

**The Federation of Behavioral, Psychological, and Cognitive Sciences
and
the Association for Applied Psychophysiology and Biofeedback**

**Science Forum on
“Mind-Body Medicine”**

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Talk Abstracts

Frank Andrasik, PhD (University of West Florida)
“How Can Biofeedback Improve U.S. Healthcare?”

A recent survey (Barnes et al., 2004) revealed that a sizeable number of adults had used some form of mind-body/complementary and alternative medicine treatment within the year studied (2002). Among the explanations for this rapidly growing interest in alternative treatments are dissatisfaction with conventional (western) medicine, and a desire of patients to be more actively involved with medical decision-making and their subsequent care. A number of procedures that are typically combined with biofeedback were rated highly (such as deep breathing exercises and meditation), but biofeedback was not specifically listed among the top alternative choices. This is surprising because biofeedback has an extensive base of empirical support, certainly equal to that for the more highly rated alternatives. The presentation by Dr. Robert Whitehouse reviews the reasons for this puzzling state of affairs.

In this era of evidence-based medicine, it is important to review what the literature has in fact shown about the clinical utility and cost-effectiveness of biofeedback. In short, the evidence is substantial. Biofeedback has been extensively reviewed from two vantage points—qualitative (examination by expert review panels, comprised of members both within and outside the profession) and quantitative (via the statistical method of meta-analysis, a way of comparing findings from diverse studies in a single analysis). A review recently completed by the Association for Applied Psychophysiology and Biofeedback (AAPB) (Yucha & Gilbert, 2004) determined that 6 disorders met the two highest standards of efficacy: anxiety, attention deficit disorder, headaches, hypertension, temporomandibular disorders, and urinary incontinence in women. Biofeedback was judged as being probably effective for numerous other disorders, with many other disorders showing promise. AAPB, in conjunction with the International Society for Neuronal Regulation, has commissioned more indepth followup efficacy reviews (Moss, LaVaque, & Hammond, 2004) for all appropriate disorders and several of these “White Paper Reviews” have been published in peer-reviewed journals to date.

In order to be judged efficacious, large-scale clinical trials are needed and funding for these biofeedback trials has been quite limited, which helps to explain why more disorders have not been placed into the higher evidence categories. Further, biofeedback clinical trials are often evaluated by conventional criteria, such as the JADAD rating system and the pharmacological “gold-standard” for double-blinding of conditions, which is inappropriate. Other considerations are important, too, such as the need for effectiveness trials for this type of treatment. Review panels look for studies yielding negative findings (nonsupport) as well as those reporting negative side effects. No major side effects have surfaced in the extant biofeedback clinical trials.

Clinical trials that have incorporated cost-effectiveness analyses provide further evidence of the value of biofeedback (these are summarized in Shellenberger et al., 1994). Preliminary findings from these studies have shown evidence for a number of favorable returns: reductions in medication, physician visits, medical costs, claims filed, costs of insurers/employees, hospital stays, rehospitalization, mortality, and morbidity and increases in quality of life. A recently completed investigation (Ryan & Gevirtz, 2004) examined the effectiveness and cost feasibility of offering biofeedback in the treatment of “functional” disorders presenting in a primary care setting. These types of patients have become a considerable liability in healthcare, as these patients tend to over utilize treatment and drain resources. The preliminary findings are encouraging, both with respect to patient improvement and cost-savings.

Citations to Referenced Studies and for Further Reading

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Bob Whitehouse, EdD (Colorado Center for Behavioral Health)
“Biofeedback Issues: Access, Insurance, Cost, and Legislation”

I. BIOFEEDBACK---What is it

Biofeedback is the use of biomedical instruments that monitor physiological responses that can be controlled to reduce symptoms of many medical and psychological disorders, and/or optimize function. A therapist guides the process of awareness and then skill development. It is not just relaxation training, it does nothing to you, and it is not biorhythms. It is usually complementary to medical and psychological treatment. It is also used by astronauts and Olympic athletes to optimize function. It is also called applied psychophysiology and psychophysiological therapy.

II. New Model of Self-Care

Biofeedback has been here almost 40 years. It gathers objective measures of the signs and symptoms of stress, distress, disease, and injury. As a form of Self-Regulation, it helps individuals in prevention and treatment of these as well as marking improvement and outcome. It facilitates lifestyle changes for improved health and well-being.

