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Clinical Studies of Biofield Therapies: Summary, Methodological Challenges, and Recommendations

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ABSTRACT

Biofield therapies are noninvasive therapies in which the practitioner explicitly works with a client's biofield (interacting fields of energy and information that surround living systems) to stimulate healing responses in patients. While the practice of biofield therapies has existed in Eastern and Western cultures for thousands of years, empirical research on the effectiveness of biofield therapies is still relatively nascent. In this article, we provide a summary of the state of the evidence for biofield therapies for a number of different clinical conditions. We note specific methodological issues for research in biofield therapies that need to be addressed (including practitioner-based, outcomes-based, and research design considerations), as well as provide a list of suggested next steps for biofield researchers to consider.

INTRODUCTION

Healing practices that purport to sense and modulate "subtle energies" of the body have existed for thousands of years in a wide range of cultures.[1] This family of practices, which includes healing touch (HT), Johrei, Pranic healing, Reiki, qigong and therapeutic touch (TT), is increasingly referred to as *biofield therapies*, a term coined during the US National Institutes of Health Conference in 1992.[2] In this paper, biofield therapies are defined as noninvasive, practitioner-mediated therapies that explicitly work with the biofield of both the practitioner and client to stimulate a healing response in the client.

At this same 1992 conference, *biofield* was defined as "a massless field, not necessarily electromagnetic, that surrounds and permeates living bodies and affects the body."[2] For this paper, we expand the definition to consider biofields as endogenously generated fields, which may play a significant role in information transfer processes that contribute to an individual's state of mental, emotional, physical, and spiritual wellbeing.

A challenge for the general incorporation of biofield therapies into conventional clinical care is the limited understanding of the mechanisms of these therapies within the biomedical paradigm (see Hammerschlag et al, this issue). But despite controversies and current gaps in research, biofield therapies are widely used by the public and by certain patient populations. Patient groups who often report using biofield therapies include those with cancer and those receiving palliative care.[3,4] An epidemiological survey from 2007 states that in the year prior, over 1.2 million adults and 161 000 children reported receiving at least 1 session of a biofield therapy.[5] More recent data from the 2012 National Health Interview Survey reveal that over 3.7 million US adult citizens surveyed "have ever" seen a practitioner for energy healing therapy, with over 1.6 million adults in the US reporting seeing an energy healing therapy practitioner at least once in the past 12 months. Further, only 8% of the survey group reported that any costs of seeing an energy practitioner was covered by insurance.[6]

Other indicators of biofield therapy utilization are that training in these practices is increasingly prevalent among healthcare professionals and that such practices are offered to patients in a limited number of clinical settings, including hospitals.[7] Biofield therapies such as TT are recognized in the *Nursing Intervention Classification Code*[8] and are recognized by some state licensure boards as within the scope of nursing practice. Given the relatively high use of biofield therapies by the US public, coupled with the current paucity of insurance coverage, it is important to examine the evidence base for these therapies to assess their effectiveness for clinical populations.

When assessing clinical effectiveness of biofield therapies, it is important to recognize 2 main distinctions in the manner they are practiced. First, biofield therapies may be delivered either proximally (with the practitioner and the receiver in the same room) or distally (with the practitioner and receiver not in the same room; in some cases, separated by hundreds or thousands of miles). This latter form of distal treatment,

usually called *distant healing*, is described in a separate article in this supplement (Radin et al) and is not further discussed here.

When reviewing clinical trial-based evidence of biofield therapy effectiveness, it should be noted that proximally delivered treatments are performed both with and without physical touch, often within the same clinical session. Thus distinct research questions can be asked when evaluating the evidence base for biofield therapies. We can ask whether these practices have been found effective in trials that assessed the more common, real-world mode of delivery, ie, with the practitioner free to combine hands-on and hands-off procedures. We can also ask, as an approach to more directly examine biofield involvement, whether biofield therapies appear effective when treatment has been delivered only with practitioners moving their hands above and along the body with nonphysical contact.

Clinical trials and recent systematic reviews that address each of these aspects of proximal healing (trials testing combined hands-on and hands-off treatment and trials that have reported using only hands-off treatment) will be summarized in the first section of this article as a means of assessing the strength of the current evidence base for biofield therapy. Following the review of clinical trial-based evidence, we examine the methodological challenges facing the design and implementation of biofield therapy trials. While some attention is given to research design issues shared with other trials of complementary and alternative medicine (CAM) modalities (eg, chronic underpowering due in part to the paucity of funding opportunities), a major focus of this section is on methodological challenges that are particularly unique to clinical trials of biofield therapies, where the nature of what is being tested—what is occurring between practitioner and receiver during a healing session—is unknown.

