experts and with both AHRQ and NCCAM.

The initial search was guided by the following research questions:

- What disease states/body systems are the major foci of the studies?
- What modalities are the major foci of the studies?

- What types of outcomes were measured?
- What types of study design were used?
- What languages other than English are predominant? Are they readily accessible?

Based on the results of this search and further discussions with our technical experts and the sponsoring agencies, we chose mind-body therapies for gastrointestinal conditions as the focus of the comprehensive review presented in this report.

Mind-Body Literature Search Design

Technical Expert Panel

We recruited a group of technical experts to advise us. The technical experts were from diverse disciplines including acupuncture, ayurvedic medicine, chiropractic, dentistry, general internal medicine, gastroenterology, integrative medicine, neurophysiology, nursing, pharmacology, psychiatry, psychoneuroimmunology, psychology, sociology, and traditional Chinese medicine. The technical experts assisted the project in several ways. They assisted the research group in defining and conducting the initial overall survey of the field of mind-body research. They reviewed the results for completeness and were consulted on what topics appeared to be good candidates for a comprehensive review. Members of the expert panel reviewed the search terms we used. (Some members of the panel also acted as reviewers of the preliminary report along with the reviewers listed in the Acknowledgments.) Members of the expert panel, along with their affiliations, are listed in the Acknowledgments.

Literature Search Terms

We used “mind/body metaphysics” and “mind body therapies” as our preliminary MeSH terms. We then generated a set of synonyms, based on reviewing recent citations, under which mind-body could occur:

1. mind/body medicine
2. mind/body wellness
3. bodymind medicine
4. mind/body therapies
5. psychosomatics/psychosomatic/psychosomatic medicine
6. wisdom of the body
7. self healing
8. placebo
9. healing force of nature

10. healing consciousness
11. biopsychosocial
12. psychoneuroimmunology²
13. wellness

We further refined the search by confining it to the list of interventions recognized by NCCAM as being alternative or complementary mind-body modalities. Because this list is itself extensive, we restricted the search to those therapies that involve clinical interventions with some form of mind-body therapy. These include relaxation therapy, meditation, imagery/visualization, hypnosis, and biofeedback; placebo is included only when used as a therapeutic intervention. All of these therapies involve a conscious mind or awareness on the part of the patient. Furthermore, in an attempt to limit the search to original clinical research studies as opposed to background or descriptive articles, we included terms that would identify publications reporting on outcomes. Two expert reviewers in mind-body research evaluated the initial title search to determine if it was sufficiently inclusive. No new terms for the search were recommended.

Appendix A reports the details of the literature search strategies. We searched MEDLINE[®], HealthSTAR, EMBASE[®], Allied and Complementary Medicine[™], MANTIS[™], *Psychological Abstracts*, Social Science Citation Index[®], and two files of Science Citation Index[®] (1990–99 and 1974–1989). We retrieved a total of 2474 items from these databases, resulting in 2460 unique citations after accounting for duplicate entries. After we selected GI as our focus topic, we conducted an additional search of the same terms in the CINAHL[®] database.

Concurrent with the review of mind-body research, the project team also conducted a literature search on ayurvedic medicine as part of a separate project. This search identified a small number (10) of mind-body studies, which were included in this report.

Mind-Body Study Review Strategy

Once we generated a list of article titles from the search, we reviewed each title and rejected ones that were clearly not related to mind-body treatment for human conditions, for example, studies that were purely pharmacological and ones that were conducted on animals. If it was unclear from the title whether or not the study included mind-body interventions, we included the study for more in-depth examination.

We then designed a screening form detailing article characteristics that we intended to abstract for each study. This form included items for data source (whether the information gathered was based on the title alone, the article's abstract, or the article itself); subject of the article (to screen out studies that were clearly not mind-body); language; focus (whether the article specifically attempted to study mind-body modalities or used a mind-body therapy in the course of studying a disease state or body system); body system(s) or disease states studied; outcomes measured; mind-body modalities used; subject population; and study design (see Appendix B). When any information was unclear from the title, we ordered abstracts, or articles if abstracts were themselves unclear or unavailable, to obtain this information. Two reviewers

² Psychoneuroimmunology is such a vast field in its own right that we confined our focus to those articles that either specifically indicate a mind-body therapy or indicate a specific diagnosis.

independently completed the screening form and together compared their answers, reconciling disagreements by consensus.

When screening was reasonably complete, we analyzed the data to describe the general characteristics of the mind-body field. This was an important first step in defining our focused review. Although this process was crucial in refining the research questions for this particular project, it has a wider importance in that it measures significant parameters of the general field of mind-body research, such as the general distribution of study designs, modalities, and body systems examined.

We discuss the specific outcomes of this analysis in Chapter 3, "Results." We used this analysis to help inform the choice of GI conditions as our focus for a detailed review.

Focused Search

We used the initial search to identify the breadth of studies in mind-body. We then conducted a second, more focused search to identify studies specific to mind-body interventions for GI conditions. We searched the same online databases as in the initial search but substituted the general "outcomes" terms with ones that would identify articles on GI conditions specifically. This search identified 6065 titles. The total number of records was culled to remove studies that were clearly not related to mind-body therapy, and duplicate entries were removed. This resulted in a final total of 1888 titles being entered into our database for mind-body.

We wished to verify that our two searches were sufficiently defined so as to be as comprehensive and unbiased as possible. Several external reviewers suggested additional searches that might also generate research studies in mind-body in general, as well as for mind-body applied to GI conditions. As a result of these suggestions, we conducted four additional searches. First, we searched for all GI terms from the focused search, plus terms for psychophysiology, plus the word "human." We also added a search for the terms "mind-gut" or "brain-gut" and one for terms relating to hypertension. Finally, we conducted the initial and focused searches in the CINAHL[®] databases (see Appendix A for details of all of these searches). We scanned the results from all of these new searches for studies that were relevant to mind-body and were possibly original research studies; we found that our first round of initial and focused searches had identified the vast majority of relevant studies that these additional searches generated.

The Review Process

The multi-step search and review process is shown in Diagram 1.

Mind-Body Literature Search and Review Strategy



As described in the previous section, the initial online search identified 2460 unique titles of the mind-body literature. The focused search of GI conditions produced 1888 titles, and 49 came from other sources. This produced a total of 4397 titles. Two reviewers independently screened each title for relevance to mind-body, and disagreements were resolved by consensus. We accepted 1362 titles as either definitely or possibly mind-body; the remaining 3035 titles were excluded as not being clearly relevant to mind-body. We used the following criteria for exclusion:

1. Those conditions that are behavioral/mental, such as phobias, panic disorder, obsessive/compulsive disorders, posttraumatic stress disorders, and fears.
2. Therapies such as dance and music therapy, which are not included in this review unless combined with one of the included therapies.
3. Those articles dealing with an assessment tool and not a therapy.
4. Those studies not conducted on humans.
5. Those studies not focused on any body system/condition.

The titles that passed the initial title screening for relevance to mind-body included studies of depression, insomnia, and placebo. However, studies of placebo were only included among the accepted titles if this treatment was used as a deliberate mind-body intervention therapy.

The 1362 accepted titles were screened to collect basic data using the short form shown in Appendix B. For each article, this review identified the body system and/or disease focused on in the study, the mind-body modality used, the outcomes measured, and the type of research design used (plus other variables as shown on the form). Based on this review, we rejected an additional 123 articles and accepted 1239 for analysis (details discussed Chapter 3).

After we analyzed these 1239 articles, 1162 were deemed not acceptable for detailed review, and 77 were identified as *possibly* meeting the full criteria for inclusion in the study, that is, they were mind-body interventions for GI conditions assessed using a controlled trial design. Of these studies, on further review 53 were identified as RCTs or CCTs and contributed data to our analysis.

The full articles (or abstracts, if that was all that had been published) of the 53 approved titles were then subjected to a detailed review using the long form (Appendix C).

We assessed the completeness of the library search by reviewing the references in articles identified as review articles and from selected publications in the field by frequently cited authors. These articles were entered into the title database to identify duplications or new citations. If the articles were duplications, they were rejected; if new citations, they were added. These new titles were then taken through the steps outlined above.

Data Extraction/Data Synthesis

The information from both the short screening form (Appendix B) and the long screening form (Appendix C) provide the data for the quantitative analysis that follows. For each study, a score was calculated using a system developed by Jadad (1996) to assess the trials for quality.³

³ Trials were scored for quality according to criteria developed by Jadad (1996). These criteria were developed from published clinical trial data and assess details of blinding and randomization, and accounting for patient

We determined that the 53 studies that met the criteria for inclusion (RCT or CCT) were clinically too heterogeneous to support meta-analysis. Therefore, our in-depth analysis of these studies is, by necessity, qualitative.

The qualitative analysis involved review of each article in terms of the condition studied, the subject population (age, gender), size of the sample in the comparison arm, the interventions used, length of the intervention, outcomes measured, method of measurement, length of interval for measuring outcomes, and the outcome. From these reviews, data were then synthesized in terms of the outcomes for each modality, for each condition studied, and for modalities by conditions.

dropouts. The 0 to 5 quality scoring system has been shown to discriminate between clinical trials, with a score of 3 and above indicating "high quality" or "good quality" (Moher et al., 1998). Disagreements were resolved by an independent third review. A fuller description of the scoring system is given in Chapter 3 under "Synthesis of the Evidence."

Chapter 3. Results

The purpose of our analysis was twofold: (1) to describe the content and designs of the published studies in mind-body research and (2) to use this information to inform the selection of a topic for full review. In this chapter we present the results of our examination of the general mind-body literature, discuss how this informed our choice of gastrointestinal conditions as the topic of our full review, and describe characteristics of the gastrointestinal literature specifically.

General Content of Mind-Body Literature

Our initial search yielded 2460 unique titles that were potentially mind-body studies. After filtering out 1672 titles that were obviously not related to the subject, we were left with 788 publications for which we filled out the short screening form. We referred to abstracts or full article texts when titles alone did not provide enough information to fill out the form. Of the 788 publications, we rejected 98 from further analysis (13 studies were clearly not relevant to any body system; 78 were not mind-body studies; 1 study was not on humans; and 6 were missing critical data). Through this screening process we identified 690 studies for further analysis.

The next screening phase was designed to meet our first major research goal: to describe the content and designs of the published studies in mind-body research. We analyzed the study design, body systems or health conditions, and mind-body therapies (or modalities) of the 690 accepted articles.

Table 1 shows the distribution of the study designs. The majority of the 690 titles fell under our heading of *Research Studies*. These are broken down into the following categories:

- *Possible comparative study*. This includes randomized controlled trials where subjects are randomly assigned to an intervention. We were particularly interested in RCTs, but given their probable scarcity, we broadened this design category. It included controlled clinical trials, where the allocation is not done randomly, as well as any study that might have a comparison group; that is, a study that compares patients treated with a mind-body therapy to patients treated in some other way. This category accounted for more than 55 percent of all research studies identified. Since studies with a comparison group are the only type suitable for pooling, this category is the primary focus of this report.
- *Case control study*. This is a study in which subjects are chosen because they have a disease, and they are compared to a control group that does not. This category accounted for 3.3 percent of all research studies identified.
- *Case series*. This category includes both series and single-case studies without a comparison group. Such studies usually involve a simple series of sequential cases (or a single case). This category accounted for 11.2 percent of all research studies identified.
- *Cohort study*. This is a large group of patients with a given characteristic that is followed over time and assessed for a given outcome, usually following exposure to some variable. This category accounted for 1.4 percent of all research studies identified, although many

more may have been coded as possible comparative studies due to the difficulty making this determination without an in-depth reading of the article.

- *Review articles.* These accounted for 16.4 percent of all research studies identified.
- *Unclear study.* These are studies for which the two reviewers were unable to determine from the title the study design. This category accounted for 12.3 percent of all research studies identified.

In addition to the 554 research studies, our search found 126 articles that were historical or descriptive in nature. The remaining 10 titles involved other kinds of study designs, or their design was unclear.

