Empirically Supported Psychological Treatments
The Challenge of Evaluating Clinical Innovations

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Abstract: Clear and transparent standards are required to establish whether a therapeutic method is "evidence based." Even when research demonstrates a method to be efficacious, it may not become available to patients who could benefit from it, a phenomenon known as the "translational gap." Only 30% of therapies cross the gap, and the lag between empirical validation and clinical implementation averages 17 years. To address these problems, Division 12 of the American Psychological Association published a set of standards for "empirically supported treatments" in the mid-1990s that allows the assessment of clinical modalities. This article reviews these criteria, identifies their strengths, and discusses their impact on the translational gap, using the development of a clinical innovation called Emotional Freedom Techniques (EFT) as a case study. Twelve specific recommendations for updates of the Division 12 criteria are made based on lessons garnered from the adoption of EFT within the clinical community. These recommendations would shorten the cycle from the research setting to clinical practice, increase transparency, incorporate recent scientific advances, and enhance the capacity for succinct comparisons among treatments.

Key Words: Evidence-based, epigenetics, EFT, Emotional Freedom Techniques, standards

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The trend in healthcare to require that interventions be "evidence based" rewards practices that demonstrate clinical efficacy through sound empirical methodology (Melnyk and Fineout-Overholt, 2005). In 1995, Division 12 (the Society of Clinical Psychology) of the American Psychological Association (APA) published a list of "empirically supported treatments" (Task Force on Promotion and Dissemination of Psychological Procedures, 1995). A series of articles by Chambless and colleagues (Chambless et al., 1996, 1998; Chambless and Hollon, 1998) based on the work of this task force followed. These articles formulated a set of standardized criteria against which the empirical support for a psychological treatment can be measured.

The Division 12 criteria were initially applied to assess the evidence base of existing therapies, and they provided investigators a set of standards that has shaped the course of subsequent psychotherapy research. They did not, however, attempt to address the trajectory from the introduction of a clinical innovation to its being adopted into widespread practice. A field's ability to develop more effective methodologies, address new social challenges, and incorporate scientific advances pivots on its ability to recognize and use innovation. That is the topic of this article.

The "translational gap" from innovation to implementation is a concern in both psychotherapy and medicine (Committee on Quality of Health Care in America, Institute of Medicine [IOM], 2001), and it is addressed here with a focus on how the psychotherapy profession can facilitate the rapid movement of sound clinical invention from inception to the consulting room. The path of a novel therapy, Emotional Freedom Techniques (EFT), is used as a case in point in reviewing how the Division 12 criteria impact the translational gap. Finally, recommendations are offered to a) update the Division 12 standards so they shorten the cycle from the research setting to clinical practice, b) increase transparency, c) incorporate recent scientific advances, and d) enhance the capacity for succinct comparisons among treatments.

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THE TRANSLATIONAL GAP

Even after a treatment has successfully met scientific standards of efficacy, there is no guarantee that it will become available to those who could benefit from it. A report by the US government's IOM notes substantial "translational gaps" between the empirical validation of a treatment and its implementation in clinical practice (Committee on Quality of Health Care in America, IOM, 2001). Sometimes referred to as "practice gaps," these are considered a serious impediment to quality care. The IOM report found that only 30% of efficacious innovations make the transition and that, for those that are translated from clinical trials into the practical realm of patient care, the transition takes a mean of 17 years. The other 70% of potential improvements in care never cross the translational gap, and their benefits are lost to patients. The report uses the word "chasm" to characterize the size of the problem.

The healthcare field has been especially slow to adopt innovations. Intel's former Chief Executive Officer, Andy Grove, has made pointed comparisons between the field of computing and that of healthcare in the adoption of innovations (Grove, 2007). Whereas new computer products are often rapidly developed and adopted, Grove asserts that the current system of healthcare research creates "conformity of thoughts and values," which leads to "more sameness and less innovation" (p. 72). He calls for "a cultural revolution" in the healthcare research community.

THE DIVISION 12 CRITERIA

The Division 12 criteria guide research, and the Division sponsors a Web site that continually updates and maintains its lists of "research-supported psychological treatments" for a spectrum of psychological disorders and behavioral problems. Disorders are divided into 17 categories, ranging from adult attention-deficit/hyperactivity disorder to chronic pain, insomnia, posttraumatic stress disorder (PTSD), schizophrenia, and substance and alcohol use disorders. A wide range of treatments are also evaluated. For example, 13 therapies for depression are listed as empirically supported, with six of them showing "strong research support": behavior therapy/behavior activation, cognitive therapy, cognitive behavioral analysis, interpersonal therapy, problem-solving therapy, and self-management/self-control therapy (current as of April 16, 2014). All were evaluated against a common list of essential criteria for evidence-based therapies.

Lists of empirically supported therapies have been controversial (*e.g.*, Beautler et al., 2005; Wampold, 2001). Division 12's Web site readily acknowledges that there is "healthy debate about what constitutes research support" and provides numerous sources that are critical of the approach it uses. Among the frequently cited criticisms are that

the lists, based on manualized treatment approaches, do not evaluate therapy in a "naturalistic" manner (*i.e.*, therapies are not investigated as typically practiced); evaluations do not account for therapist or client variables; and criteria do not adequately recognize certain nonspecific factors that are not easily controlled for, such as the quality of the therapist-client relationship. Despite these shortcomings, a uniform system of reviewing research is clearly necessary. An overview of the Division 12 criteria follows.