The final section of this article will utilize the state of the evidence base, together with the identified research design issues to inform a set of recommendations to guide further progress in this emerging area of biofield therapy research. Clinical trials of biofield therapies are of obvious value for assessing whether there is a "there there," as well as to offer directions for physiological studies of endogenous biofields (Hammerschlag et al, this issue). In a reciprocal manner, research on biofield physiology and biofield-related medical devices (Gurfein et al, this issue) is of considerable value for identifying relevant biomarkers that may strengthen the design and outcomes of future clinical trials of biofield therapies.

A separate but related set of therapies, often called energy psychology therapies, combine biofield interventions like tapping on specific points of the face or body with cognitive behavioral techniques. These therapies are often used to target psychological outcomes, such as posttraumatic stress disorder (PTSD), depression, anxiety, and addictions. Energy psychology therapies include Thought Field Therapy, Emotional Freedom Technique, Tapas Acupressure, and others. While this paper precludes the review of these energy psychology therapies, the interested reader may find more information on the IONS (http://www.noetic.org/research/project/mapping-the-field-of-subtle-energy-healing/#eft) and Association of Comprehensive Energy Psychology website (http://www.energypsych.org) about these and other related therapies.

CLINICAL STUDIES OF BIOFIELD THERAPY EFFECTIVENESS: STATE OF THE EVIDENCE

Systematic reviews of clinical trials of biofield therapies have been conducted from a number of different perspectives. Such reviews have included (1) all biofield therapies tested for any condition[9]; (2) all biofield therapies tested for specific conditions, eg, cancer,[10–12] pain,[13] and cardiovascular disease[14]; (3) specific biofield therapies for any condition, eg, HT[15] and Reiki[16–19]; and (4) specific biofield therapies for specific conditions, eg TT for wound healing[20] or for pain.[21] In addition (as briefly discussed above), while biofield therapies are commonly delivered via a combination of hands-on and hands-off procedures, 2 recent systematic reviews have focused on randomized controlled trials (RCTs) of biofield therapies for any condition that have reported use of only nonphysical touch forms of treatment.[22,23]

In this section, we highlight findings from the broadest of the above-listed systematic reviews as an approach to identify those clinical areas with the most promise for integration of biofield therapies into conventional care as well as for future research.

Pain

To date, there have been over 30 published clinical trials reporting effects of biofield therapies for pain in ambulatory and hospitalized patient populations with chronic pain, arthritis, and movement restriction. A systematic review by Jain and Mills[9] that included both RCTs and quasi-experimental studies of biofield therapies applied best-evidence synthesis criteria and suggested that proximally practiced biofield therapies demonstrated strong evidence (evidenced by at least 2 high-quality RCTs and minimal to no conflicting evidence) for reducing self-reported pain intensity (generally measured via the visual analog scale) in a variety of patients, including the elderly and those with chronic pain. Several studies in this review had large effect sizes indicating both statistical and clinical significance. Similar positive findings were reported in a prior independent Cochrane review[16] that examined RCTs of biofield therapies for pain and concluded that biofield therapies reduced pain beyond that of sham- and no-treatment controls. Overall, studies suggest that biofield therapies may be particularly promising for alleviating pain intensity as compared to sham treatments. However, the effectiveness of biofield therapies assessed with pain measures that incorporate more affective and evaluative labeling, such as the McGill Pain Inventory, are less clear.[9]

Research on biofield therapies for pain could benefit, as could pharmacological trials of pain, from interdisciplinary research that complements self-reported pain measures with assessments of other clinically-relevant outcomes (eg, pressure-pain threshold).[24] While many studies report beneficial effects of biofield therapies over and above placebo controls, it is still unclear how biofield therapies lead to reduced pain. For example, it is unclear whether biofield therapy amelioration of pain could be mediated by "bottom-up" processes, such as reductions in cellular inflammation or nociceptive signaling and/or "top-down" processes such as cortical nociceptive control mechanisms. Experimental studies examining the effects of biofield therapies on known objective pain pathways would also be helpful at this juncture. At least 1 study has examined the effects of a biofield therapy (TT) on nociceptive threshold in a mouse model.[25] Studies examining inflammatory immune, neuroendocrine (eg, oxytocin, endogenous opioids), and neural activity correlates (eg, via functional magnetic resonance imaging [fMRI]) would also be useful, and these results could be compared to those found for placebo analgesia[26,27] to determine whether common pathways exist. Finally, given that other practitioner-assisted integrative practices (such as acupuncture) have been shown to be effective for pain,[28] the incorporation of biofield therapies into comparative effective research designs to enable direct comparison with other integrative approaches would be valuable.