Table 1. Distribution of Studies According to Study Design

Design	Number	Percent of all studies	Percent of Research Studies
Total	690	100	
Historical/Descriptive	126	18.3	
Research Studies:	554	80.3	100.0
Possible Comparative Study	307	44.5	55.4
Case Control Study	18	2.6	3.3
Case Series Study	62	9.0	11.2
Cohort Study	8	1.2	1.4
Review	91	13.2	16.4
Unclear	68	9.8	12.3
Other Design, not a possible CT	8	1.2	
Unclear	2	0.3	

Table 2 shows the distribution of studies based on the target body systems or conditions. One column shows the distribution for all studies, and the other lists the 307 possible comparative studies, which are of primary interest to this report. This breakdown was used to identify potential focus areas for our comprehensive review. Since a study can focus on more than one body system or condition, the numbers in each column exceed the total number of studies for that column.

The body systems or conditions with the largest number of studies were neuropsychiatric and head/ear, nose, and throat (head/ENT); they had 179 and 109 studies, respectively. These areas also had the largest number of possible comparative studies (65 and 61, respectively). Altogether, there were 62 gastrointestinal studies, 35 of which were possible comparative studies (the third largest category for this type of design). The “other” category contained a hodgepodge of conditions.

Table 2. Distribution of Studies Based on Target Body System/Condition

Body System/Condition	All Studies	Possible Comparative Studies
Cancer-affected systems	26	10
Circulatory	58	32
Dermatologic	13	7
Endocrine	5	1
Gastrointestinal	62	35
Genitourinary	24	16
Gynecologic	18	8
Head/ENT	109	61
Hematologic	0	0
Immune system	8	7
Musculoskeletal	51	27
Neurological	23	10
Neuropsychiatric	179	65
Respiratory/Pulmonary	17	6
Rheumatologic	7	4
Other	121	25

Table 3 identifies the various mind-body therapies or modalities represented in the literature. The distribution is across modality for all studies and for the possible comparative studies. Biofeedback was the modality with the largest number of studies found in our initial search. Biofeedback was used in 191 studies overall and in 100 of the possible comparative studies. Hypnosis and relaxation therapy were the next largest identified categories. They were used, respectively, in 153 and 117 studies overall and in 53 and 66 possible comparative studies.

Table 3. Distribution of Mind-Body Modalities in the Studies

Modality	All Studies	Possible Comparative Studies
Behavioral	114	67
Biofeedback	191	100
Cognitive	67	42
Complementary	2	1
Guided imagery	29	14
Hypnosis	153	53
Meditation	18	8
Placebo	48	7
Relaxation	117	66
Other	128	56
Unclear	8	1

Table 4 shows the mind-body modalities by target body system/condition for all 689 studies identified in the initial search. Biofeedback, the most often studied modality, was used largely in the head/ENT and gastrointestinal areas. Hypnosis was also used often in the head/ENT and neuropsychiatric areas.

Table 4. Distribution of Studies by Mind-Body Modality and Target Body System/Condition

	Behavioral	Biofeedback	Cognitive	Complementary	Guided imagery	Hypnosis	Meditation	Placebo	Relaxation	Unclear	Other
Cancer-affected systems	5	1	4	1	6	8	2	1	4	0	5
Circulatory	4	22	1	0	1	3	3	2	16	0	18
Dermatologic	1	0	0	0	2	5	1	1	3	0	2
Endocrine	0	2	0	0	0	3	0	0	1	0	0
Gastrointestinal	5	45	0	0	0	5	0	0	4	1	6
Genitourinary	7	14	1	0	0	2	0	1	1	0	0
Gynecologic	0	6	0	0	1	5	0	0	4	1	3
Head/ENT	21	51	13	1	2	16	0	1	29	2	19
Immune	2	0	2	0	1	2	0	0	2	0	2
Musculoskeletal	11	19	7	0	2	9	1	1	11	2	7
Neurological	3	10	0	0	0	3	1	0	5	0	5
Neuropsychiatric	46	19	32	0	5	52	7	19	23	1	30
Respiratory	1	0	0	0	4	7	0	3	6	0	5
Rheumatologic	2	2	2	0	0	1	0	0	2	0	2
Other	14	13	7	0	5	33	3	22	15	2	28

Focused Search

The initial search not only helped us to describe the field of research in mind-body but also to choose a topic for a more focused analysis. During discussions with NCCAM, it was decided that although head/ENT was a large category, its focus was probably headache pain, and NCCAM did not want an evidence report focused on biofeedback for pain as they felt that this area has already been extensively examined. Neuropsychiatric problems were also rejected as the focus because of the difficulty with definitive diagnoses for many of the conditions. Gastrointestinal conditions were the third most commonly studied category, and this topic seemed suitable for further review as GI conditions are common and can be difficult to manage.

We conducted a focused search to specifically include studies that involve GI conditions. This search generated 1888 unique titles, of which we eliminated 1363 that were clearly unrelated to mind-body. We conducted the same title screening described in the previous section for these remaining titles. Thus we added 525 new studies from this search to the studies for examination. Of these 525 studies, on further review, 406 concerned mind-body therapies for GI conditions.

The remainder of the section discusses the characteristics of the 62 studies from the initial search, and the 406 studies from the focused search. Table 5 shows the study designs for these 468 GI studies we identified. By combining the results of the initial search of mind-body

therapies with the focused search on GI conditions, we identified 77 possible comparative studies.

Lastly, we retrieved 49 titles from the reference lists of review articles, our ongoing CAM project on ayurvedic medicine, and the suggestions of our external reviewers. Five of these studies met our inclusion criteria and contributed evidence to our detailed review.

Table 5. Study Design of the Identified Gastrointestinal Studies

Design	Number	Percent of all studies	Percent of Research Studies
Total	468	100	
Historical/Descriptive	67	14.3	
Research Studies:	400	85.5	
Possible Comparative Study	77	16.5	19.3
Case Control Study	20	4.3	5.0
Case series Study	202	43.2	50.5
Cohort Study	5	1.1	1.3
Review	94	20.1	23.5
Other Design	1	0.2	

Table 6 shows the modalities used in the 468 GI studies of which 77 are possible comparative studies.

Table 6. Mind-Body Modalities for the Gastrointestinal Studies

Modality	All GI studies	Possible Comparative Studies
Biofeedback	236	42
Hypnosis	87	12
Relaxation	33	8
Behavioral	53	10
Cognitive	9	3
Guided imagery	6	3
Placebo	8	1
Meditation	1	0
Other	62	8
Unclear	10	1

Of the 77 studies that we passed through to detailed review, 53 had an RCT or a CCT study design; 10 reported on secondary data already synthesized in our analysis; 4 were impossible to locate or translate; 3 turned out to be on urinary incontinence; and the rest had non-RCT/CCT study designs.

Synthesis of the Evidence

Description of the Evidence

Fifty-three controlled trials of mind-body interventions for gastrointestinal conditions were found during the search and review process, and they were then reviewed in depth. The Evidence Table summarizes the study characteristics. In terms of modalities, the primary focus of the 53 studies⁴ was: 17 assessed biofeedback, 8 assessed hypnosis, 8 assessed relaxation therapy, 8 assessed behavioral therapy, 4 assessed cognitive therapy, 2 assessed guided imagery, and 1 assessed a placebo intervention. Additionally, four trials used a multimodal intervention. The clinical conditions that were studied included irritable bowel syndrome (n = 15), fecal incontinence/encopresis (n = 11), constipation (n = 10), vomiting (n = 8), nausea (n = 7), abdominal pain (n = 5), inflammatory bowel disease (n = 2), peptic ulcer disease (n = 2), ulcerative colitis (n = 2), and several conditions for which there is a single study (diarrhea, diverticular disease, hiatus hernia, colorectal surgery, and a nonspecific gastrointestinal disease).

There is some similarity among the outcome measures used in GI studies of biofeedback. These measures include manometry, anal pressure, EMG measures, bowel movements, bowel dynamics, pain symptoms, and use of cathartics. In studies of relaxation therapy, hypnosis, guided imagery, cognitive therapy, and behavioral therapy, however, the outcome measures are more likely to include psychological tests. Because of the heterogeneity in patients and outcomes, we do not believe statistical pooling (i.e., a meta-analysis) of these studies is justified.

Quality of the Evidence

All studies were given a quality score based on the Jadad system, which rates trials on a 0 to 5 scale. A score is arrived at based on answers to three questions: Was the study described as randomized? Was the study described as double blind? Was there a description of withdrawals and dropouts? One point is given for each yes answer; zero for each no. An additional point is given in response to the first question if the randomization method was described and the method was appropriate. A point is deducted if the randomization method was described but it was inappropriate. A point was similarly added or deducted in response to the second question about double blinding. In the case of many CAM therapies, however, it is not feasible to do a double blind study (it is hard to blind the practitioner to the type of therapy being delivered), and the maximum Jadad score for these studies might be 3 or 4 rather than 5. Empiric evidence has shown that studies scoring 2 or less report exaggerated results compared with studies scoring 3 or more. Studies scoring 3 or more have been characterized as “good or “high” quality while studies scoring 2 or less have been characterized as “poor” quality (Moher et al., 1998).

The Jadad quality scores for the 53 RCT/CCT studies ranged from 0 to 4. Forty-five of the studies were described as randomized, but in only 16 did the study report randomization appropriately. The remainder of the other studies did not report on their method of randomization. Only three studies were described as double blinded, two of which described

⁴ The studies examined here add up to 52, rather than 53, because one article reported on two studies.

their blinding appropriately. Of the RCT studies, 14 had a Jadad score of 3 or higher; of the CCT studies, only one had a score that high.

A further methodologic problem common to most studies was lack of statistical power. Cohen (1987) defines a “small” effect size (the absolute value of difference in the treatment and control group means divided by the standard deviation) as 0.2, a “medium” effect size as 0.5, and a “large” effect size as 0.8. If we apply this standard to the studies reviewed here (based on a two-sided statistical test of level 0.05), to achieve 80 percent power to detect a small effect size difference between a treatment group and a control group, an investigator would need at least 393 treatment patients and 393 control patients. To detect a medium effect size would require 63 patients in each group, and to detect a large effect size would require 25 patients in each group. The vast majority of the studies in our systematic review had sample sizes considerably less than that required to detect even a medium effect size; sometimes they were not powered to detect a large effect size.

Of the 53 studies identified, none had sufficient power to detect a small effect, three studies (6 percent) had sufficient power to detect a medium-sized effect, seven studies (13 percent) were powered sufficiently to detect a large effect and 40 studies (75 percent) had less than 25 patients in each comparison group, meaning they were not powered to detect even large effects (three studies did not contain information on sample size).

Evidence Synthesis by Modality

Biofeedback

Of the 17 biofeedback studies with a comparison group, 11 compared a biofeedback intervention to a control group receiving no biofeedback. Of these, the conditions assessed were encopresis (four studies), fecal incontinence (three studies), constipation (three studies), and abdominal pain (one study). All trials included male and female subjects. Two of the studies reported a positive outcome for biofeedback (both in adults), while nine showed no benefit compared to the control group. Of these nine studies, seven involved children, and two involved adults. In the following discussion we will first examine those studies with a no-biofeedback control group followed by those without a no-biofeedback control group. We present the studies reporting a positive outcome first.

Biofeedback studies with a no-biofeedback control group. Two studies with a no-biofeedback control group reported a positive outcome using biofeedback for fecal incontinence in adults.