III. CAM or Traditional

Biofeedback has been in the CPT code books and reimbursed by some insurances for many years, yet it also fits into the 2nd of 5 CAM categories---Mind-Body Interventions. The number of hospitals that have CAM programs has more than doubled since 1998.

IV. Clinical Efficacy

Biofeedback is used for over 40 medical and psychological disorders, varying in efficacy from treatment of choice to experimental, and recently rated on 4 levels, from “Not Empirically Supported” to “Efficacious.” Double-blind studies are not appropriate for biofeedback.

V. Cost Effectiveness

Outcome studies have shown Biofeedback treatment to be Cost Effective in these 6 areas: 1) Reductions in Medication and/or Physician Usage, 2) Decrease in Medical Care Costs to Patients, 3) Decrease in Number of Claims and/or Costs to Insurers and Employees, 4) Reduction in Hospital Stays and Rehospitalization, 5) Reduction of Mortality and Morbidity, and 6) Enhanced Quality of Life.

VI. Access issues

Access to Biofeedback is difficult because of inconsistent policies between government programs and major medical insurance companies whereas Workers Compensation and Auto policies usually cover it. Many programs only allow physicians or psychologists and some licensed clinical social workers as the providers.

VII. Insurance coverage and gaps

CHAMPUS/Tricare covers biofeedback for about 28 diagnoses. Medicare covers 14 (mostly incontinence) but not pain or psychological disorders. Aetna covers 10 medical conditions only. Medicaid does not cover biofeedback. The Blues typically now only cover incontinence (per Medicare) and deny others, citing biofeedback effects as nonspecific, i.e. not proven to be due to the instruments, and not proven to be more effective than other counseling/relaxation methods, and therefore considered experimental or investigational, and not medically necessary. About 50% of major medical insurance companies reimburse for biofeedback for some diagnoses and by some providers licensed in medicine or mental health.

VIII. Certifications and requirements

There is currently no licensure for Biofeedback. There is voluntary certification. The most recognized is by the Biofeedback Certification Institute of America (www.bcia.org) which has 3 certifications: General Biofeedback, EEG Biofeedback or Neurofeedback, Pelvic Muscle Dysfunction Biofeedback. In addition to the prerequisite education in one of the above fields, there are biofeedback requirements in: didactic education, personal & mentored practical training & case presentations, human anatomy & physiology, and a written examination covering the relevant Blueprint Knowledge areas.

Vincent J. Monastra, PhD (FPI Attention Disorders Clinic)
“EEG Biofeedback Treatments for ADHD: Rationale and Empirical Foundation”

Historically, pharmacological treatments for Attention-Deficit/Hyperactivity Disorder (ADHD) have been considered to be the only type of intervention effective for reducing the core symptoms of this condition. These stimulatory medications appear to promote improved attention and behavioral control by increasing the availability of catecholamines (e.g. dopamine; norepinephrine) at the synaptic level, thereby increasing cortical activation in targeted brain regions (e.g. Frontal lobes, Rolandic Cortex). Treatment response rates for stimulant therapy vary in the published research, with approximately 75% of patients responding positively to stimulant therapy.

Paralleling the emergence of stimulatory medications during the past three decades is a type of behavioral therapy, called EEG biofeedback. Like stimulant medication, this intervention seeks to treat symptoms of inattention, impulsivity and hyperactivity by increasing cortical underarousal over frontal and central, midline regions of the brain. During EEG biofeedback, patients are reinforced (via video and auditory stimuli) for producing half-second “bursts” of high frequency brain waves (called “beta” or “smr”) while simultaneously reducing the amplitude of “slow” frequency brain waves, thereby increasing levels of cortical “arousal.” The results of a series of case and controlled group studies examining the effects of EEG biofeedback indicate that children, teens, and adults diagnosed with ADHD are able to improve attention behavioral control, increase scores on tests of intelligence and academic achievement, demonstrate increased cortical activation on QEEG examination, and exhibit increased activation of the cingulate gyrus, the caudate nucleus, and the lateral prefrontal cortex on fMRI following 20-50 minute sessions of this type of treatment. Similar to studies of medication effects, approximately 75% of patients treated with EEG biofeedback have responded positively in controlled group studies.