Cancer

More than 15 clinical trials have been conducted with biofield therapies in patients with cancer, both during and after conventional biomedical treatment. Most studies have focused on the effects of biofield therapies as adjunctive care to reduce symptoms of pain, fatigue, anxiety, and depression. In a 2010 systematic review, evidence for reducing cancer-related pain with biofield therapies was rated "moderate" in at least 1 high-quality RCT, though "conflicting evidence" was found for reducing fatigue and improving quality of life.[9] Since this review, several high-quality studies of HT for cancer-related symptoms have been published[29-32] with reports of clinically significant reductions in depression and persistent fatigue, as well as positive effects on clinically-relevant biological markers.[29,30] For example, significant effects of biofield treatments have been seen on diurnal cortisol variability in fatigued breast cancer patients as compared to mock treatments or standard care,[30] and in cervical cancer patients, biofield treatment improved depressive symptoms and blunted the drop in natural killer cell cytotoxicity otherwise seen in the relaxation therapy and usual care comparison groups.[29] However, most studies with biofield therapies in cancer have not investigated the potential impact of these therapies on clinical biomarkers. Additionally, not all cancer studies have shown improvements with biofield treatments.[11,32]

Whereas the impact of biofield therapies on cancer tumor markers and other clinical biomarkers has been minimally studied, several preclinical (animal and cell) studies, many with sham controls, have investigated the impact of biofield therapies in various cancer models (Gronowicz et al, this issue). As examples, biofield therapies have been tested on multiple tumor types, with reports of inhibition of DNA synthesis and mineralization in osteosarcoma, inhibition of cell cycle and induction of apoptosis in prostate cancer cells[33] and colorectal cancer cells,[34] and inhibition of migration and invasion of breast cancer cells.[35] Results from these promising preclinical studies suggest a need to further investigate biological signaling mechanisms in biofield therapies in treating cancer and cancer-related symptoms. Importantly, effects of biofield therapies on clinical outcomes and disease trajectory in cancer patients have not yet been investigated.

OTHER CLINICAL CONDITIONS WARRANTING FURTHER STUDY

A few clinical studies have been conducted evaluating biofield therapies on cardiovascular function,[36-39] with promising results in terms of increasing heart rate variability (HRV) and reducing stress-related symptoms such as anxiety, which is known to negatively impact cardiovascular function in coronary patients. Notably, a recent RCT of Reiki on autonomic activity in inpatients during recovery from acute coronary syndrome reported a statistically significant improvement in high-frequency HRV compared to both a classical music control and resting control. Effect sizes for the Reiki condition were comparable to that of propranolol.[36] Another RCT noted the reduction of both anxiety and length of hospital stay for coronary artery bypass graft (CABG) patients receiving HT vs nurse visits alone or treatment as usual, with no differences found between groups on pain medication use or atrial fibrillation incidence.[37] Notably, both of these studies provided very brief interventions: 1 session of Reiki in the coronary syndrome RCT[36] and 3 sessions of HT (1 day before, immediately before, and 1 day after surgery) for the CABG RCT.[37] These studies suggest that even brief biofield interventions can generate salutogenic effects and elicit questions regarding the potential effects with longer durations or frequencies of treatment.

While limited in number, these promising findings suggest a need to further examine the effects of biofield therapies on psychosocial symptoms, cardiovascular function, and cost-effectiveness outcomes in cardiovascular disorders. Due to the paucity of studies in this area, little is known about the potential effects of biofield therapies on physiological indices related to cardiovascular outcomes. Of note, improvements in heart rate homeostasis in rats in response to Reiki relative to sham Reiki[38] suggest that effects of biofield therapies may reach beyond placebo effects. Given that HRV is an important prognostic indicator of cardiovascular events including sudden cardiac death,[39] further

studies examining the potential biobehavioral links between biofield therapies, psychosocial symptom reduction, and clinical outcomes are warranted.