Guillemot, Bouche, Gower-Rousseau et al. (1994) examined the long-term results from a controlled clinical trial of biofeedback to treat fecal incontinence in adult males and females. There were 16 patients in the biofeedback arm and eight in the control group receiving antidiarrheal therapy or enema. The mean age was 62 years, and 53 percent of the patients were female. Anorectal manometry (upper and lower anal sphincter resting and squeezing pressures, anal reflex after distension, sensation threshold, maximum tolerable volume) was performed using a triple balloon probe. The biofeedback used a system where the data were digitized and displayed on a computer screen. Clinical scores were calculated before treatment and at followup at 24- to 36-month intervals. An intermediate score was calculated at 6 months. The clinical scores were based on frequency of soiling, incontinence of flatus only, or feces and flatus, type of feces, quality of feces, and time of soiling. The intervention was repeated at home, twice a

day, four times weekly. The authors reported that the fecal incontinence score was significantly lower at 6 months for the biofeedback group than the score for the control group. However, the improvement deteriorated over time (30 months), although no biofeedback was given after 6 months. The Jadad score is 1.

Miner, Donnelly, and Read (1990) randomized 25 patients (68 percent female, ages 30 to 76) for a study of biofeedback to treat fecal incontinence. Thirteen patients were assigned to an active sensory training group. During three 20-minute sessions, these patients were taught how to recognize when a rectal balloon was inflated with small volumes of air and to reduce or eliminate their sensory delay. The 12 patients in the control group were taught the same procedure, but they received no instruction on how to improve their performance. After 1 month, the diary entries of the biofeedback patients were used to measure their degree of fecal incontinence. At this point the control group crossed over to active sensory training. After all subjects had completed the sensory training, they were again randomly allocated to two groups. One received strength training during three 20-minute sessions over 3 days. The subjects were taught how to develop maximum squeeze pressure with a manometric catheter in place, and they were given a 1-month exercise program to enhance muscle strength and endurance. The second group received coordination training. These patients were taught how to respond to balloon inflation with a voluntary squeeze in less than 0.5 seconds and to maintain anal pressure above preinflation values. The authors reported that active sensory training significantly reduced the patients' sensory threshold, corrected any sensory delay, and reduced the frequency of incontinence. The control intervention did not reduce the frequency of incontinence. Subsequent strength and coordination training did not significantly improve incontinence. The functional improvement was sustained over 2 years in those patients available for followup (73 percent). The Jadad score is 2.

There are nine studies with a no-biofeedback control group that showed no benefit from biofeedback. Of these studies, two are for adults and seven are for children.

McHugh, Walma, Diamant et al. (1986) reported on a randomized study of fecal incontinence in 18 subjects (67 percent female, mean age 55 years) that compared a dietary fiber intervention to a standardized biofeedback protocol (not described) and to a voluntary sphincter exercise. This study used a crossover design. The biofeedback included three sessions at 2-month intervals. The voluntary exercise was done using a home manometer. Outcomes measured included fecal incontinence, fecal staining, and number of bowel movements. The dietary fiber intervention benefited some subjects. However, there was no significant difference in treatment results between the biofeedback and the voluntary sphincter exercise. The Jadad score is 2.

Koutsomanis, Lennard-Jones, Roy et al. (1995) also compared a control group (which received muscular coordination training) to a group receiving the same intervention plus biofeedback in a study of adults with constipation ($n = 59$). There were 30 patients in the control group and 29 in the biofeedback group. The patients ranged in age from 20 to 63, and 86 percent were female. The biofeedback patients were taught to control and contract the anal canal in response to an inflated rectal balloon while watching the results of their action on an EMG trace monitor. The control group had the same training but without the visual display. The number of training sessions depended on what the patient and the doctor considered adequate. The biofeedback group required a mean of three sessions (range one to seven), and the muscular coordination control group required a mean of two sessions (range one to four). Outcomes measured included patient assessment of improvement, bowel frequency, number of straining episodes, digitations, abdominal pain, and laxative consumption. Outcome measurements were

taken both before and at the end of treatment as well as at a later followup time (not given). This study found that adding biofeedback to muscular training had no additional benefit for treating intractable constipation compared with muscular training by itself. About 40 percent of the patients in both groups thought their symptoms had improved. The authors also found significant improvements in both groups for bowel frequency, straining episodes, and duration of abdominal pain. The Jadad score is 3.

The following seven studies of children using a no-biofeedback control group reported no benefit from biofeedback. Three are from the same research team and should not be considered as independent studies. Three studies were on encopresis, three on constipation, and one on abdominal pain.

In a study of the long-term outcome for biofeedback to treat chronic constipation and encopresis in children, Loening-Baucke (1995) combined two studies to give a total sample of 63 patients who received biofeedback and 66 patients who had conventional care. Patients in the first study were randomized to either conventional care ($n = 19$) or to conventional treatment plus biofeedback ($n = 21$). In the second study, 42 patients received biofeedback after 6 months in conventional care during which they had not recovered. In the combined sample, the mean age was 12 years with 48 percent female patients. The conventional care included laxatives, enemas, and treatment for social and psychological problems, including education about constipation. Patients in the biofeedback group were shown normal manometric and EMG tracings compared with their own tracings. A rectal balloon was used to record the data. During training, the children received constant verbal, visual, and audio reinforcement to encourage them to correct their external anal sphincter (EAS) contraction and relaxation. At least two but up to six training sessions were conducted, depending on how soon the child learned to relax the EAS. Each training session lasted approximately 45 minutes, and they were given 7 days apart. Outcome measures included quality of stools, soiling, medication diary, abdominal pain, defecation dynamics, and urinary incontinence. Abdominal and rectal examinations were conducted. Recovery was defined as having three or more bowel moments per week and two or fewer soilings per month while not receiving laxatives for 4 weeks. The average followup time for the patients was 4.1 ± 1.5 years. Eighty-six percent of the conventionally treated patients and 87 percent of those in the biofeedback group had improved in encopresis. In addition, 62 percent of the conventionally treated patients, 50 percent of those in the biofeedback group, and 23 percent of patients who were unsuccessful biofeedback-treated patients had recovered from chronic constipation and encopresis. Recovery rates were similar for patients in both groups who learned normal defecation dynamics. Learning normal defecation dynamics with biofeedback training did not increase long-term recovery rates in children with chronic constipation, encopresis, and abnormal defecation dynamics above the rates achieved with conventional care alone. The length of followup was significantly related to recovery. The Jadad score for this study is 3.

Loening-Baucke (1994) in a study of constipation in children (age and gender not provided) evaluated the long-term effect of biofeedback on abnormal anorectal function including anismus (paradoxical contraction of the striated pelvic floor muscles, indicated in this study by the designation cEAS). In past studies children with chronic constipation and encopresis who also had cEAS had significantly lower recovery rates compared with children who could relax their striated pelvic floor muscles (rEAS). A total of 215 children with chronic constipation and encopresis (86 with rEAS and 129 with cEAS) were treated with timed toilet sittings (no description provided) and laxatives. Of the 129 children with cEAS, 63 were given biofeedback (technique not described), and 50 of them learned rEAS in approximately three biofeedback

sessions. Recovery was defined as three or more bowel movements per week and two or fewer soilings per month while off laxatives for at least 1 month. At a mean followup time of 4 years, patients with rEAS, with BFrEAS (biofeedback + rEAS), and with cEAS had similar recovery rates: 62, 50, and 62 percent, respectively. Soiling frequency per week and stool frequency per week were similar in all groups at the beginning of the study. Both conditions had decreased significantly in all groups at followup, but they were not different between the groups. Biofeedback did not affect the long-term outcome in patients with cEAS. The Jadad score is 0.

Wald, Chandra, Gabel et al. (1987) evaluated biofeedback to treat childhood encopresis in 50 children (20 percent female, ages 6 to 15 years). Anorectal studies using a rectal balloon were performed on the proximal rectum, the internal anal sphincter, and the external anal sphincter. The children were then randomized to two treatment groups. One group (n = 26) received conventional treatment, which consisted of ingesting mineral oil. They were followed up at 2, 4, and 8 weeks. The second group (n = 24) received biofeedback. They viewed their manometric recordings, which were explained to them, and they were shown what these responses looked like during contraction and simulated defecation. Those with abnormal defecation dynamics were instructed to normalize the pattern through trial and error (generally during a 10- to 20-minute exercise). Those children with encopresis but with normal defecation dynamics simply repeated the exercise first with and then without biofeedback. All sessions lasted 25 to 30 minutes. After the sessions ended, the children were instructed to use the technique to normalize their defecation whenever they needed to defecate. Reinforcement biofeedback was given at 2, 4, and 8 weeks. Outcomes measured included frequency of defecation and the number of soiling episodes (stars were awarded for days when no soiling occurred) as recorded in a calendar kept for 12 weeks following initiation of therapy. Followup interviews occurred at 3, 6, and 12 months by a blinded assessor. There were no significant differences in clinical outcome between the two groups at 3, 6, and 12 months. However, at 12 months, six out of the nine children with abnormal defecation patterns in the biofeedback group were in remission compared with only three out of nine in the control (mineral oil) group. This difference in proportion, while large, is not statistically significant with this small sample size. The Jadad score is 2.

Nolan, Catto-Smith, Coffey et al. (1998) compared one group of children (n = 15) receiving usual and customary care (not described) to a second group (n = 14) receiving usual and customary care plus biofeedback to treat constipation and fecal incontinence in children 4 to 14 years old (gender not given). The principal outcome was remission of fecal incontinence and the lack of need for laxative treatment at the 6-month followup. Anorectal manometry using the balloon method was performed at baseline and at 6 months after randomization. During biofeedback training, electromyograms were recorded, and the patient focused on the EMG display, which indicated both visually and aurally if there was contraction or relaxation of the external sphincter. The aim of the biofeedback was to eliminate anismus during defecation attempts. Up to four sessions at weekly intervals were conducted for each patient, with each session involving 30 to 35 defecation attempts. If patients achieved 10 relaxations of the external anal sphincter without visual biofeedback in two successive sessions, they did not complete further sessions. The authors reported no lasting benefit for biofeedback at 6 months. This study also included a child behavior checklist (CBCL). Although the total behavior-problem scores from the CBCL were not significantly different between the two groups, the biofeedback group did have significantly better school scale scores, which form part of the CBCL. This study has a Jadad score of 2.

In a study by van der Plas, Benninga, Redekop et al. (1996), biofeedback was used to treat encopresis in a group of boys and girls (n = 32), with a median age of 9 years. One group received usual and customary care (high fiber, daily enemas, oral laxatives), and the other received usual and customary care plus biofeedback. The biofeedback involved showing the children normal manometric and EMG tracings. A balloon was used to develop rectal sensation and for evacuation. Both visual and verbal reinforcement was used. The treatment involved 6 weeks of intensive training and included home sessions as well. Outcome measures included defecation dynamics as determined by manometric measure, a child behavior checklist, a teacher report form, self and parent reports of frequency of defecation, soiling and/or encopresis, consistency and size of stool, pain, and other symptoms such as enuresis. Initially those children given usual and customary care and biofeedback had higher success rates, but the researchers reported that at 12 and 18 months, there were no differences between groups. The Jadad score for this study is 2.

In a similar study, van der Plas, Benninga, Buller et al. (1996) compared usual and customary care (laxatives, diet, toilet training) with usual and customary care plus biofeedback to treat boys and girls (n = 98) from 5 to 16 years old with constipation. The biofeedback training was identical to the previous study. Outcomes measured were defecation dynamics (manometry) and laxative use. The authors reported that at 1 year, although there were improvements in defecation dynamics in the biofeedback group, there were no differences among groups in clinical outcomes. The Jadad score is 3.

In a third related study, Benninga, van der Plas, Taminiau et al. (1996) randomly allocated 29 children (55 percent female, median age 9 years) with recurrent abdominal pain to a control group receiving usual and customary care (enemas, laxatives, high fiber diet, and toilet training) or to a group receiving biofeedback plus usual and customary care. The type of biofeedback was not described, but it is assumed to be the same used in the previous two studies. Outcome measures included use of laxatives, abdominal pain, and manometry measures. The subjects were assessed at 6 weeks and at 6 months. The study found that the children with recurrent abdominal pain benefited equally from either biofeedback and usual and customary care or from usual and customary care alone. The Jadad score is 1.