Basic Requirements

Division 12 classifies research-supported psychological treatments according to whether there is "strong" or "modest" evidence for the intervention. Those designated as "strong" align with Chambless and colleagues' (1998) criteria for a "well-established treatment." To be classified as having strong support, there must exist at least two well-designed studies by independent investigators comparing groups receiving the treatment of interest and at least one other treatment condition. The study must also demonstrate that the treatment of interest is either a) statistically superior to a placebo or unvalidated intervention or b) statistically equivalent to an already established treatment.

A therapy may still be considered "probably efficacious" in the presence of modest rather than strong research support (Chambless et al., 1998, p. 4). To qualify, one well-designed study must have compared groups receiving the treatment of interest and at least one other treatment condition and demonstrated that the treatment of interest is a) statistically superior to a placebo or unvalidated intervention or b) statistically equivalent to an already established treatment. Alternatively, two strong studies showing that the treatment of interest is statistically superior to a wait-list control group also meet the criteria for probably efficacious.

Additional Requirements

Chambless and Hollon (1998) described five facets of research that should be considered when assessing whether a treatment is well established, probably efficacious, or still unvalidated. These facets include overall research design, sample description, outcome assessment, treatment implementation, and data analysis. As applications of the 1998 standards have evolved, Division 12 has identified for each of the five facets essential criteria for determining that the standard has been met as well as additional criteria not classified as "essential" for establishing efficacy but still deemed "desirable" or "highly desirable" as ascertained by published sources as well as dialogues with the Division 12 Web site editor (E. D. Klonsky, personal communications, August 21, 2012; September 4, 2012). A total of seven essential criteria (ECs) are in use, supplemented by the highly desirable and desirable attributes, organized below according to Chambless and Hollon's five facets. At least one EC is associated with each of the five facets.

Overall Research Design

Essential

Subjects were randomly assigned to either the treatment of interest condition or one or more comparison conditions (EC1). The study included an adequate sample size to detect statistically significant ($p <$ 0.05 or better) differences between the treatment of interest and the comparison condition(s) (EC2).

Highly desirable

A target sample size of at least 25 to 30 subjects in each treatment condition is highly desirable for demonstrating equivalence to a treatment that has already been established or for showing superiority to a no-treatment control condition.

Sample Description

Essential

The population for which the treatment was designed and tested must be clearly defined through a) diagnosis by qualified professional(s), b) cutoff scores on reliable and valid questionnaires, c) interviews identifying the focus of the study's interest, or d) some combination of the three (EC3).

Highly desirable

The use of a structured diagnostic interview to assign diagnoses to subjects is highly desirable, as is the use of standardized diagnostic procedures to assess difficult diagnoses.

Desirable

Evaluation and control of characteristics of the study population that might limit the generalizability of the research findings is encouraged.

Outcome Assessment

Essential

Tools used for assessment must have demonstrated reliability and validity in previous research (EC4). Any interview assessments should have been made by interviewers who were blind to group assignment (EC5).

Highly desirable

Researchers should not have relied solely on self-report. They should use multiple methods of assessment and follow-up assessments.

Desirable

Assessments of the treatment's clinical value, possible negative effects, and effects on functioning and quality of life are encouraged.

Treatment Implementation

Essential

Researchers must follow treatment manuals that make clear the nature of the treatment being tested. Alternatively, if the treatment is relatively simple and a treatment manual is unavailable, researchers should describe the treatment protocol in the procedure section of the published research (EC6).

Highly desirable

Researchers should take steps to ensure that fidelity to the procedures outlined in the treatment manual is enforced and assessed.

Desirable

Assessment of the possible influence of the therapist's or investigator's allegiance to a treatment is encouraged.

Data Analysis

Essential

Researchers' published report on their study should include enough data that a study's conclusions can be reviewed for appropriateness. At minimum, this should include sample sizes, explanation of the instruments used to detect changes targeted by the study's design, and the magnitude of statistical significance (EC7).

Highly desirable

Where dropout rates differ substantially between treatment groups, intention-to-treat analyses should be conducted for all individuals who had been randomized to treatments.

Desirable

Researchers are encouraged to describe the site where the study was conducted, the therapist's training and experience or inexperience with a particular modality, and the investigator's allegiance to a treatment.

As is evident from the previous summary, the Division 12 criteria are carefully conceived and well articulated. The basic requirements are stated explicitly, but there is enough flexibility to allow for validation of a treatment through different research approaches. Thus, it is an eminently practical system that controls for as many variables as is reasonably possible in rating the efficacy of therapeutic interventions for treating particular disorders. The Food and Drug Administration (FDA), publishing guidelines developed concurrently with the APA criteria, also stipulated two randomized controlled trials (FDA, 1998). The Affordable Care Act supports the use of evidence-based treatments (Greaney, 2010), and the Division 12 criteria constitute the most systematic and comprehensive attempt within psychology to address this need. Yet the question remains: how do they work in practice, particularly for evaluating new clinical developments?

AN OVERVIEW OF EFT

Originally developed by Craig and Fowlie (1995), EFT is a psychophysiological intervention incorporating elements found in two established therapies: cognitive behavior therapy (CBT) and exposure therapy. CBT and exposure techniques were found, in a review by the IOM, to be efficacious for PTSD (IOM, 2007) and are classified as well-established treatments of a number of disorders according to the Division 12 Web site (http://www.div12.org/PsychologicalTreatments/index.html). To these established methods, EFT adds the novel component of somatic stimulation using acupuncture points (or "acupoints"). Comparison studies (Fox, 2013; Baker and Siegel, 2010; Wells et al., 2003) find that the stimulation of acupoints is a potent active ingredient in the positive outcomes in EFT treatments, independent of the cognitive and exposure elements that are also used.