Current assessment of efficacy of EEG biofeedback is that it has been determined to be “probably efficacious” for the treatment of ADHD (using standards published by the Association for Applied Psychophysiology and Biofeedback and by the International Society of Neuronal Regulation, Monastra et al, 2005. In Press). Hirshberg, Chiu, and Frazier (2005) using the American Academy of Child and Adolescent Psychiatry guidelines for recommending evidence-based treatments, considered EEGH biofeedback to meet “Clinical Guidelines” for use of this treatment, indicating that a psychiatrist should anticipate positive responses in approximately 75% of patients. No other psychological or behavioral therapy meets this level of efficacy in treating the core symptoms of ADHD.

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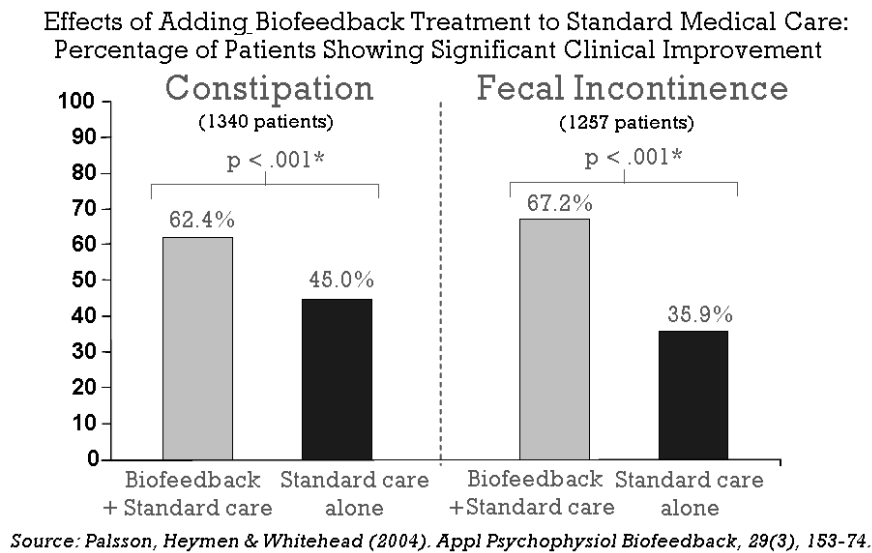
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Olafur Palsson, PsyD (University of North Carolina, Chapel Hill)
“Biofeedback for Pelvic Floor Disorders and Incontinence”

Functional fecal incontinence (FI): FI is a chronic disorder defined as recurrent uncontrolled passage of fecal material. About 0.7% of the overall adult population (and 2% of children) has severe FI and 7% of adults have minor FI. Risk factors for developing FI include childbirth (pudendal nerve and sphincter damage), chronic diarrhea or chronic constipation, physical immobility, cognitive impairment, and physical injury or illness that leads to sphincter, nerve or sensory damage. Fecal incontinence is a greatly underestimated problem because patients rarely discuss it with others due to its private and embarrassing nature. FI commonly has serious negative effects on patients’ lives, including social isolation, poor self-esteem, impairment of intimate relationships, reduction in mobility and inability to travel freely. FI is one of the leading causes of nursing home placement of elderly adults: 45-47% in U.S. nursing home residents have fecal incontinence vs. only 3% of the community-dwelling elderly.

Chronic constipation: Affects about 3-6 % of the population. Women outnumber men 2-3 times. Risk factors include poverty, low fiber diet, sedentary lifestyle and race (more common in African Americans than Caucasians). There are three main types of constipation; pelvic floor dyssynergia or PFD (due to failure to relax, or paradoxical contractions of, the pelvic floor muscles during defecation attempts), slow transit (due to biologically slow bowel), and constipation as a symptom of irritable bowel syndrome.

Biofeedback as a treatment option for constipation and fecal incontinence: Biofeedback is the treatment of choice for (a) pelvic floor dyssynergia (PFD), one of the most common types of constipation (accounting for about ¼-½ of adult constipation and ½ of childhood cases) and (b) for fecal incontinence cases that are not due to serious anatomical defects nor just a side effect of diarrhea. A recent comprehensive review of all relevant studies in the scientific literature in the past 30 years (Palsson, Heymen & Whitehead *Appl Psychophysiol Biofeedback*. 2004, 29(3):153-74) found that when biofeedback treatment is added to standard medical care, patients with fecal incontinence are 87% more likely, and constipation patient 39% more likely, to show improvement in their symptoms compared to patients only receiving standard medical treatment (see figure below).