In summary, our literature search identified 11 studies that provided information on the efficacy of biofeedback. Four of these studies were of adult patients, and they reported mixed results. Two studies of adult patients reported statistically significant benefits of biofeedback to treat fecal incontinence. Both studies had quality scores characterized as “poor.” One additional study of adult fecal incontinence did not report a benefit of biofeedback; this study also had a quality score characterized as “poor.” A fourth study of biofeedback, this time as treatment for adults with constipation, also did not report any benefits of biofeedback compared with muscular training.

In contrast to the mixed results for adults, all of the studies of biofeedback for children reported no statistically significant benefit of biofeedback compared to conventional care.

Biofeedback studies without a no-biofeedback control group. Six studies did not have a no-biofeedback control group; they used some form of biofeedback in all study arms. The types of biofeedback compared in these studies included visual manometry readings, EMG outputs (although where these were taken from varies), balloon sensory input, augmented biofeedback (a combination of audio and visual), direct visualization of the anus using a mirror, and contingent biofeedback (given in conjunction with the onset of a problem such as abdominal pain). Five of the six studies are identified as adult studies (one is indeterminate); and the conditions treated

included constipation (four studies), fecal incontinence (two studies), abdominal pain (one study), irritable bowel syndrome (one study), and diarrhea (one study). One study was directed at more than one condition. Four of the studies involve females, one involves both males and females, and one is indeterminate with regard to gender. One study found that biofeedback without psychotherapy was insufficient; another found EMG biofeedback was superior to sensory biofeedback; two found no significant differences in results based on the type of biofeedback used; one found that an augmented type of biofeedback had the best outcomes; and one found that a contingent reinforcement biofeedback yielded the most significant results.

Leroi, Duval, Roussignol et al. (1996) treated sexually abused women (n = 15) for abdominal pain, constipation, diarrhea, and fecal incontinence. The women were divided into three groups based on their preference: one received biofeedback alone, another received biofeedback plus group therapy, and the third received biofeedback and individual psychotherapy. The biofeedback was generated by measuring pressure in the upper anal canal with a manometry probe and displaying the tracings on an oscillograph screen so the patient could see what normal and abnormal tracings looked like. The patients were then encouraged to become aware of the sensation of rectal distention while watching the change in their anal pressure on the screen. Those patients who could not tolerate a probe were shown an EMG recorded from the perineal skin. A third option offered to the women was viewing their anus with a mirror without having a probe inserted. The interval between biofeedback sessions varied, but it was generally 2 weeks. The length of the sessions is not described. The outcome measured was somatic symptoms. Biofeedback alone was initially chosen by all the women as the preferred treatment; none of the women initially chose treatment that included group or individual psychotherapy, but later some of the women did move into these groups. However, the researchers reported that biofeedback alone was not always sufficient to cure these abused patients at a 6- to 10-month followup (although 46 percent who received some biofeedback completely recovered from their symptoms). The study has a Jadad score of 1.

Glia, Gyllin, Gullberg et al. (1997) used biofeedback to treat functional constipation and paradoxical puborectalis contractions in females and males (n = 13) with a mean age of 55 years. The authors reported that the treatment improved abnormal contractions and symptoms at 6 months. The patients were divided into two groups. One received biofeedback with EMG of the anal sphincter, which was produced by a needle electrode inserted into the puborectalis muscle. The second group received biofeedback with anal manometry, which measured maximum resting pressure, maximum squeeze pressure, and the length of the anal sphincter. Rectal evacuation was determined with a balloon expulsion test. Transit time was measured with radiopaque markers and radiographs. Defecation was monitored with cinedefecography (continuous fluoroscopy and video recording). Patients received biofeedback 1 to 2 times a week, up to a maximum of 10 sessions. The study reported a significant improvement in both bowel functioning (58 percent improved anorectal functioning) and abdominal symptoms (75 percent improvement) at a 6-month followup. Both biofeedback treatments were equally effective. This study has a Jadad score of 3.

Heymen, Wexner, Vickers et al. (1999) used biofeedback in a study of constipation in females (n = 36) with an average age of 61 years. All patients received weekly biofeedback sessions for 1 hour. The women were divided into four groups, each receiving a different treatment combination: (1) biofeedback (EMG activity of the pelvic floor muscles) with education and pelvic floor exercise; (2) biofeedback (EMG activity plus balloon sensory training) with education and pelvic floor exercise; (3) biofeedback (EMG activity plus home

trainer using a portable EMG biofeedback unit) with education and pelvic floor exercise; and (4) biofeedback (EMG activity, balloon training, and home trainer) as well as behavioral therapy with education and pelvic floor exercise.

The outcomes measured were unassisted bowel movements and a decrease in the use of cathartics (laxatives, enemas, suppositories, or digitation). The researchers reported that biofeedback significantly improved bowel movements in groups 1, 2, and 4; groups 1 and 2 also reduced their use of cathartics as did group 3. No significant difference was found among the treatments. The EMG biofeedback alone was as effective as with the addition of balloon training, home training, or both. However, the treatment combination with a single biofeedback technique (group 1) was no more effective than the treatment combination that included behavioral therapy (group 4). The timeframe for this study was not reported. The Jadad score is 1.

Fynes, Marshall, Cassidy et al. (1999) reported significant improvement for fecal incontinence after 12 weeks of biofeedback in a study of females ($n = 20$) with a mean age of 32 years. The women were divided into two groups. One group received sensory pelvic floor biofeedback training using exercises to improve awareness and strength of the pelvic floor muscles. A perineometer was inserted into the vagina, and the patient performed both slow and fast twitch contraction. The second group received augmented biofeedback, which combined the audiovisual biofeedback from the perineometer with electrical stimulation from an edoanal probe connected to a monitor, which displayed vaginal contraction. Surface EMG readings were obtained. Outcomes measured were changes in continence scores (from a symptom questionnaire) and in anorectal physiology. The improvement in symptoms was greatest in the group receiving augmented biofeedback (audiovisual and electrical stimulation) rather than in the group receiving sensory biofeedback alone. Only the augmented biofeedback produced objective changes in anal canal pressures. The Jadad score is 3.

Bleijenberg and Kuijpers (1994) compared two methods of biofeedback for treatment of constipation in a study of 20 patients (20 to 50 years old, 80 percent female). The authors randomly assigned the patients to receive either EMG biofeedback or biofeedback using a balloon catheter during an 8-week period that involved both weekly clinical sessions and home exercises. All patients had been diagnosed by a gastroenterologist as having a spastic pelvic floor syndrome; the diagnosis was confirmed using EMG. Patients in the EMG biofeedback group received printouts that showed their results during training. During training, the patients were connected to a personal computer that calculated a quality score based on the EMG signal. The score measured relaxation during straining on a 0 to 100 scale—the higher the quality score the better the straining behavior. Patients in the balloon biofeedback group were simply taught to sense the balloon catheter and its evacuation. Outcome assessments included EMG readings and a self-observation diary that reported psychological symptoms (such as anxiety, depression, hostility, neuroticism, etc.) and physical symptoms (such as constipation, defecation frequency, incidence of difficult defecation, incomplete defecation, hard stools, use of laxatives, and abdominal pain).

Patients in the EMG biofeedback group significantly increased their mean straining score (indicating better straining behavior), and their self-reports showed significant reductions in the percentage of difficult evacuations, incomplete evacuations, hard motions, false urges, and duration of pain, as well as in their abdominal complaint score. The constipation score was reduced significantly. In addition, this group showed progress on psychological symptom scales—improvement was noted on the symptom subscales for depression and inadequacy. In contrast, patients in the balloon biofeedback group showed no significant changes in EMG

readings, in self-observation diary entries, or in constipation scores. They improved only on the physical symptom scale and on interpersonal sensitivity, and hostility measures from the psychological scale. These results remained significant at followup (mean 14 months for the EMG group, 9 months for the balloon group). The authors calculated that 8 out of the 11 patients in the EMG biofeedback group had improved compared with only 2 out of the 9 patients in the balloon biofeedback group. Subsequently, five of the balloon biofeedback patients had the EMG treatment, and four of them had a good result. The Jadad score for this study is 2.

Welgan, Bondi, and Hoehler (1986) compared biofeedback and stress management and contingent biofeedback and contingent stress management for irritable bowel syndrome (IBS). Twenty patients (gender and age are not given) with IBS were divided into two groups and given 20 treatment sessions each lasting 1 hour. During these sessions, both groups were given 20-minute periods of biofeedback and stress management training. During the first 10 sessions, both groups were instructed to practice the techniques four times daily. During the last 10 sessions, one group was directed to use the technique only at the onset of abdominal pain or discomfort (contingent reinforcement) while the second group continued as before. Outcome measures included EMG, galvanic skin response, and bowel sounds, as well as abdominal pain and discomfort. The reported results showed that biofeedback and stress management significantly reduced central and autonomic arousal states and that EMG and bowel sounds declined significantly. Furthermore, the contingent-reinforcement group produced significantly more reports of reduced pain and discomfort than the group not instructed in contingent reinforcement. The Jadad score is 0.

In summary, our literature search identified six studies that assessed the efficacy of different types of biofeedback or of different therapies in addition to biofeedback. Four of the six studies had quality scores characterized as “poor.” Two studies reported no significant differences between types of biofeedback, while the other four each compared something different. No conclusions can be drawn, other than it is possible that there may be ways to improve the efficacy of biofeedback for gastrointestinal conditions.

Hypnosis

There were eight studies using hypnosis, seven of which had a no-hypnosis control group. These studies examined the use of hypnosis for irritable bowel syndrome in adults (three studies), nausea and vomiting in children following treatment for cancer (two studies), duodenal ulcer in adults (one study), and ulcerative colitis in adults (one study). Six of these studies reported a positive outcome. The one negative study focused on irritable bowel syndrome (age and gender of patients not given). All hypnosis studies had quality scores characterized as “poor.”

Hypnosis studies with a no-hypnosis control group. Whorwell, Prior, and Faragher (1984) evaluated 30 patients in a randomized study of treatment for severe, refractory irritable bowel syndrome (23 to 54 years old, 87 percent female). The control arm received a placebo (not described) and psychotherapy (seven half-hour sessions). The intervention arm received seven half-hour sessions of hypnotherapy plus a tape for daily autohypnosis. Hypnotherapy involved only general relaxation for control of intestinal motility; there was no hypnoanalysis. At the end of 3 months of treatment, the hypnotherapy group (n = 15) reported either mild or absent symptoms, and the patients were significantly better in terms of abdominal pain, bowel habit, abdominal distention, and well being. The control group (n = 15) showed a small but significant improvement for all symptoms except bowel habit. The difference between the two groups

reached significance by the fourth week of treatment for bowel habit, abdominal distention, and well being, and by the fifth week for abdominal pain. No long-term assessments were reported. The Jadad score is 1.

Colgan, Faragher, and Whorwell (1988) studied the use of hypnosis in a randomized study of 30 patients (mean age 40 years, 47 percent female) for relapse of duodenal ulcer. All patients had at least one confirmed relapse in the 6 months prior to the study. The treatment group (n = 15) received seven sessions of hypnotherapy (involving imagery/visualization for control of gastric secretion) and an audiotape for autohypnosis plus medication for the ulcer for 10 weeks after healing. The control group (n = 15) received only the medication regime and was seen as frequently as the treatment group. After the medication was stopped, the two groups were reviewed every 3 months for an additional year with the treatment group continuing to receive hypnotherapy during this time. All subjects had an endoscopic exam at the end of the study. At the 12-month followup, there was a statistically significant difference in relapse rates: 53 percent for the hypnosis treatment group and 100 percent for the control group. The Jadad score is 1.