The use of acupuncture for psychological disorders is still relatively rare, although a number of studies have demonstrated its efficacy for PTSD (Hollifield, 2011; Hollifield et al., 2007; Jonas et al., 2011). Whereas acupuncture uses needles, other forms of acupoint stimulation, such as the massage method known as Shiatsu, use pressure with the fingertips on the points instead of needling. Placing pressure on acupoints ("acupressure") has been shown to significantly reduce anxiety (*e.g.*, Lang et al., 2007), and placing pressure on acupoints has been found to be as effective as needling (Cherkin et al., 2009). In a randomized controlled trial (RCT) comparing CBT and CBT with acupoint stimulation using an electronic acupoint stimulator in the treatment of earthquake-induced PTSD, both treatment conditions led to significant improvement, but the outcomes for the latter group were significantly ($p < 0.01$) stronger (Zhang et al., 2011).

The EFT Protocol

EFT therapy sessions have clients recall traumatic memories and negative cognitions that contribute to anxiety, depression, phobias, and PTSD. Clients pair the vivid memory of a traumatic event (*i.e.*, exposure) with a cognitive reframe of self-acceptance (*i.e.*, CBT) as they tap or massage 12 specific acupoints. A report of Subjective Units of Distress (SUD; after Wolpe, 1973) is obtained before and after performing the EFT protocol. Therapy continues until a client's distress is significantly reduced, ideally approaching zero on the SUD scale (where 0 signifies no distress; 10 extreme distress). Once one memory or negative cognition has been treated, the client uses EFT on another, until a series of disturbing memories or negative cognitions have been neutralized.

Uses of EFT as a Clinical and Self-Help Therapy

Since the mid-1990s, the number of users of EFT has swelled. *The EFT Mini-Manual* (Church, 2009) and its predecessor, *The EFT Manual* (Craig and Fowlie, 1995), have been downloaded from the Internet by more than 2 million individuals. The number of visits to the top five EFT Web sites during the month of June 2013 was tracked using a statistical tool called *trafficestimate* (http://www.trafficestimate.com). When results were tallied, trafficestimate reported more than 6 million visitors to these sites during that month alone. A recent Google search on the simple term "Emotional Freedom Techniques" yielded 2.7 million hits.

A professional organization (http://www.energypsych.org) with an established code of ethics and standards of practice has 1300 members at the time of this writing. Practitioners have published some 5000 case reports of effective EFT treatments with a wide range of conditions (available for download at www.EFTuniverse.com). Of particular note is the use of EFT by response teams after earthquakes, volcanic eruptions, tsunamis, terrorist activities, and other disasters. Encouraging outcomes for acupoint tapping have been reported in more than a dozen countries, producing hundreds of documented cases of successful treatments of severe trauma (Connolly et al., 2013; Connolly and Sakai, 2011; Feinstein, 2008). According to charities that offer EFT and similar tapping therapies to traumatized populations, more than a million people have received treatment (Capacitar International, http://capacitar.org; Trauma Relief and Emotional Support Techniques, http://www.trestaid.com; Thought Field Therapy [TFT] Foundation, http://www.tftfoundation.org; and the Veterans Stress Project, http://stressproject.org).

The large number of anecdotal reports about EFT's efficacy is being corroborated by its developing research base. In the APA journal *Review of General Psychology*, Feinstein (2012) reported that 51 articles published in peer-reviewed journals, including 18 RCTs, had found positive outcomes after treatments using EFT or TFT, the approach from which EFT was derived.

ASSESSING EFT'S EFFICACY ACCORDING TO THE DIVISION 12 CRITERIA

The Division 12 criteria have provided a credible benchmark for evaluating the EFT research base. Applying the criteria to existing studies show EFT to meet the standards as a research-supported treatment of four conditions on Division 12's list: anxiety, depression, phobias, and PTSD. Table 1 lists 15 studies that meet the seven essential Division 12 criteria (note that some of the studies demonstrated positive outcomes with more than one target condition). Each study is compared with each criterion. Studies that do not meet all the criteria are excluded from consideration. For instance, Benor et al.'s (2009) study is excluded because of inadequate randomization (EC1). Waite and Holder (2003) compared EFT with a placebo and two sham tapping conditions for fear, but their study is excluded because it failed to qualify the population (EC3), did not use valid and reliable instruments (EC4), and failed to apply EFT with fidelity to the manual (EC6). The studies that do meet the standards, grouped by condition treated, are briefly discussed below.

Essential Requirements for Establishing Efficacy With Four Division 12 Conditions

Anxiety

Nine studies support the efficacy of EFT in the treatment of anxiety. Produced by six independent research teams, five (Brattberg, 2008; Church et al., 2012, 2013; Geronilla et al., 2014; Jones et al., 2011) showed that EFT was statistically superior to wait-list, no treatment, or continuation of independent existing treatment (treatment-as-usual) controls (thus meeting Chambless et al.'s [1998] minimum requirements to be considered probably efficacious). The other four

TABLE 1. Summary of EFT Studies Meeting the Criteria for Empirically Supported Treatment