Advantages of biofeedback for chronic constipation and fecal incontinence:

- Inexpensive (3-6 sessions with a nurse or technician)
- Practically no adverse side effects
- Therapeutic benefit often lasts for years
- Complements standard medical care and significantly enhances clinical outcomes
- Sometimes makes surgery (an intervention causing permanent anatomical change with substantial risk of negative side effects) unnecessary
- Can reduce the serious negative psychological, social and quality-of-life consequences of these disorders and help elderly people live independently in the community instead of needing nursing home care

Paul Lehrer, PhD (UMDNJ Robert Wood Johnson Medical School)

“Heart Rate Variability Biofeedback: A New Approach to Fostering Cardiorespiratory and Emotional Control and Improving Human Performance”

Heart rate variability (HRV) is highly correlated with health and fitness. It is negatively related to age and with most physical and mental illnesses. Depressed HRV is a strong predictor of death from all causes. Similar findings have been obtained for “baroreflex gain.” The baroreflexes are important mechanisms that help control blood pressure and emotional reactivity. They are triggered by sensors in the large blood vessels. When blood pressure changes, the baroreflexes act to restore the previous level, and thus help keep the body stable. When HRV is low or the baroreflexes are disordered, the body’s “control reflexes” do not work properly, so the body can no longer adapt normally to normal physical and mental stress. Illness or death may result.

HRV can be easily modified by biofeedback.

Also, HRV biofeedback greatly stimulates both HRV and the baroreflexes. Although great increases in these measures are easily seen within a few minutes of training in almost all people, the technique usually takes about four sessions of training to fully master. Regular practice of HRV biofeedback systematically exercises the baroreflexes, and increases “baroreflex gain” (a measure of the strength of the baroreflexes) *at rest*.

HRV biofeedback also causes people to breathe at the specific rate at which respiration and heart rate vary in phase with each other, so that heart rate increases exactly when we inhale, and decreases exactly when we exhale. This improves respiratory efficiency. More blood is circulating through the lung (from higher heart rate) exactly when the lung has the most oxygen in it (during inhalation). This allows the best absorption of oxygen from the lung. When people breathe at this rate their blood becomes maximally saturated with oxygen, and they become more resistant to such respiratory stressors as exercise, high altitude, or high carbon dioxide concentration (as may occur in a crowded stuffy room).

We will present data showing that HRV biofeedback is clinically helpful for asthma, emphysema, hypertension, depression, and fibromyalgia. We also will show improvements in athletic performance, tolerance for altitude and exercise, and resistance to hyperventilation.

HRV biofeedback also allows a standardized and sensitive method for comparing HRV among various populations. By having people breathe at the rate that, for each individual, maximizes both respiratory efficiency and the baroreflex, we can develop a test that measures the aspects of health and adaptability in each person. We then can find out how specific diseases, stressors, etc. each affect health and the body’s ability to adapt.

For convincing proof of our findings, we still need to do larger controlled clinical trials, and pilot trials for various populations who have not yet been studied. We believe that these methods may particularly help people whose autonomic nervous systems are not functioning properly. An example of this is people with spinal cord injuries high in the spine, who have no use of their bodies below the neck. In these people, the brain’s control of part of the autonomic nervous system is completely destroyed. We believe that HRV biofeedback can help train the remaining parts of the autonomic nervous system to compensate for this loss. We also need further studies of HRV biofeedback for improving athletic performance and exercise tolerance, for managing stress, for altitude tolerance, and for prevention of anxiety due to hyperventilation (over-breathing)..

Also further research is needed to study the baroreflex itself. Previous research has measured the way that the baroreflexes affect heart rate. However they also affect dilation and constriction of the arteries. This function of the baroreflexes is particularly important in controlling blood pressure, and has been studied very little.