Hawkins, Lioffi, Ewart, Hatira et al. (1995) conducted a randomized study of 30 children with cancer (5 to 17 years old, 60 percent female), comparing one group (n = 10) receiving usual care for nausea and vomiting (antiemetic medication) with a second group (n = 10) receiving both medication and hypnotherapy and with a third group (n = 10) receiving medication and therapist contact. All the children continued to receive the medication. Five days before inpatient admission, children in the hypnosis and therapist groups participated in a 1-hour training session either undergoing hypnosis or talking with the therapist. Hypnosis was induced by relaxation; visual imagery was used for self-hypnosis. The children were asked to practice self-hypnosis at home and to do the exercises prior to each chemotherapy session. After admission, the children receiving hypnosis had a 20-minute booster session while the others simply met for 20 minutes with their therapist. Outcome measures were assessments of retching and vomiting made retrospectively by the patients and by the nursing staff. The number of retching/vomiting episodes decreased by 33 percent in the hypnotherapy group and by 11 percent in the therapist contact group. However, it increased by 6 percent in the control group receiving usual care (antiemetic medication) alone. For anticipatory nausea, the severity decreased by 40 percent in the hypnosis group and by 20 percent in the therapist contact group, but it increased by 11 percent in the control group. The Jadad score is 2.

Zeltzer, LeBaron, et al. (1987) also examined the use of hypnosis for the treatment of chemotherapy-related nausea and vomiting in a study of 42 children (5 to 17 years old, gender not reported). The patients were randomized to a hypnosis, support, or control group. The number of children in each group is not known. Their reaction to two baseline courses of chemotherapy was compared with their reaction to two matched courses with intervention added. Assessment included patient, parent, and observer ratings before and after chemotherapy. Nausea and vomiting were significantly reduced for the hypnosis group, but patients in the support group stayed the same. Children in the control group reported a 20-percent increase in the extent to which the chemotherapy bothered them as well as a worsening of all symptoms over time. The Jadad score is 2.

Schmidt (1992) used hypnosis in the treatment of ulcerative colitis in 30 patients (60 percent female, ages not given). The patients were assigned to either a hypnosis group or to a control group and were monitored four times annually by blinded assessors. The hypnosis combined hypnotherapy and imaginative therapy, and the patients in this group meet weekly. The control group was treated with drugs and diet counseling while the study group added hypnosis. The

study had a 5-year followup. Outcome measures included number of relapses, necessity of surgical intervention, and repeated inflammation. All patients in the hypnosis group were relapse-free after 50 months, while no one in the control group showed any continual improvement. The Jadad score for this study is 1.

Galovski and Blanchard (1998) used the Whorwell protocol (Whorwell, Prior, and Faragher, 1984) for hypnotherapy to treat irritable bowel syndrome. The study had 12 participants (23 to 58 years old, 83 percent female). Six matched pairs (matched for anxiety disorder scores, susceptibility to hypnosis, age, and gender) were randomly assigned half to a hypnosis treatment group and half to a control group. Subjects in the treatment group received half-hour to 1-hour hypnosis sessions weekly for 12 weeks. Subjects in the control group had their symptoms monitored, and they were crossed over to the treatment arm after 6 weeks. The subjects kept a daily diary of gastrointestinal symptoms. At the end of the 12 weeks, all participants completed two psychological tests. They were contacted 2 months later to complete another 2 weeks of diaries, psychological tests, and a global rating of treatment outcome. Outcome measures included pre- and post-treatment symptom ratings based on diary entries as well as global ratings of symptoms (pain, bowel regularity, general sense of well being) made at the 2-month followup. Symptoms improved significantly, and anxiety scores decreased, in the hypnosis group. Furthermore, when control group subjects crossed over to the treatment arm, they also showed improvements. The Jadad score for this study is 2.

Anton, Schoen, Mayer, and Fullerton (1997) studied the use of hypnosis to treat irritable bowel syndrome. In their study, subjects (gender and age not given) were randomized to either a treatment group (n = 11) receiving weekly individual hypnosis or to a control group (n = 7) receiving one-on-one attention. The hypnosis was not directed at specific irritable bowel symptoms. Outcomes measured included severity of abdominal pain, discomfort, number of bowel movements, and quality of life. There were no changes in any of the outcomes in the sample as a whole. At 6 weeks there were no significant differences in symptoms between the treatment group and the control group. Only the overall quality of life score showed a significant increase for the hypnosis group. The Jadad score is 2.

Hypnosis study without a no-hypnosis control. In a study of irritable bowel syndrome, Forbes, Macauley, and Chiotakakou-Faliakou (1999) compared individual gut-directed hypnotherapy with a prescribed audiotope in a randomized trial involving 52 patients (median age 37 years, range 19 to 71 years, 71 percent female). No description was provided about the type of hypnosis or tape used. The subjects kept a diary of symptoms for 3 months. At the end of the study, symptom scores fell in 76 percent of the subjects in the individual hypnosis group and in 56 percent of those in the audiotope group. In the intention to treat analysis there was a median reduction of -3 symptoms for the individual hypnosis group compared to -1 for the audiotope group. For those subjects who completed the protocol, this reduction reached statistical significance (-5.5 versus -1). A blinded assessor considered 52 percent in each group had improved; this increased to 67 percent and 57 percent, respectively, for those fully compliant in each group. The authors recommend using the tapes as initial treatment, given their low cost and ease of use, and substituting individual hypnosis sessions for treatment failures. The Jadad score for this study is 2.

Relaxation Therapy

There were eight trials using relaxation therapy, all of which had a no-relaxation control group. Six of these studies reported a statistically significant benefit for treatment (two for

irritable bowel syndrome, two for nausea/vomiting, one for ulcer, and one for GI distress). The two studies that showed no effect from relaxation therapy were for constipation in children and vomiting in adults. One study had a quality score characterized as “good”; all others were “poor.”

Relaxation studies reporting a benefit. Of the five studies reporting a benefit, one dealt with the reduction of nausea, vomiting, and anxiety resulting from chemotherapy; one dealt with chronic pain from an ulcer; two were for irritable bowel syndrome; and one was for gastrointestinal distress.

Meyer (1983) reported on the use of relaxation in the treatment of nausea, vomiting, and anxiety resulting from chemotherapy. In this study, 37 patients (all over 18 years old, 68 percent females) were randomly assigned to one of three groups: a standard control group (n = 12), a systematic desensitization group (n = 13), and a relaxation training group (n = 12). The control group received no treatment. The desensitization group received training to modify anxiety and included progressive relaxation exercises. This group received one pretraining session, two treatment sessions, and one followup session. The relaxation group used meditation to achieve relaxation in two 1-hour relaxation training sessions. Outcomes measured were nausea, vomiting, and anxiety. Both desensitization and relaxation were effective against nausea and anxiety and somewhat effective against vomiting; however, desensitization was more beneficial than relaxation. The Jadad score is 3.

Giles (1978) reported the results of a randomized controlled study of gastrointestinal distress (type not specified). A total of 40 subjects (ages 18 to 33 years, gender not indicated) were randomly assigned to one of four treatment groups (n = 10 each): (1) stress management training (psychotherapy); (2) biofeedback relaxation; (3) combined treatment; and (4) a waiting list control. The stress management group received eight 50-minute therapy sessions. The biofeedback group had 50-minute training sessions, during which patients listened to half-hour relaxation tapes and practiced deep relaxation techniques. They received feedback on both muscle tension and body temperature as monitored by EMG and galvanic skin response. Treatment for both groups lasted about 8 weeks, although this could vary for individual patients as decided by the therapist. The combined treatment group received about 1 hour more stress management and biofeedback treatment per week during the 8-week period. The control group was simply a waiting list control. These patients could opt for treatment after the treatment period ended; therefore, the study no longer had a control group at the 8-month followup. Measurements taken before and immediately after treatment, as well as at the 8-month followup, included symptom reports along with psychological scales (e.g., locus of control) and psychiatric scales (e.g., Hopkins Symptom Checklist). For physical symptoms, all three treatment groups, but not the control group, had improved bowel movements and nausea; there was no reported difference for constipation among the four groups. The results were similar at the 8-month followup. The biofeedback relaxation group had better measures of loose bowel movement than did the combined treatment and stress management groups. For psychiatric symptoms, results for the combined treatment group were superior to those for the biofeedback and the stress management groups. The findings were similar for psychological measures. There were no significant differences among the groups for physician visits. The study concluded that the combination of biofeedback relaxation and stress management can be effective and that the effects continue for months after treatment. The Jadad score is 2.

Shaw and Ehrlich (1987) examined the use of progressive relaxation to treat chronic ulcer pain in a randomized study of 40 patients (ages 20 to 60, 50 percent female). One group received

six treatment sessions of progressive relaxation over a 6-week period. These subjects were also given relaxation audiotapes and told to practice with them at home at least once a day. Patients in the control group were told that they were on a waiting list to join the study and were updated weekly about their status during the 6-week intervention. They were given the option of relaxation therapy at the end of the study. Both treatment and control subjects were tested before and immediately after the study as well as 6 weeks later. Outcomes measured included self-reports, using the subject's own words, of the pain; intensity, duration, and frequency of pain episodes; pain relief; use of pain medication; and distress. The relaxation group was significantly better than the control group on six out of seven outcome measures both immediately after treatment and at 6 weeks. The results were not different when the subjects took pain medication, but only a few were actually taking it. The Jadad score is 1.

Blanchard, Greene, Scharff et al. (1993) studied irritable bowel syndrome in 14 patients (22 to 64 years old, 78 percent female), treating one group with relaxation therapy and simply monitoring a control group for the duration of the study. All patients had received an IBS diagnosis from a physician. Prior to the study, all patients received a psychiatric interview and completed an anxiety disorders interview schedule. The treatment involved abbreviated progressive muscle relaxation, which focused first on 16 muscle groups and then on 8 and finally on 4. Training was done individually at two sessions during the first 2 weeks and then once per week for 6 weeks. Regular home practice with an audiotape was also prescribed. The study examined the daily GI symptom diary that subjects kept for 4 weeks before and after the treatment and during the 8-week treatment period. The symptom diaries recorded abdominal pain, abdominal tenderness, diarrhea, constipation, bloating, flatulence, and nausea. The control group was monitored through the diaries for 16 weeks. Using a measure of multiple symptoms (the Composite Primary Symptom Reduction scores, CPSR), the authors reported that the relaxation group showed significantly more improvement than the control group. Fifty percent of the relaxation group reached a conventional level of clinically significant improvement while only 13 percent of the control group did so. The Jadad score is 1.

Hentschel, Bauer, Loew et al. (1994) conducted a randomized study of irritable bowel syndrome comparing physical relaxation with a placebo treatment. No information was given on the age or gender of the 57 subjects. The relaxation therapy combined body perception with physiotherapy on the skeletal joints carried out for 10 hours over 5 weeks. The placebo treatment consisted of tablets taken three times daily for 12 weeks. Outcomes measured were abdominal complaints and symptoms based on patient diaries. At the end of the treatment period, the relaxation group was significantly better than the placebo group in terms of reduced physical and mental stress in coping with their disease, general well being, satisfaction with activities of daily living, and global life satisfaction. The two groups, however, were not significantly different in vegetative dysfunction. The Jadad score is 1.

Arakawa (1995) reported the results of a randomized study of progressive muscle relaxation therapy to reduce nausea, vomiting, and anxiety for patients receiving chemotherapy (n = 60, ages 22 to 74 years, 40 percent female). The treatment group (n = 30) was given muscle relaxation instruction and an explanatory booklet. The initial training session took 45 to 60 minutes, and the patients met with the researcher once a day for additional sessions (number unknown). They were also given a 25-minute audiotape and instructed to use it to practice the relaxation technique at home twice daily. The treatment group was assessed on nausea, vomiting, and anxiety every 12 hours for 72 hours after the initiation of chemotherapy. The control group (n = 30) received routine nursing care, antiemetics, and met with the researcher once a day. They

too were assessed on nausea, vomiting, and anxiety every 12 hours for 72 hours after the initiation of chemotherapy. The author reported that progressive muscle relaxation reduced the total scores for nausea, vomiting, and retching in the treatment group compared to the control group and reduced anxiety scores as well for the treatment group. The Jadad score is 2.

Relaxation studies reporting no effect. There are two controlled studies reporting no effect from relaxation therapy, one on children with abdominal pain and constipation and the other on vomiting in adult chemotherapy patients.