Study	Treatment	Control 1	Control 2	*N*	Symptom Change	ECs						
						1, Randomization	2, *p*	3, Assessment	4, Validated	5, Blind Intervention	6, Manual[a]	7, Report
Anxiety												
Brattberg (2008)	EFT, 8-week online course	8-week WL		62	−23%	Random allocation	<0.03	HADS	Yes	N/A	Yes	Yes
Church et al. (2013)	EFT, six sessions	6-week WL		59	−55%	Permuted block randomization	<0.0002	SA-45	Yes	N/A	Yes	Yes
Church et al. (2014)	EFT, six sessions	TAU		21	−47%	Permuted block allocation	<0.0001	SA-45	Yes	N/A	Yes	Yes
Church et al. (2012)	EFT, one session	Supportive interview, one session	Rest period 1	83	−58%	Random allocation	<0.002	SA-45	Yes	N/A	Yes	Yes
Geronilla et al. (2014)	EFT, six sessions	TAU		54	−65%	Permuted block randomization	<0.001	SA-45	Yes	N/A	Yes	Yes
Jain and Rubino (2012)	EFT, 2-hr group	Diaphragmatic breathing		40	−13%	Random allocation	<0.05	WTAS	Yes	N/A	Yes	Yes
Jones et al. (2011)	EFT, 45 min	WL		36	Not reported	Random allocation	<0.000	PRCA	Yes	N/A	Yes	Yes
Karatzias et al. (2011)	EFT, four sessions	EMDR, four sessions		46	−42%	Random allocation	<0.002	HADS	Yes	Yes	Yes	Yes
Sezgin and Özçan (2009)	EFT, one session + self-treat	Progressive muscular relaxation		32	−37%	Random allocation	<0.05	TAI	Yes	N/A	Yes	Yes
Depression												
Brattberg (2008)	EFT, 8-week online course	8-week WL		30	−29%	Random allocation	<0.02	HADS	Yes	N/A	Yes	Yes
Church et al. (2012)	EFT, four sessions	No treatment		18	−74%	Random allocation	<0.05	BDI	Yes	N/A	Yes	Yes
Church et al. (2013)	EFT, six sessions	6-week WL		59	−51%	Permuted block randomization	<0.0001	SA-45	Yes	N/A	Yes	Yes
Church et al. (2014)	EFT, six sessions	TAU		18	Not reported	Permuted block allocation	<0.0001	SA-45	Yes	N/A	Yes	Yes
Church et al. (2012)	EFT, one session	Supportive interview, one session	Rest period 1 hr	83	−41%	Random allocation	<0.001	SA-45	Yes	N/A	Yes	Yes
Geronilla et al. (2014)	EFT, six sessions	TAU		54	Not reported	Permuted block randomization	<0.001	SA-45	Yes	N/A	Yes	Yes
Karatzias et al. (2011)	EFT, four sessions	EMDR, four sessions		46	−32%	Random allocation	<0.006	HADS	Yes	Yes	Yes	Yes
Stapleton et al. (2013)	EFT, four sessions	4-week WL		98	−10%	Random allocation	<0.05	SA-45	Yes	N/A	Yes	Yes
Phobias												
Baker and Siegel (2010)	EFT, one session	Supportive interview, one session	No treatment	31	−68%	Random allocation	<0.004	FQ	Yes	Yes	Yes	Yes
Salas et al. (2011)	EFT, one session	Diaphragmatic breathing	Crossover	22	−45%	Random allocation	<0.0001	BAI	Yes	N/A	Yes	Yes
Wells et al. (2003)	EFT, one session	Diaphragmatic breathing		35	−53%	Random allocation	<0.005	FQ	Yes	Yes	Yes	Yes
PTSD												
Church et al. (2013)	EFT, six sessions	6-week WL		59	−51%	Permuted block randomization	<0.0001	PCL	Yes	N/A	Yes	Yes

Church, Piña, et al. (2012)	EFT, one session	No treatment		16	−92%	Random allocation	<0.001	IES	Yes	N/A	Yes	Yes
Church et al. (2014)	EFT, six sessions	TAU		21	−40%	Permuted block allocation	<0.0001	PCL	Yes	N/A	Yes	Yes
Geronilla et al. (2014)	EFT, six sessions	TAU		54	−62%	Permuted block randomization	<0.008	PCL	Yes	N/A	Yes	Yes
Karatzias et al. (2011)	EFT, four sessions	EMDR, four sessions		46	−35%	Random allocation	<0.004	PCL	Yes	Yes	Yes	Yes

With the exception of those studies for which particular criteria were not applicable (N/A), all studies included in the table met all essential criteria. The criteria are defined as follows: EC1, randomization; EC2, sufficient sample size to detect differences of $p < 0.05$; EC3, population defined by cutoff scores on assessment; EC4, validated assessments; EC5, blind assessment interviews, if applicable; EC6, treatment manual; EC7, data reporting.

BAI, Beck Anxiety Inventory (Fydrich et al., 1992); BDI, Beck Depression Inventory (Beck et al., 1988); FQ, Fear Questionnaire (Mavissakalian, 1986); HADS, Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983); IES, Impact of Events Scale (Horowitz et al., 1979); PCL, PTSD Disorder Checklist (Weathers et al., 1991); PRCA, Personal Report of Communication Apprehension (McCroskey, 1970); SA-45, Symptom Assessment-45 (Davison et al., 1997); TAI, Test Anxiety Inventory (Spielberger, 1980); TAU, treatment as usual; WL, wait list; WTAS, Westside Test Anxiety Scale (Driscoll, 2007).

[a]All studies followed the manualized method described in *The EFT Manual* (Craig, 2008, 2010).

studies showed that EFT was statistically equivalent or superior to another treatment: the supportive interview (Church et al., 2012), diaphragmatic breathing (Jain and Rubino, 2012), eye movement desensitization and reprocessing (EMDR; Karatzias et al., 2011), and progressive muscular relaxation (Sezgin and Özcan, 2009). Thus, according to Division 12 criteria, this body of research qualifies EFT for consideration as a well-established treatment of anxiety.