Frank Andrasik, PhD (University of West Florida)

“New Horizons in Pain Management: Headache as a Case in Point”

Pain is a common complaint and accounts for considerable suffering, impairment, functional limitations, and disability. For example, migraine headache affects 20-25 million Americans and is under diagnosed and under treated. The American Migraine Study showed that migraine afflicts more people in the US than many chronic conditions including diabetes, asthma, osteoarthritis and depression. Over 80% of migraine sufferers have moderate to severe attacks with most having some level of disability one or more days per month. Migraine prevalence is greatest during the peak years of productivity and has large direct and indirect costs. Direct costs are estimated at about \$1 billion per year. There is an estimated \$13 billion loss to employers because of absences from work or decreased work productivity.

Of the various recurrent pain conditions, headache has been investigated most extensively by biofeedback and related procedures. This presentation reviews the status of research on headache treatment and points out future avenues for investigation. Although the talk focuses on headache, many of the findings and suggestions apply to other pain conditions (and psychophysiological disorders). Biofeedback (chiefly EMG and thermal), relaxation, and cognitive stress coping training are the most common nonpharmacological treatments for both pediatric and adult recurrent headache. Evidentiary reviews conducted by professional groups, such as the US Headache Consortium (composed of the American Academy of Family Physicians, American Academy of Neurology, American Headache Society, American College of Emergency Physicians, American College of Physicians-American Society of Internal Medicine, American Osteopathic Association, and National Headache Foundation), the American Psychological Association, the Canadian Headache Society, and AAPB, and statistical or meta-analytic reviews conducted by various authors beginning in 1980 document the clinical value of these treatments. Outcomes for these procedures have been compared to those obtained with prophylactic medications as well. Consideration of these sources of evidence lead to the following conclusions: these treatments produce significant improvements in headache activity, although a sizeable number of patients remain unhelped; improvements are similar among the treatments, including those obtained for pharmacological treatment; improvements exceed those obtained by various control conditions; and effects appear to endure well over time. There is some evidence to suggest that biofeedback can enhance medication treatment effects over time, particularly with difficult to treat patients. It is notable to point out that the US Headache Consortium concluded that relaxation training, thermal biofeedback combined with relaxation training, EMG biofeedback, and cognitive-behavioral therapies yielded a consistent pattern of findings and were recommended as treatment options for migraine. All of these therapies were given Grade A efficacy, the highest rating that this evidence-based group gave for preventative therapies including pharmacotherapy.

The following are among the topics warranting further investigation. 1) Although a number of behavioral treatments have been shown to be valid from work conducted in specialized research or treatment centers, these treatments are not readily accessible to those most needing them. Translational research, applying these treatments in the settings where headache and pain patients first present (primary care), is sorely needed to evaluate the “effectiveness” of these approaches. 2) In a related fashion, consideration needs to be given to ways to make treatment more available and affordable, by reducing the number of treatment sessions required and by reaching out to patients in more creative ways (limited contact, self-help with tailored messaging, mass communication, internet delivery, use of nontraditional providers, etc.). 3) Although nonpharmacological and pharmacological treatments are effective for a number of patients, many patients are not helped to a measurable degree. Research examining patient selection variables and the optimal sequencing of treatments, behavioral and medical, is also needed. Serotonin agonists are playing an increasing role in headache management. Integration of behavioral treatments with these medications has the potential to enhance outcomes and minimize medication doses. 4) It is likely that some of the patients who are not helped optimally by pharmacological or behavioral treatments may respond to nontraditional/conventional approaches, such as acupuncture, pulsed magnetic fields, and nutritional therapies, to name just a few. 5) Even the most potent medication will not be effective if taken inappropriately. Behavioral strategies can help patients decide among possible medication options and employ methods to maximize adherence. 6) Greater attention needs to be given to mechanisms of treatment and development of biofeedback treatments that are more directly tied to underlying pathophysiology, such as EEG biofeedback. 7) A number of headache types are particularly difficult to treat or have been given insufficient attention in the literature to date (those with significant psychiatric comorbidity, posttraumatic headache, medication overuse, cluster headache, and migraines related to the menstrual cycle). These, too, warrant an increased focus. 8) The advantages of computers and the internet for facilitating both assessment and treatment need further attention. Computers and information systems could be used to support headache management programs, identify when to use empirically-derived treatment guidelines, and assist in their implementation. 9) Finally, the main outcome measures have focused on pain parameters and

medication consumption. Greater attention needs to be given to impact and improvement in other domains that are important to patients, such as disability, affective distress, and quality of life.