Edwards, Finney, Bonner et al. (1991) used relaxation therapy to treat abdominal pain and constipation in boys ($n = 4$) and girls ($n = 7$), ages 6 to 12 years (64 percent female). The relaxation therapy was a progressive muscle relaxation procedure taught through weekly sessions and daily home practice with audiotapes. The study lasted from 10 to 18 weeks, depending on the type of intervention. Subjects were treated with either a simple fiber regime, a fiber regime followed by a period of relaxation therapy, a period of relaxation therapy followed by a fiber regime, or a fiber regime followed by a combination period of fiber plus relaxation therapy. Outcomes measured included pain and disruption of social functioning. The researchers reported that, although the children improved at greater than 6 months, in only one instance could improvement be attributed to the relaxation therapy. The Jadad score is 0.

In a study of chemotherapy-induced vomiting, Holli (1993) randomized 43 subjects (ages 19 to 84 years, gender not given) to an intervention of relaxation therapy and 24 subjects to a control group. Both groups received the normal antiemetics before chemotherapy. The control group received no other active intervention beyond completion of the evaluation. The relaxation group received progressive deep-muscle relaxation training before and after chemotherapy. The outcome evaluation, made by both the subjects and by an observer, looked at onset, quantity, and duration of vomiting. The study found no significant differences between the two groups. The Jadad score is 1.

In summary, we identified eight studies assessing the efficacy of relaxation therapy for a variety of gastrointestinal disorders. The single study characterized as “good” quality reported a benefit for relaxation therapy in reducing nausea and anxiety associated with chemotherapy.

Behavioral Therapy

There are eight studies of behavioral therapy, all of which reported a significant benefit. Six of these studies had a no-behavioral therapy control group, and they studied encopresis in children (one study), nausea and vomiting in children and adolescents (one study), nausea and vomiting in adults (one study), abdominal pain in children (one study), and irritable bowel syndrome in adults (two studies). The two studies without a no-behavioral therapy control group were for encopresis and irritable bowel syndrome.

Behavioral therapy study with a no-behavioral therapy control. Cox, Sutphen, Borowitz et al. (1998) investigated the use of biofeedback and enhanced toilet training (ETT, a behavioral therapy) in a study of encopresis in children ($n = 29$) from 6 to 15 years old. The children were randomly assigned to three groups: one received intense medical care (usual and customary care for this clinic); the second received behavioral therapy (ETT with incentives) plus intense medical care; and the third received behavioral therapy, biofeedback (surface EMG shown on a video display), and intense medical care. Baseline measures involved 14 days of recording toilet behavior by parents in a voice-mail diary. The subjects underwent psychological, physical, and manometric tests. However, because the researchers also wished to determine cost effectiveness, the number of treatments was open-ended, with sessions scheduled every 1 or 2 weeks as

needed. The sessions were terminated based on the child's performance and by a therapist/parent decision. During the 2 weeks of treatment and 3 months after the initial treatment, the parents repeated the 14-day voice-mail diary. Although both interventions that included behavioral therapy (ETT) produced similar reductions in fecal incontinence and were superior to intensive medical care alone, children in the group that combined behavioral therapy with intense medical care used fewer laxatives, required fewer treatments, had fewer relapses at 3 months, and had lower treatment costs at 3 months. The Jadad score for this study is 2.

Zeltzer, LeBaron, and Zeltzer (1984) compared a group receiving behavioral therapy (supportive counseling) with a control group and with a group receiving hypnosis in a study of 19 children (ages 6 to 17 years, gender not specified) receiving chemotherapy. The control group received only antiemetic treatment for nausea and vomiting. The supportive counseling consisted of distracting the children's attention during chemotherapy administration by helping them focus on other objects, using breathing exercises, and playing guessing games. The intent was to avoid the use of imagery, fantasy, or other hypnotic techniques. The parents were instructed to keep the children as active as possible at home to avoid having them focus on symptoms. In the hypnosis intervention, the child was helped to become involved in imagery and fantasy, with the fantasy taking on a sense of reality. The children were also given posthypnotic suggestions to help them use imagery at home. Ratings of nausea and vomiting as well as the bothersomeness of the chemotherapy were obtained from the parents and the children. Ratings were taken before, during, and after the intervention (the time interval was not given). Both supportive counseling and hypnosis were equally effective and were associated with a significant reduction in nausea, in vomiting, and in the extent to which these symptoms bothered the patient. These results remained after termination of the intervention. The Jadad score is 3.

Morrow and Morrell (1982) studied the use of behavioral therapy to control nausea and vomiting in adults receiving chemotherapy (60 patients, ages 19 to 76, 70 percent female). Patients were randomized to one of three groups: systematic desensitization, counseling, or no treatment. All patients received antiemetics. The systematic desensitization group received two 1-hour training sessions between the fourth and fifth chemotherapy treatments. During training they were individually taught a progressive deep-muscle relaxation technique for 20 minutes and then asked to create a hierarchy of increasingly intense anticipatory side effects. Once deeply relaxed, the patients revisited the hierarchy and were desensitized to it. The objective was for the patients to remain relaxed while visualizing the distressing situations. The second group received counseling to control for placebo effects. The patients met individually with the experimenter for two 1-hour sessions between the fourth and fifth chemotherapy treatments. Nausea and vomiting (frequency, severity, and duration) were assessed through patient reports. Two followup evaluations were conducted (no time interval was given). Significantly more patients receiving desensitization reported no anticipatory nausea before their fifth and sixth chemotherapy treatments than those receiving counseling or no treatment. Desensitized patients also reported significantly less severe anticipatory nausea and vomiting and a shorter duration of anticipatory nausea than patients in the other two groups. The Jadad score is 3.

Sanders, Rebgetz, Morrison et al. (1989) reported on a cognitive-behavioral intervention for nonspecific abdominal pain in 16 children (6 to 12 years of age, gender not given). After medical screening, the children were randomly assigned to one of two groups with eight in each: one group received a cognitive-behavioral intervention, and the other was a wait list control group. The treatment arm of the study received 8 weeks of therapy sessions. The treatment

sessions (length not given) involved both the child and the child's mother, and they had both a behavioral component and a cognitive coping skills component. The behavioral component involved self-monitoring of pain; a differential reinforcement of other behavior; a schedule for increasing pain-free periods and prompting distraction; and competing activities. The cognitive component consisted of a cognitive self-control procedure that included self-monitoring, self-instruction, self-efficacy statements, self-administration of rewards, self-induced relaxation, and an imaginal strategy to reduce pain. Self-reports of pain were used, as were parent and teacher observation reports. Members of the research team also observed the child and parent at home for 30 minutes. In the pretest assessment, children and parents kept observational records. Parents and teachers also completed a questionnaire. The children and parents in both the treatment and control groups completed pain diaries, and parents kept pain observation records during the 8 weeks of treatment. At the 3-month followup, all pretest measures were repeated for both groups. The results reported show that although both the control group and the cognitive-behavioral group had reduced their level of pain, the latter group improved more quickly, the effects generalized to the school setting (the children were rated better by the teachers for pain scores), and a larger proportion of the subjects (87.5 percent vs. 37.5 percent for the control group) were completely pain free by the 3-month followup. The Jadad score is 1.

Shaw, Srivastava, Swann et al. (1991) randomized 35 patients (ages 22 to 72 years, 45 percent female) to a conventional therapy group (n = 17) or to a stress management group (n = 18) for treatment of irritable bowel syndrome. The conventional care included antispasmodic medication taken three times daily. The stress management involved a 40-minute, individual weekly session with a physiotherapist. The number of sessions varied (a median of six sessions). During training, the patients identified areas of stress and were taught breathing exercises that were used to both identify and control tension. Patients were tested before and after treatment and 6 weeks later. The trial lasted 6 months with at least one review of the intervention. Patients were again interviewed at the end of the trial. The outcome measured was the change in symptoms. A followup was done at 12 months after the start of the trial. Sixty-seven percent of the stress management group (compared with 18 percent of the control group receiving conventional care) rated the program effective for relieving symptoms; they also experienced fewer and less severe attacks. This benefit was maintained for 12 months. The two groups differed significantly on these three variables. The Jadad score is 1.

In a study of irritable bowel syndrome using cognitive therapy, Greene and Blanchard (1994) reported that the cognitive therapy group had significantly greater symptom reduction than a control group. The 20 patients (18 to 70 years old, 75 percent female) were randomly assigned to a symptom-monitoring control group or to cognitive therapy group. The patients were assessed at baseline for physical symptoms, psychosocial functioning, and psychiatric symptoms. At the first visit all patients began a daily GI symptom diary that recorded severity of abdominal pain, abdominal tenderness, constipation, diarrhea, flatulence, belching, and bloating. The diaries were checked after 1 week and then kept during the 2-week pretreatment period, throughout the 8-week treatment, and for a 2-week post-treatment period. Subjects in the cognitive therapy group also completed the diaries for 2 weeks before the 3-month followup. The cognitive therapy involved ten 1-hour individual sessions: two sessions per week for the first 2 weeks and then one session per week for 6 additional weeks. Therapy focused on increasing patient awareness of the association between stressors, thought, and IBS symptoms as well as identifying and modifying threatening stimuli. The therapy used verbal and behavioral techniques to modify psychological mechanisms, beliefs, and assumptions. Self-recording of thoughts was encouraged, and the

patients were provided with monitoring sheets, which identified cognitive responses of the patient that the therapist could focus on. Patients in the control group continued to monitor their GI symptoms for 10 weeks (8 weeks to match the treatment group and 2 more weeks for the post-treatment period.). They were also seen at the mid-point for collection of the diaries and for assessment. At the conclusion, this group crossed over into the cognitive therapy group and then had treatment for 8 weeks. The primary outcome measured was IBS symptoms, but the researchers also measured cognitive changes. Symptom reduction was significantly greater for subjects in the treatment group than for those in the control group. At post-treatment, 80 percent of the cognitive therapy group showed clinically significant improvement while only 10 percent of the control group did. The results also held up at the 3-month followup. Within the cognitive therapy group, the reduction in symptoms correlated well with an increase in positive thoughts and with a reduction in negative ones. The Jadad score is 2.

In summary, we identified six studies that assessed the efficacy of behavioral therapy, all of which reported a statistically significant benefit. The two studies whose quality scores characterized them as “good” quality reported in children and adults receiving chemotherapy that behavioral therapy significantly decreased nausea and/or vomiting.

Behavioral therapy studies without a no-behavioral therapy control. Nolan, Debelle, Oberklaid et al. (1991) reported on a randomized trial of children that compared the use of laxatives and behavior modification (n = 83) to the use of behavior modification alone (n = 86) for encopresis. The ages of the children ranged from 3 to 16 years, and 27 percent were female. The primary outcome measured was remission from encopresis (at least one continuous 4-week period with no soiling episodes). Relapse was defined as soiling that reoccurred more than twice a month after a period of full remission. Treatment failure was defined as having made no substantial progress toward remission by at least 6 weeks from study entry. Both groups received a standard pediatric behavior modification intervention. This consisted of clarification of encopresis during a joint parent-child interview. The bowel training program used positive reinforcement for successful defecation in the toilet and reinforcement for every 24 hours without soiling. Reinforcement included parental praise and the use of a star-chart diary to indicate soiling-free days. A regular 5- to 10-minute toilet-sitting time within 30 minutes of eating was used. Dietary advice, general counseling, and support were provided. In addition to behavior modification, the second group also received laxatives. Constipation was assessed by stool retention based on a radiograph at baseline and at 2 weeks after randomization. A child behavior checklist (CBCL) was done at baseline and at 12 months. Clinic followup was done at 2, 6, 14, 30, and 52 weeks and thereafter as required. Followup varied depending on the child’s clinical progress. By the 12-month followup, 51 percent of the combined therapy group compared with 36 percent of the behavioral therapy alone group had achieved remission, a significant difference. Partial remission was 63 percent and 43 percent, respectively. The combined therapy group achieved remission significantly faster than the behavioral therapy alone group. The authors report that the combination of laxatives and behavioral therapy offers a considerable benefit over behavioral therapy alone for children who are able to maintain regular toileting. The Jadad score is 1.