Depression

Eight studies support the use of EFT in the treatment of depression. Of these, six (Brattberg, 2008; Church et al., 2012, 2013, 2014; Geronilla et al., 2014; Stapleton et al., 2013) compared EFT against wait-list, no-treatment, or treatment-as-usual controls and found EFT to be statistically superior. Church et al. and Karatzias et al. (2011) compared EFT against a supportive interview and EMDR, respectively. Again, both found that EFT was statistically equivalent or superior to the control group. Thus, by Division 12's requirements, this body of research qualifies EFT for consideration as a well-established treatment of depression.

Phobias

Three RCTs have tested EFT in treating phobias. Baker and Siegel (2010) compared EFT with a supportive interview as well as a no-treatment group. Salas et al. (2011) and Wells et al. (2003) compared EFT with diaphragmatic breathing. Salas et al. added a second control, using a crossover design. All found that EFT was statistically superior to the control conditions—thus demonstrating that EFT meets the requirements as a well-established treatment of phobias based on the Division 12 criteria.

Posttraumatic Stress Disorder

Five studies that meet all seven ECs demonstrated strong favorable outcomes: Church et al. (2013) compared an EFT treatment group with a wait-list control, Church et al. (2014) and Geronilla et al. (2014) compared EFT with treatment-as-usual wait-list controls, Church et al. (2012) compared EFT against a no-treatment control, and Karatzias et al. (2011) compared it with EMDR—thus demonstrating that EFT meets the requirements as a well-established treatment for PTSD based on the Division 12 criteria.

Additional Considerations

EFT outcome studies also suggest that the technique satisfies several other criteria that Chambless and Hollon (1998) address for determining a treatment's overall efficacy. Among them are as follows: treatment effects that continue to hold at follow-up assessments made months and sometimes years after the treatment concludes; treatment outcomes that improve general functioning and quality of life; high rates of patient compliance; demonstrated efficacy across a range of clinical settings, conditions, therapists' theoretical orientation and experience level, and delivery mechanisms (*e.g.*, in-office, telephone-delivered, group therapy, and online therapy [Brattberg, 2008; Hartung and Stein, 2012; Stapleton et al., 2013]); ease of dissemination; and cost-effectiveness. For example, all three phobia studies used only a single session of EFT to reduce symptoms from between 45% and 68%.

These studies also show that EFT is not only efficacious in treating different conditions but also effective in treating different conditions within different populations. For instance, studies have demonstrated its efficacy for treating anxiety in patients with fibromyalgia (Brattberg, 2008), in college students preparing for a test (Jain and Rubino, 2012; Sezgin and Özcan, 2009), in clients with public speaking apprehension (Jones et al., 2011), in veterans (Church et al., 2013), and in hospital patients (Karatzias et al., 2011).

A CONTEMPORARY TRANSLATIONAL GAP: EFT FOR PTSD AS A CASE STUDY

Translational gaps can have profound consequences for society. Today, the condition most emblematic of this phenomenon may well be PTSD. The National Institutes of Health (NIH) has used the term "epidemic" to describe PTSD, with some 7.1 million Americans affected as of 2009 (NIH, 2009). PTSD has proven itself to be notoriously difficult to treat effectively (Bradley et al., 2005; van der Kolk et al., 2007).

The Veterans Health Administration (2012) has estimated that more than 800,000 veterans have returned from the wars in Iraq and Afghanistan with PTSD. The cost to society of each veteran with PTSD is estimated at $1.4 million (Kanter, 2007; Murphy, 2012). PTSD also produces sequelae in other social segments. In veteran populations, PTSD is implicated in higher levels of domestic violence (Orcutt et al., 2003), higher use of medical services (Beckham et al., 1998; Boscarino, 2005), overrepresentation in the prison population (Greenberg and Rosenheck, 2009), and secondary traumatization of family members (Ben Arzi et al., 2000; Galovski and Lyons, 2004).

Widespread failure of treatment programs for veterans with PTSD is well documented in the popular press, with references to homelessness among veterans and suicide rates that exceed combat fatalities. The actual effectiveness of such programs is, however, difficult to establish because, according to an IOM study, the Department of Veterans Affairs (VA) does not adequately track treatment outcomes (Shane, 2012). The treatment of choice for PTSD is generally considered to be CBT combined with psychological exposure (Bryant et al., 2008), but "half of patients do not respond" (p. 555). Dropout rates are another indicator of the failure of contemporary treatment approaches. In a study of 49,425 Iraq and Afghan war veterans with newly diagnosed PTSD, less than 1 in 10 who sought care from facilities run by the VA completed the prescribed course of treatment (Seal et al., 2010).

That the VA has neither adopted nor tested the use of EFT for this cohort is an instance of a translational gap that has been costly to innumerable veterans suffering with PTSD. Church et al. (2013) found a 64% reduction in PTSD symptoms, with 84% of veterans going from above to below the PTSD cutoff on a standardized military symptom checklist, after six sessions of EFT. Geronilla et al. (2014) replicated Church et al.'s results in an independent study. Research on veterans at risk for PTSD produced similar results (Church et al., 2014), whereas Karatzias et al. (2011) found that EFT remediated PTSD in a mean of four sessions. Clinical reports of EFT's efficacy with veterans were documented as early as 1994 (Craig, 1994). In 2009 and 2010, published pilot studies demonstrated significant drops in PTSD symptoms after EFT treatment sessions ranging in duration from six sessions to a 5-day group retreat (Church, 2010; Church et al., 2009).