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Margaret A. Chesney, PhD (National Center for Complementary and Alternative Medicine, NIH)
“Brain, Body and Behavioral Medicine Research: The NCCAM Perspective”

Among the domains within the area of integrative, complementary or alternative medicine (CAM), one of the most widely practiced is mind-body medicine, which involves the interplay of mind, brain, other body systems, and behavior. Research in this domain encompasses basic studies on how the mind and body interact and communicate, epidemiological studies of the key psychological characteristics and health of a given population, and clinical studies of the how mind-body interactions affect health and disease.

As with a variety of CAM practices, many mind-body techniques are ancient. Some remain intrinsic to Eastern systems of healing. In the West, they formed a part of the Greek and Roman tradition of medicine, which survived at least through the 17th century. While dualism pervaded Western medicine, interest in more integrated approaches survived. Today, there is evidence that patients faced with chronic and even terminal illness—particularly conditions like heart disease and cancer—can learn and employ a variety of mind-body practices to achieve a level of symptom relief and a better quality of life, and in some cases, improvements in health outcomes. Among these practices are various forms of meditation, yoga, and tai chi, and a range of other interventions for which there is not evidence sufficient to lead to their integration into mainstream medical or behavioral medicine practice. Important to the understanding of these practices, there is an growing body of basic research, much of it in the neurosciences, psychoneuroimmunology, and behavioral medicine. This research is aimed at elucidating the underlying mechanisms of action in mind-body techniques, using a variety of biochemical markers and physiological measures, as well as advances in brain imaging technology. Together, this body of clinical and basic research is expected to lead to the integration of efficacious mind-body interventions into a new, more comprehensive approach to care.

NCCAM is committed to supporting research on the interactions between the mind, brain, body and behavior and identified four specific goals for this research in its new strategic plan:

Goal 1: Identify the common and specific features of widely used mind-body medicine practices

Goal 2. Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.

Goal 3. Explore the value of CAM therapies to reduce the burden of stress-related chronic illnesses

Goal 4. Explore the value of CAM therapies to enhance resilience, positive affect, and coping in order to improve health and well-being, prevent or slow disease progression, and treat disorders, diseases and their symptoms.

Peter G. Kaufmann, Ph.D. (National Heart, Lung, and Blood Institute, NIH)
“Clinical Research in Biofeedback: Benefits of Developing Evidence-Based Practice”

In spite of a long history of research and good evidence of effectiveness for treating several conditions, biofeedback interventions struggle for recognition. The issues facing biofeedback are not unique – they are faced by many other psychological treatments. In order to achieve greater acceptance and reimbursement for behavioral interventions it is essential that we promote high standards for judging effectiveness, increase our expertise in design and conduct of randomized clinical trials (RCTs), and establish a process for continuous internal review of clinical practice guidelines. In the case of biofeedback, the process already under way should be continued and harmonized with third-party payers.^{1,4}

Based on my experience with several large clinical trials sponsored by the National Heart, Lung, and Blood Institute involving psychological interventions such as stress management, biofeedback, and cognitive behavior therapy for cardiovascular disease patients, I will argue for a greatly expanded program of clinical research. Of the nine years that life expectancy increased in the US between 1970 and 2000 the majority, namely six years, are due to a decrease in cardiovascular deaths. About half of that improvement is due to treatments developed through a vigorous program of RCTs – a record of proven success that can be emulated in behavioral interventions.

Evidence shows that too much emphasis in psychology is placed on mechanistic research before undertaking RCTs; that sample sizes in behavioral RCTs are too small, yielding unstable results;⁵ and, that high quality RCTs are too few in number, with insufficient replication and extension of initially promising results to encompass broader segments of the population.³ Moreover, lack of agreement persists in review committees concerning the value of clinical outcomes as the primary, even the only, objective of an RCT; of the optimal choice of control group; and the need to support a full spectrum of trials: efficacy, effectiveness, and translation, depending on the level of development of an intervention and the specific objectives of a given trial.

A broad base of support exists in the US and internationally for conventional RCT methodology as the highest standard of evidence to support clinical decisions.² At stake is the confidence of research funding agencies and third-party payers. Success of our efforts can be bolstered substantially by endorsing RCTs as the gold standard of evidence, training a cadre of sophisticated investigators thoroughly versed in RCT methods and increasing the role of clinical practice guidelines for advancing psychological interventions.

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