Fernandez, Perez, Amigo et al. (1998) compared two behavioral interventions to study irritable bowel syndrome—stress management and contingency management—in 90 patients (mean age of 44 years, 66 percent female). The patients were randomly assigned to one of four study arms: a control group that received conventional medical care; a placebo group using visualization; a stress management group using progressive muscular relaxation, self-instruction,

problem solving, and coping; and a contingency management group that involved both the patient and relevant others (family etc.) practicing behaviors more adaptive to IBS symptoms. These patients identified which situations made them worse and learned to stop inappropriate reactions using a contingency contract, self observation, shaping, stimulus control, restructuring of time, and training in social skills. The stress management and the contingency management interventions consisted of 12 individual training sessions. Patients were assessed at the end of treatment (10 weeks) and at 1 year through diaries in which they rated the presence and severity of symptoms. The symptom diaries were kept at baseline for 2 weeks and then throughout the 10-week treatment period. The contingency management group showed significant reductions in all the digestive symptoms (abdominal pain, diarrhea, constipation, dyspepsia). At the end of treatment, 50 percent of these patients remained asymptomatic, and 37.5 percent had reduced their symptoms by at least 50 percent. Thirty-three percent of the patients in the stress management group got rid of all their symptoms, and this group showed significant reductions in abdominal pain, diarrhea, and dyspepsia. No significant changes were observed in the conventional care control group. These results were maintained 1 year after the intervention. The changes noted in the placebo group, however, were determined not representative because of the high dropout rate for these patients. Nevertheless, the authors concluded that behavior modification can eliminate or lessen chronic-illness behavior symptoms. The Jadad score for this study is 4.

Cognitive Therapy

There are four cognitive therapy studies, all with a no-cognitive therapy control group. Three of these studies concerned irritable bowel syndrome, and one concerned duodenal ulcer. The three studies on irritable bowel syndrome reported positive results, while the study concerning ulcer patients reported that cognitive therapy combined with hypnosis had the most benefit for the patients.

Lynch and Zamble (1989) report on the use of a behavioral relaxation treatment for irritable bowel syndrome. Although this study used relaxation therapy and is considered by the authors to be behavioral therapy, because its purpose is to control stress-producing cognitions, we have included it under cognitive therapy. Twenty-one patients (66 percent female, mean age of 38 years) were randomly assigned to either a treatment group ($n = 11$) or to a waiting list group ($n = 10$). The waiting list group received the treatment after 3 months on the waiting list. During this time they completed an evaluation, which consisted of keeping a diary of symptoms for 1 month followed by a questionnaire session. They then had no further contact for 2 months. After the waiting period, they then had a pretreatment evaluation, followed by 2 months of treatment, then a post-treatment evaluation. Followup was at 3 months after treatment. The treatment group followed the same procedure but without the initial evaluation and waiting period. These patients were given eight 2-hour sessions of behavioral relaxation training (the specific technique was not described). In addition to instruction in relaxation skills, the patients were also given a relaxation tape and were instructed to practice with it twice daily for 1 week. The patients were also taught stress inoculation techniques to do through homework assignments and assertion techniques (neither technique was described). The intent of the treatment was to enable the subjects to control stress-producing cognitions. At the conclusion of the eight training sessions, subjects were asked to bring in four completed weeks of post-treatment diaries, which provided information on symptoms (number of bowel movements, vomiting, etc.), use of medication, and relaxation practice sessions. Patients also completed a severity of bowel symptom scale along

with reports on pain and discomfort, diarrhea, and constipation. In addition, each subject completed a battery of seven tests involving psychological measures.

In a comparison of pre- and post-treatment results, patients in the treatment group had significantly greater improvement on two ratings (discomfort and constipation) than those in the waiting list group. On a composite measure of four primary ratings (pain, discomfort, diarrhea, and constipation), the treatment group did significantly better than the waiting list group. When the two groups were combined for analysis—that is, after the waiting list group was treated—the patients showed significant improvement on six diary ratings (pain, discomfort, diarrhea, constipation, bloating, and anxiety). This improvement remained over 7 months to followup. The authors define clinical improvement as having diary ratings of symptoms decrease by 50 percent or more between evaluation periods. Based on this criterion, 7 of the 11 patients in the treatment group were clinically improved. None of the 10 patients in the waiting list group improved during the waiting period, but 4 out of the 10 did so after they had been treated. The Jadad score is 2.

Payne and Blanchard (1995) randomly assigned 32 patients (ages 25 to 70 years, 91 percent female) with irritable bowel syndrome to one of three groups: cognitive treatment group, self-help support group, or a symptom-monitoring waiting list control group. Cognitive treatment was done individually and focused on increasing the patient's awareness of the association among stressors, thoughts, and IBS symptoms; training the patient to identify and modify their cognitive appraisals and interpretations of situations, thoughts, and behaviors; and changing the patient's underlying depressive or threatening schema or life scripts. These patients had individual sessions over 8 weeks—two 60-minute sessions each week for the first 2 weeks, then one weekly 60-minute session for the next 6 weeks. The self-help support group met weekly for 8 weeks in group sessions lasting around 75 minutes. The sessions provided patients with information about IBS as well as an opportunity for them to share experiences and become involved in supporting each other. The therapist leading the sessions gave no directions or advice for change to the patients. Outcome measures included individual GI symptoms and an index for symptom change as well as psychological measurements. A followup occurred at 3 months. Comparing pre- and post-intervention measurements showed that the cognitive therapy group had significant reductions in both individual GI symptoms and in the composite index for symptom change; the self-help support group and the control group did not. The cognitive therapy group also showed a significant improvement on the psychological measures of depression and anxiety. The Jadad score is 3.

van Dulmen, Fennis, and Bleijenberg (1996) compared a waiting list control group of 20 subjects (mean age 48 years, 40 percent female) to a group of 27 patients (mean age 44 years, 51 percent female) receiving cognitive-behavioral therapy for irritable bowel syndrome. All patients in the treatment group underwent eight 2-hour sessions over 3 months. Treatment consisted of patient education about cognition, behavior, emotions, and environment, and correcting unjustified or dysfunctional attributions; homework to change complaint-related cognitions; group conversations; and training in progressive muscle relaxation. All material was also provided to the patients in a course book. Patients were assessed by a questionnaire before and after treatment; this assessment was made for the control group before and after the waiting period. All study patients also kept a diary in which they recorded a daily abdominal complaint score based on rating abdominal pain four times daily; activities avoided because of the pain; and symptoms (flatulence, belching, nausea, heartburn, abdominal rumbling, and defecation). An abdominal complaint inventory was kept along with details of coping strategies and use of

medication. A psychological well-being score was also recorded by the patients. A patient was considered clinically improved when the daily abdominal complaint score had decreased by 50 percent. The patients were followed up, but the time interval ranged from 6 months to 4 years. The abdominal complaints of those receiving treatment improved significantly more than those in the control group awaiting treatment. The number of successful coping strategies also increased, and avoidance behavior decreased, in the treatment group. The positive changes persisted at the followup. The Jadad score is 1.

Tosi, Judah, and Murphy (1989) compared three treatment interventions with a control group for individuals with duodenal ulcer diagnosed by gastroscopy and/or radiography. There were 25 patients in the study (40 percent female). The subjects were randomly assigned to a cognitive experiential group that used hypnosis and cognitive restructuring (6 subjects); cognitive restructuring only (6 subjects); hypnosis only (5 subjects); and no treatment control group (8 subjects). Cognitive restructuring takes a patient through a progression of six stages: awareness, exploration, commitment, implementation, internalization, and stabilized behavior. The subject is asked to imagine a distressing event and then to imagine negative or self-defeating response sequences. Subsequently, the subject imagines the same sequences, but this time they are restructured to be positive and self-enhancing. Seven training sessions were conducted for each treatment mode over a 6-week period. The study measured psychological outcomes using a Common Belief Survey, the Millhon Behavioral Health Inventory, and patient self-reports of the frequency of gastrointestinal disturbances. Outcomes for the group receiving combined cognitive restructuring and hypnosis differed significantly from those for all other arms of the study with regard to the locus of control psychological measure. They were also significantly different from the outcomes for the control and hypnosis-only groups on self-reported frequency of GI disturbances. The authors conclude that the combination of hypnosis and cognitive restructuring had the greatest impact on treating duodenal ulcer in this study. The Jadad score is 1.

In summary, we identified four studies that assessed the efficacy of cognitive therapy. The sole study whose quality score characterized it as “good” reported that cognitive therapy improved symptoms in patients with irritable bowel syndrome compared to a waiting list control.

Guided Imagery

The review identified two studies of guided imagery with a control group not receiving guided imagery. One study reported a beneficial effect only in terms of the patient’s perception of the chemotherapy experience. There was no effect on other outcomes. The other study also reported an effect on some but not all outcomes.

Tusek, Church, Strong, Grass et al. (1997) used guided imagery for patients undergoing colorectal surgery (130 patients, male and female, percentages not given, ages 17 to 78). This was a prospective study in which patients were randomized to either standard preoperative care or to a guided imagery group (n = 65). The treatment group listened to a guided imagery tape with background music twice daily for 3 consecutive days before their operation. The guided imagery tape encouraged them to be calm and focused. Then a tape of the background music alone was played during induction and during surgery, in the recovery room, and for 6 postoperative days. Both tapes were 20 minutes long. Both the treatment and control groups received postoperative analgesia. Outcome measures included ratings of pain and anxiety, narcotic consumption, time to first bowel movement, length of stay, and number of complications. The ratings were collected before the patients had a first meeting for the surgery, before surgery itself, and during the morning and evening for 6 days following surgery.

Compared to the control group, the total analgesic requirements were significantly lower in the guided imagery group; the time to first bowel movement was significantly less, but the median length of stay for surgery was not. Anxiety before surgery increased in the control group but decreased in the guided imagery group, and the worst pain score and the least pain score were significantly better for the guided imagery group. The groups did not differ in postoperative complications. The Jadad score is 3.

In a study of nausea and vomiting related to chemotherapy, Troesch, Rodehaver, Delaney et al. (1993) randomly assigned 28 patients (33 to 80 years old, gender not given) to a control group receiving standard antiemetic therapy or to a treatment group receiving antiemetic therapy plus guided imagery. The subjects completed a questionnaire 4 hours prior to treatment and then every 12 hours thereafter for 48 hours. The subjects in the guided imagery group were instructed verbally and with an audiotape about visualizing a positive experience with the chemotherapy. For each course of treatment, the subjects used the tape for 60 minutes prior to treatment, the following morning, and the following evening. There was no significant difference between the two groups in terms of patient perception of nausea, vomiting, retching, and the distress associated with these as measured at five points in a 48-hour period. However, there was a significant difference in patient perception of the chemotherapy experience: the guided imagery group perceived themselves as significantly more in control, more powerful, more relaxed, and more prepared than the control group. The Jadad score for this study is 3.

Placebo Therapy

In placebo therapy, we included only the one study found that assessed placebo for its active properties rather than using placebo as a control for the assessment of some other potentially active therapy.

Hodgson (1977) used a double blind trial to compare the effect of two tablets, one a placebo, the other methylcellulose (Celevac), on 30 patients with diverticular disease (60 percent female, mean age 63.4 years for the females, 56.8 years for the males). The patients' diagnosis was confirmed with a barium enema and a radiological examination. Each patient in both groups took two tablets daily. The placebo group was then crossed over to the medication (Celevac) group after 3 months. The patients completed a self-report of symptoms and signs that was scored to determine outcomes, which included severity and frequency of pain and severe disturbance of bowel habit. Although the patients on placebo who completed the trial (11) did show a small mean improvement, it was not statistically significant. There was a significant improvement for the medication group. The Jadad score is 3.