Because of the pressing nature of the problem of PTSD in veterans returning from the Middle East conflicts, interim data from some of the studies using EFT for PTSD were circulated to VA officials several years ahead of publication (A. Bains, personal communication, June 9, 2013). The chair of the Senate Armed Services Committee, Senator Carl Levin, wrote a letter to Eric Shinseki, then Secretary for Veterans Affairs, in early 2009, enclosing preliminary data on EFT's efficacy for PTSD and urging investigation by the VA. This letter and the other formal and informal presentations to the VA failed to produce any examination of the evidence by that institution.

Frustrated by the absence of progress and concerned by rising numbers of constituents with PTSD, a group of members of the US Congress wrote another detailed and extensive letter to Shinseki in 2010. Copies were sent to the heads of public health agencies, including the NIH and the Defense Center for Excellence in PTSD and traumatic brain injury. These members of the Congress suggested seven simple and low-cost steps that the VA might take, such as examining the PTSD evaluations of service members who had received EFT, circulating published trials of EFT to VA physicians, inviting EFT practitioners to demonstrate EFT in VA settings, and referring veterans with PTSD to practitioners trained in EFT.

None of the seven recommendations were implemented. One congressman who signed the letter to the VA invited two of the authors of this article to testify before the House Veterans Affairs Committee, presenting the evidence for EFT for treating PTSD. In 2011, one of the authors testified before the House Homeland Security Committee. These efforts were equally unsuccessful in generating institutional interest within the VA in bridging the translational gap.

Resistance to EFT and other psychotherapies that use the stimulation of acupoints traces to numerous factors (Feinstein, 2009). Nothing in the training or background of most physicians or researchers prepares them to understand how acupressure can play a role in overcoming severe psychological disorders or account for the speed and power of positive clinical results. The explanatory constructs derived from Oriental Medicine postulate energy fields and other esoteric concepts at odds with the Western biomedical model. Although outcome studies for PTSD and other conditions have proliferated, there are only a handful of studies showing the physiological mechanisms of action of acupoint tapping, such as cortisol regulation, brain state regulation, and muscular relaxation.

As a counterpoint, drug therapies for PTSD did not face similar obstacles, nor did financial considerations produce an equivalent translational gap. The drug risperidone was initially advocated as a treatment for PTSD until a 2011 controlled trial found it no more effective than placebo treatment (Krystal et al., 2011). Between 2000 and 2010, the VA spent more than $700 million on prescriptions for risperidone (Tal, 2013). For that same sum, the VA could have offered six sessions of EFT to every Afghanistan/Iraq veteran with PTSD twice over. Meanwhile, the number of PTSD disability claims faced by the VA swelled, and a 600-day backlog in processing claims developed.

During the decade that the VA failed to respond to congressional and private efforts to encourage investigation of EFT while prescribing a failed drug at a much larger cost, therapists increasingly began using the EFT methodology. Case studies proliferated. Supporting evidence reached critical mass. Although the VA as an organization has still not endorsed EFT as a recognized treatment for PTSD, a number of VA therapists have begun using the technique within VA hospitals and centers, whereas others are able to use it only outside the VA, listing their services on the Web site of the Veterans Stress Project, an online clearing house designed to connect veterans with therapists and life coaches offering EFT (www.StressProject.org).

The authors of the current article have been actively involved in research efforts to establish the efficacy of EFT. The Division 12 criteria have played a decisive role in shaping that research. Investigators have looked to these standards for guidance on the kinds of studies that needed to be formulated to test the method's efficacy and how to design them. The field's peer-reviewed journal, *Energy Psychology: Theory, Research, and Treatment*, includes the Division 12 criteria in its instructions to authors. The criteria have played a decidedly constructive role in guiding efforts to demonstrate EFT's efficacy. Our involvement with the development of EFT has also brought to our attention ways that the Division 12 criteria could be more effective in reducing the translational gap for noteworthy clinical innovations as well as in evaluating existing therapies, and we discuss these in the remainder of the article.

RECOMMENDED REVISIONS TO THE DIVISION 12 CRITERIA

Considering the complexity and increasing sophistication of clinical research since the Division 12 Task Force formulated their criteria in the mid-1990s, it is a testament to the soundness of the original vision and execution of the project that they have served so well. Although the Division 12 criteria were instrumental in guiding empirical investigation into EFT and are highly influential in the design of almost all

psychological research, they are not static or purely objective precepts. Given the dynamism of clinical practice, the criteria for evaluating its methods are required to evolve as psychological treatments evolve. Division 12's Web site on research-supported psychological treatments, in fact, explicitly requests feedback from clinical psychologists and other mental health professionals. Drawing on our experience in using the criteria to guide EFT along the path to professional acceptance and our observations of the strengths and potential pitfalls of these guidelines, we offer our recommendations for revising the criteria.

Just as client welfare is the overarching principle in clinical practice, creating research standards that ultimately result in maximum benefit for clients must be the overriding goal in reviewing and revising the Division 12 criteria. Those who use the criteria—including researchers, editors, administrators, practitioners, and clients—are the individuals who are best positioned to help shape the conversation about how evidence-based standards might best evolve. These recommendations are formulated to meet the following aims:

1. Shorten the cycle from research setting to clinical practice.
2. Incorporate recently developed models of the biological bases of psychological conditions.
3. Capitalize on social media and other electronic technologies to conduct research.
4. Minimize duplication and enhance the capacity for succinct reporting and comparison.

We offer 12 recommendations that support these aims.

Shorten the Cycle From the Research Setting to Clinical Practice

Establishing a treatment's validity as a technique that has strong empirical support is a notoriously slow process, and in the interim between development of an intervention, study design, publication, and review and validation by official gatekeepers, patients who could benefit from new treatments are often left waiting (Committee on Quality of Health Care in America, IOM, 2001). This first set of recommendations would encourage the fastest pace of effective innovation consistent with safety.