Multimodality Studies

A number of trials in mind-body therapy involve multiple interventions. In many ways this reflects the typical clinical situation in which therapies are frequently used in combinations. We discuss here five such studies, two of which were reported in the same publication.

Humphreys (1998) compared children with recurrent abdominal pain (n = 61, ages 4 to 18 years, 25 percent female) in four randomly assigned groups, three of which received combinations of the following active treatments: increased dietary fiber, parental support, cognitive/behavioral therapy, and biofeedback-assisted cultivated low arousal. One group received all four treatments (fiber, biofeedback, cognitive/behavioral therapy, parental support); a second group received three treatments (fiber, biofeedback, cognitive/behavioral therapy); and

a third group received two treatments (fiber and biofeedback). A fourth group—the control group—received fiber only. The children received six training sessions. Outcome measures included abdominal pain, improvement in symptoms, utilization of medical services, medication use, and school attendance. Level of pain and symptoms were recorded by both patients and their parents. All groups showed improvement on pain, but the active treatment groups showed significantly more improvement from pre- to post-treatment than the control group. Ninety-six percent of the patients in the active treatment groups had reduced levels of pain, and 72 percent experienced complete elimination of symptoms. There was no significant difference in the intervention groups. The Jadad score is 3.

Blanchard, Schwarz, Suls et al. (1992) reported two studies of patients with irritable bowel syndrome. In the first study, 30 patients (age range 23 to 75 years, 77 percent female) were randomly allocated to one of three arms: a multicomponent treatment, an attention placebo, and symptom monitoring. The patients kept a diary recording their GI symptoms, avoidance activity, and medications. At the pretreatment interview, a battery of psychological tests was given.

Training for the multicomponent treatment was given individually, in 12 sessions, over an 8-week period (twice per week for 4 weeks, then once per week for another 4 weeks). It included education about normal bowel function, progressive muscle relaxation, thermal biofeedback, and cognitive stress coping. An audiotape was used for the muscle relaxation therapy at each session. The tape was also used for home practice done for 20 to 25 minutes each day at first and then every other day. Patients gave themselves relaxation ratings at each session, and they recorded their practice at home in detailed diaries. Thermal biofeedback, which took about 32 minutes, was introduced in session seven and continued through the next five sessions. At home, the patients used a thermometer as a trainer for hand-warming response exercises. A portion of each session was devoted to cognitive stress coping training, during which patients were taught to use positive imagery and relaxation as coping strategies.

Patients in the attention placebo group were instructed in “pseudomeditation” for the first six sessions during which patients were told to sit erect and not to relax while mentally scanning their body. During the last six sessions, the patients were given biofeedback training to suppress their alpha waves. The patients were instructed to reduce the biofeedback tone of an electroencephalogram (EEG) reading obtained from contacts placed over the occipital lobe and over the right mastoid, with the forehead serving as ground. Home practice was also used with this group. Patients in the symptom monitoring group were told that their treatment would be delayed by several weeks but to continue monitoring their GI symptoms. Followup occurred at 2 weeks after treatment. Outcomes measured included the composite symptom reduction scores and psychological tests.

The multicomponent group had 60-percent clinical improvement, with a 45-percent improvement on the composite symptom reduction score, as well as significant reductions in most symptoms and on all psychological tests. However, this group was not significantly different from the attention placebo group on any measure. This study has a Jadad score of 1.

The second study reported in Blanchard, Schwarz, Suls et al. (1992) used the same three study arms (multicomponent treatment, attention placebo, symptom monitoring) but increased the sample size to 115 patients and extended the symptom monitoring periods to 4 weeks before and after treatment. The symptom-monitoring group was also crossed over to the multicomponent group after the 1-month followup. Again the authors found no advantage for the multicomponent group over the attention placebo group. Both groups had significant reductions

in GI symptoms, in trait anxiety, and in depression. The GI symptom reductions held up at a 6-month followup. This study has a Jadad score of 2.

Calloway, Fonagy, Pounder et al. (1983) compared two behavioral methods for the treatment of aerophagia in 12 patients (ages 21 to 62 years, 70 percent female). All patients continued their regular medical care (not described). One group (six patients) received progressive relaxation therapy that was augmented by home practice; they also received biofeedback from a relaxometer (based on galvanic skin resistance). They had three therapy sessions. The other group (six patients) received audio biofeedback on their swallowing from a specially designed device with a portable microphone and ear piece that amplifies the sound of swallowing. It was used twice daily. These patients were also shown behavioral alternatives for reducing excessive swallowing, such as breathing, biting on pencils, yawning, etc. Cognitive and situational antecedents were discussed with each patient in these groups. The patients kept diaries of their progress and symptoms. After 4 weeks of treatment, the swallowing rate and skin conductance were reassessed for all patients, who were also examined by a blinded physician and rated on a three-point scale. Patients were also seen at 1 month and at 9 months after this assessment. Although the overall swallowing rate of the patients decreased, there were large individual differences. In the first group, only 33 percent had a reduction, compared with 67 percent in the second group. This is a statistically significant difference. The reduction in symptoms was significantly associated with reduction in swallowing. All patients who reduced their swallowing rate were also rated as having improved symptoms; only one patient improved symptomatically without improving the swallowing rate. Only eight patients were examined at the 9-month followup. Six of these patients had shown improvement initially, but only three (50 percent) had maintained that improvement. The Jadad score is 0.

Bergeron (1983) compared cognitive stress management, progressive muscle relaxation, and biofeedback in a study of irritable bowel syndrome that involved 37 patients (mean age 39 years, gender not described). The cognitive stress management group met as a group once weekly for 2 hours to discuss and participate in cognitive stress reduction and assertiveness training. Patients in the relaxation intervention met in groups of four twice weekly for 75 minutes. During this time they practiced progressive muscle relaxation, guided imagery, autogenic phrases, and systematic desensitization. Patients in the biofeedback arm met in groups of two twice weekly for 1 hour to practice relaxation using bowel sound biofeedback, EMG biofeedback, peripheral skin temperature biofeedback, guided imagery, autogenic phrases, and systematic desensitization. Outcomes measured included abdominal pain, bowel function, GI symptoms, and IBS severity rating, as well as psychological measures for anxiety and locus of control. Information came from patient self-reports and from two gastroenterologists who acted as judges of the symptom data. All three treatment methods caused a decrease in physical IBS symptoms, but only the stress management and the biofeedback caused a decrease in the psychological symptoms. There were no differences among the three groups in symptoms. The Jadad score is 3.

Chapter 4. Conclusions and Future Research

Conclusions

This evidence report assessed the distribution of published studies of mind-body therapies in general and performed a more detailed review of mind-body therapies for gastrointestinal disorders.

With regard to mind-body therapies in general, we identified a large body of literature.

- The most common conditions for which studies of mind-body therapies have been published are:
 - > Neuropsychiatric
 - > Head/ear, nose, and throat
 - > Gastrointestinal
 - > Circulatory
 - > Musculoskeletal
- The mind-body therapies that have been most commonly the subject of published studies are:
 - > Biofeedback
 - > Hypnosis
 - > Relaxation
 - > Behavioral
 - > Cognitive

Our review supports the following conclusions regarding mind-body therapies for gastrointestinal disorders:

- The controlled trials of mind-body therapies have substantial methodologic shortcomings that affect the internal validity of the results.
- About 75 percent of the controlled trials of mind-body therapies are not powered sufficiently to detect even large therapeutic benefits.
- There is no evidence to support the efficacy of biofeedback therapy for children. Seven controlled trials have all failed to demonstrate statistically significant benefits of biofeedback compared to other therapies.
- There is limited evidence (at least one trial whose quality score characterized it as “good” that reported statistically significant benefits and the majority of other studies also report

statistically significant benefits) to support the efficacy of the following mind-body therapies:

- > Relaxation
- > Behavioral
- > Cognitive
- > Guided imagery

This level of evidence falls short of conclusive proof of efficacy, but does suggest that these therapies are the most promising for further, high quality studies assessing efficacy and effectiveness.

- The methods shortcomings of studies reporting beneficial effects of hypnosis preclude drawing conclusions about its efficacy. Although all but one of the studies of hypnosis reported statistically significant benefits, none of the studies had a “good” quality score and therefore we can only conclude that more research is needed.
- There are mixed results regarding the use of biofeedback in adults. There was one study of biofeedback in adults whose quality score characterized it as “good,” and this study did not report any benefits of biofeedback. Three other studies of lesser quality were additionally found, one also reporting no benefit and two others reporting some benefit of biofeedback. These disparate results will need to be clarified by additional research.
- There were no reports of the mind-body therapies being associated with any harms.

Limitations of the Review

Four factors prevent any stronger conclusions being drawn from the data other than the ones presented here.

(1) The low number of small (in terms of sample size) studies for some conditions and some therapies supports the hypothesis that publication bias occurred. This research situation, in which there exists a small number of relatively small and low-powered published studies, might occur because the small sample size and nonsignificant results deter publication of other studies. Because of the heterogeneity of the studies, and the lack of a common outcome measure and sufficient data on means and variance measures of some sort, we are not able to do a test for publication bias that requires a common statistic across studies. Therefore, we cannot address this issue statistically.

(2) The poor quality of the controlled trials may be exaggerating the estimate of the effect of the mind-body therapies. Empiric evidence has shown that studies whose quality is characterized as “poor” report substantially increased beneficial effects. When combined with the concern about publication bias, above, this means our review may overestimate the efficacy of mind-body therapies.

(3) The third factor also stems from our inability to calculate a common statistic across studies that would allow a more quantitative comparison among and synthesis of the studies. We present our results in the form of a qualitative and narrative review that discusses each individual

study similarly and includes a systematic presentation of study characteristics in our evidence table. Some of our discussion focuses on the number of studies that showed beneficial results versus the number that did not in certain settings. This might be considered to be an application of the meta-analytic method of “vote counting” in which each study is given equal weight in the consideration of the results. This method is often all that is possible in a synthesis when the individual studies do not have comparable outcomes and are heterogeneous. However, this method has been criticized on several dimensions (Bushman, 1994). Under a strict vote counting method, all studies are counted equally, regardless of sample size or quality. We tried to minimize this by placing more emphasis in our summary on those studies characterized as “good” quality. The method also does not produce a clinically interpretable result, and the strength of the conclusion is not apparent, unlike in a quantitative synthesis, which produces a pooled effect size and confidence interval. The last problem is that vote counting has been shown to have low statistical power to detect small effect sizes (Hedges and Olkin, 1980). Given these drawbacks of the method, we have attempted in our discussion of the results to consider each study individually rather than just to present the overall number of studies in each category, and we have presented our caveats about the method as well.

(4) The conclusions of this review are based on the limitation that arises from focusing on controlled trials only. Although this is methodologically a good decision, it may be that review of studies that do not achieve this status would result in the identification of promising areas for further research. However, as the controlled trials identified do not establish the efficacy of any of the mind-body therapies, sufficient areas of promising research are already identified without having to assess studies of lesser interval validity with respect to efficacy.

Future Research

Our review of the literature has identified several areas where future research into mind-body therapies could benefit from our findings. We have noted recurring shortcomings in the design and execution of published studies that weaken the conclusions that can be drawn from the studies. Future research needs to be better designed and implemented. Studies need to enroll adequate numbers of well-defined, clinically homogeneous populations. They also need to compare the mind-body interventions both to other potentially effective therapies and to a convincing control, if possible. Furthermore, future studies should employ randomization, use blinding where feasible, and measure outcomes that are meaningful to patients and that can be reliably assessed. Ultimately, only those studies with a control group for comparative analysis can address the question of the efficacy of mind-body therapies.

In addition to needing improved design, future trials of mind-body therapies need better reporting. This would aid interpretation and the application of the research results. Two types of information are essential: a clear description of the research design, particularly of the control and comparison groups, and a detailed description of the patient sample. It is frequently difficult to tell from published studies how comparable the patient populations are, not only demographically but also clinically, in order to interpret the diagnosis and prognosis.