Recommendation 1

Create formal gradations of proof, placing case studies on the lowest tier and meta-analyses on the highest. Resources are not readily available for research on clinical innovations. Explicit rather than implicit gradations of proof would give new therapies a clear path for demonstrating promise during the early phases of their development.

Recommendation 2

Assign a numerical weight to each type of proof. For instance, a single case study might be given a weight of 1; a case series, a weight of 3; an uncontrolled trial, a weight of 10; an RCT, a weight of 20; and an RCT with a statistical significance higher than $p < 0.001$, a weight of 30; and so on. With the current standards, an entire body of research (*e.g.*, 200 high-quality single case reports) may be ignored where some weight may be appropriate. As a result of some sort of weighting system, Division 12's assessment of a treatment would be made transparent and less subject to potential bias. A numerical system would also make it possible to present the strength of evidence as a point on a continuum rather than as one of three options: efficacious, probably efficacious, or unsubstantiated.

Recommendation 3

Develop clear guidelines for what constitutes an acceptable single case study or case series. Publish examples of excellence for each. Although the maxim popular among researchers that "the plural of anecdote is not data" underscores an important principle, it is also the case, as Kuhn (2012) observed in his classic *The Structure of Scientific Revolutions* that early indications of efficacy come from anecdotal case reports. Providing standards for the legitimate use of case material would allow practitioners of new therapies, without significant funding or institutional support, to begin to demonstrate the results of their treatments, gathering preliminary data that would lay the foundation for outcome studies and subsequent RCTs.

Incorporate New Understandings About the Biological Bases of Psychological Conditions Into the Criteria

Under the current criteria, no weight, and thus no encouragement, is given to research into the biological mechanisms underlying psychological effects. When the criteria were developed, fields such as neural plasticity, psychoneuroimmunology, and epigenetics were in their infancy. New avenues of inquiry have sprung up in tandem with the growth of these fields, as is evident in energy psychology research. In addition to designing studies to establish the sound evidence base that Division 12 requires, EFT researchers have investigated the hypothesis that it is the intersection among exposure therapy, CBT, and acupuncture that gives EFT its particular power. It is believed that the acupressure component affects neurochemical changes in the brain that extinguish maladaptive conditioned responses to adverse cognitive and environmental triggers, and a parallel branch of EFT research is contributing support to this theory.

For example, using electroencephalography, Diepold and Goldstein (2009) showed that high-frequency brain waves evoked by traumatic memories normalized after acupoint tapping, and Swingle (2010) reported increased brain regulation after EFT in clients with seizure disorders. Swingle et al. (2004) showed that EFT decreased frontal cortex arousal in motor vehicle accident survivors reporting moderate-to-severe stress. In a triple-blind RCT with 83 participants, Church et al. (2012) found that symptoms of anxiety and depression declined in the EFT group by more than twice the amount of the supportive counseling group ($p < 0.0001$) and were significantly correlated with reductions in cortisol levels.

Now that more is known about the interaction between psychology and physiology (see, *e.g.*, Feinstein and Church, 2010), collaborations between the two fields would benefit each. Ideally, mechanistic understanding (how a treatment works versus whether it works) would be incorporated into the assessment criteria.

Recommendation 4

Encourage biological measures in association with psychological assessment. Biological correlates of psychological stress can be easily and inexpensively measured: for example, heart rate variability via a smartphone fingertip pulse detector or cortisol using a saliva swab. The interaction of biological markers with subjective measures, diagnoses, and behavioral changes can be assessed, for instance, whether there is a significant relationship between a decline in anxiety and a decline in cortisol.

Recommendation 5

Encourage meaningful biological determinants of generalizability, rather than relying solely on sociological indicators such as occupational and demographic groups. The current fashion in reporting is to treat occupational groups as though they were unique species. For example, a study of anxiety in school teachers might state that further research is required to determine whether the results also hold for other occupational groups. There is, however, no biological basis for this distinction. At the same time, factors that may reasonably be expected to affect the generalizability of a specific approach, such as biological markers of the condition being treated, age group, and sex, might be considered.

Recommendation 6

Recognize shared biological factors in diverse psychological symptoms. For instance, although depression and anxiety differ markedly in their diagnostic criteria (American Psychiatric Association, 2013), biologists have found many more biological similarities than differences between these conditions. Among the shared biological markers are dysregulation of the nervous and endocrine systems and common patterns of gene expression. Although biologists have been cataloging the biological similarities between disparate psychological diagnoses for more than a decade (*e.g.*, Eley and Plomin, 1997; Gorman, 1998), the research base for psychotherapies that target these underlying physiological mechanisms has not been well developed in part because of their absence from the criteria. Treatments that affect the biological markers for one psychological condition may very well have the same effect on another. For instance, some studies of EFT for PTSD find improvements in anxiety and depression, although the latter two are not the targets of treatment (Church et al., 2013; Geronilla et al., 2014; Karatzias et al., 2011). Biological effects of treatment may also explain why physiological conditions such as pain (Church et al., 2013) and symptoms of traumatic brain injury (Church and Palmer-Hoffman, 2014) improve after psychological treatment. Common biological pathways provide a plausible explanation for the simultaneous improvement in disparate psychological conditions. Studies that directly target such biological pathways or patterns of dysregulation should be encouraged independent of psychological diagnostic category.

Capitalize on Social Media and Other Electronic Technologies to Conduct Research

Recommendation 7

Encourage Internet-based and smartphone-based recruitment, treatment, and data collection. Given the growth in both of these types of technology, researchers should look for novel ways to incorporate them into the design of their studies. The costs of online data collection are usually far less than traditional pen-and-paper assessments and the speed with which data can be accumulated far greater (Brophy et al., 2008; Knaevelsrud and Maercker, 2007). Online research also paves the way for the examination of online treatment delivery.

Minimize Duplication and Enhance the Capacity for Succinct Reporting and Comparison

Recommendation 8

Standards should direct investigators toward naturalistic and outcomes research once RCT standards have been met. Once two or three strong RCTs are published, replications by graduate students or senior investigators do not advance the frontiers of science and are of little or no clinical benefit to patients. The highly structured manner in which treatments must be performed in a rigorous RCT bears little resemblance to the way treatments are delivered by practitioners (Seligman, 1995; Wampold, 2001). Roth and Parry (1997) characterized RCTs as "one part of a research cycle" (p. 370). Naturalistic studies that assess which populations can benefit, how to maximize benefits, and how to best deliver an efficacious therapy are of much greater clinical use once the initial research cycle of RCTs has been completed (Leichsenring, 2004). Furthermore, outcome and naturalistic studies often raise additional research questions that can be addressed by the following generation of RCTs.

Recommendation 9

Particularly, if researchers are encouraged to perform more outcome studies and fewer replications of RCTs, the initial minimum number of required RCTs should be revised slightly upward. The FDA of the US government, when developing standards at the same time as Division 12 (Chambless et al., 1996, 1998; Chambless and Hollon, 1998), also adopted the criterion of two RCTs (FDA, 1998). We suggest that three might be more appropriate to mitigate against possible research errors even in strong studies. Whatever the number, the Division 12 guidelines could propose a specific upper limit for supporting studies to discourage replications that do not add to the evidence base or advance scientific knowledge.

Recommendation 10

Studies must be adequately powered, neither underpowered so that clinically significant effects are not detected nor overpowered with a large population providing highly significant p values despite minimal clinical benefit. An advantage of using validated instruments is that clinically significant treatment effects and the variability in the target population are often known in advance, simplifying the process of designing an adequately powered study, that is, one with cell sizes that are sufficient to detect statistically significant treatment effects if present, as Chambless and colleagues recommended. For a method that repeatedly demonstrates a large treatment effect using adequate sample sizes, larger cell sizes add unnecessary cost and complexity, extending the time it takes to complete a study and delaying the date when clinical benefits flow to patients.

Imagine a treatment in which the efficacy is strongly demonstrated at $p < 0.001$ with cells of 15 participants in a study taking 6 months, after which the treatment can enter clinical practice. To instead conduct a study that takes 5 years to accumulate 150 participants to a cell delays the cycle from laboratory to clinic and represents poor research design. It should be discouraged. This obviously does not apply to data mining, epidemiological studies, and large-scale replications, which can yield layers of evidence that are not apparent in studies with smaller sample sizes. Conversely, studies that do not achieve statistical significance ($p > 0.05$) should be rejected or cautiously interpreted even if they include a large N. Studies without adequate power to detect the effect being tested simply cannot be interpreted.

Recommendation 11

Require the calculation of an indicator of the size of treatment effect (such as Cohen's d) to complement confidence measures. Although this was part of the original recommendations made by Chambless and colleagues, it was not adopted as a requirement. A uniform standard, weighted toward the magnitude of treatment effect, would provide a single composite score by which diverse therapies could be compared. In addition, a numerical score such as percent change for symptom reduction might be formulated and required as an indicator of clinical relevance. A consistent indicator of percent change would simplify researchers' and practitioners' ability to make clinical comparisons between therapeutic methods.

Recommendation 12

Abstracts should summarize the most clinically and statistically relevant data and include a sentence explaining clinical significance in lay terms. Doing so would make the research more transparent to other practitioners as well as patients, many of whom have neither the time nor the scientific background to dig down into a full-length article written in academic language to extract conclusions about the quality of the research and the significance of the findings. A generation ago, research results were available primarily in research libraries, used by professional scholars with the knowledge to extricate the material they required and the academic background to understand it. Today, public databases such as PubMed and ERIC are visited by large numbers of lay users seeking information on medical and psychological conditions, democratizing knowledge previously accessible to the few. Requiring authors to provide plain-language information about the clinical significance of a study in the abstract offers increased access to this large

population. An objective performance standard for posting new studies on the Division 12 Web site, such as within 30 days of publication, would also expand public access; currently decade-old EFT and EMDR studies are not posted, while studies of conventional therapies are usually posted promptly.

SUMMARY AND CONCLUSION

Clinical psychology, through the efforts of APA's Division 12, has developed a set of criteria for rating the effectiveness of psychological treatments for specific disorders based on the empirical evidence. These criteria have supported the development of psychology as an evidence-based field. The criteria are in wide use. One of the sources for their evolution is feedback from those who use the criteria.

This article has reviewed the experiences of a group of practitioners, researchers, and reviewers of clinical trials who have used the Division 12 criteria to guide the development of a novel clinical innovation—EFT. Recommendations have been offered for shortening the cycle from the research setting to clinical practice, incorporating new understanding about the biological bases of psychological conditions into the criteria, capitalizing on social media and electronic technologies in conducting research, minimizing duplicative effort, increasing transparency, and enhancing the capacity for succinct reporting and comparison. Incorporating the most salient suggestions from those who use the Division 12 criteria will help them evolve in a manner that is even more practical, accessible, transparent, responsive, and scientifically informed and will ultimately better serve those individuals who seek psychotherapy.

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By way of disclosure of potential conflicts of interest, the authors conduct trainings, provide clinical services, and have written books and articles related to the approach examined in this article.

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