Positive results of biofield therapies have been reported in other populations, including those patients with dementia[40-43] and osteoarthritis,[44,45] as well as pediatric oncology outpatients.[46] In addition, there is need for investigation of biofield therapies in palliative care, where these therapies are often delivered.[47]

Several reviews since the 2010 best evidence synthesis of Jain and Mills have examined clinical research based on the biofield modality.[14,15,19] Overall, these reviews point to the same general conclusions: there is promising but limited evidence based on relatively few studies with insufficient sample sizes as well as methodological issues that could be improved to better understand the effects of biofield therapies in a clinical context.

Because federal and private-sector funding for the study of biofield therapies is notably limited at present, it is important that any studies carefully address the most salient gaps in terms of knowledge and methodology. This will help to augment interest and funding for this important area of clinical research in the future. With this in mind, to aid budding and seasoned researchers in designing the most relevant and scientifically sound clinical studies in biofield therapies, the nature of these methodological weaknesses—with suggestions on how to best improve biofield therapy clinical research—is addressed in the following section.

METHODOLOGICAL ISSUES IN CLINICAL STUDIES OF BIOFIELD THERAPIES

We note that many of the methodological and statistical recommendations previously made for biofield research[48] are similar to the weaknesses of research designs utilized to assess most other CAM modalities. Such flaws commonly lie with aspects of randomization, control groups, blinding, power analysis, intention-to-treat analysis, and assessment of covariates. As general aspects of research design, these issues have been well discussed[49] and will not be reviewed again here. This section will focus on methodological issues more specific to biofield therapy research.

Treatment Considerations: Dosing, Type, and Delivery

Nearly all reviews of clinical studies on biofield therapies note that there is a lack of clarity regarding the extent to which dose, mode of delivery, and type of therapy (eg, Reiki, HT, or TT) impact clinical outcomes.

Dose

Most studies have not been designed in a manner to effectively answer a dose-response question. In particular, it is unclear whether "dose" is simply a reflection of the amount of time and frequency of treatments, since the strength of the therapy may vary according to the practitioner. In real-world practice, most practitioners apply "energy" until they feel that the field of the client/patient has "changed" or an energetic block, excess, or leak has resolved. Individualization of energetic modulation based on the patient's presentation is thought to be important for the most effective treatment. Clearly, this idea runs counter to a research design based on standardized protocols, even when specific aspects of the treatment protocol are described. Yet more creative research designs could be employed to better get at the issue of "dose." This also speaks to the need to develop better means of measuring what is occurring between practitioner and receiver.

Type of Treatment

There is little known at this point about the comparative effectiveness of different biofield healing techniques in terms of either their clinical efficacy for particular conditions or the actual type/quality of healing they provide. Questions around efficacy may arise even within each tradition, as within several of the specific therapies, there are "hands-on" and "hands-off" approaches.

While ultimately comparing and contrasting different forms of biofield therapies for given clinical ailments may prove useful in matching patients with particular types of biofield therapies, the literature base is too sparse to begin to compare different modalities in terms of their efficacy in different patient populations. However, understanding practitioner reports on how different diseases are understood and treated across different biofield healing traditions could be valuable in guiding research at this juncture. Some researchers have begun this process of comparing similarities and differences in practitioners' perceptions of their practice,[50] and further inquiry is needed to determine how different biofield therapy traditions conceptualize and treat different disease populations.

Extent of Touch: Hands-on vs Hands-off Techniques

A major distinction in biofield therapies involves whether the practitioner engages the patient's biofield with direct physical contact (hands-on) or without physical contact (hands-off). Several modalities such as Reiki, HT, and Brennan Healing contain techniques that are both hands-on and hands-off (but in close proximity), with these different techniques used for different purposes. Others (such as Johrei and external qigong) are generally practiced with hands at a slightly further distance from the body.

From a practitioner perspective, comparing a hands-on approach with a hands-off approach may not make sense for a given clinical condition, as the technique is selected based on the clinical presentation and used for a specific effect. However, some scientists who are interested in research concepts and designs to elucidate mechanism of biofield therapies view hands-on approaches as confounded by touch, which has its own beneficial effects that may well be mediated by sensory nerve endings and/or hormonal release. A recent review, which specifically examined only RCTs with non–

physical contact biofield modalities, identified 28 trials with heterogeneous populations that met inclusion criteria (20 of the 28 having sham controls). Further investigation of the subgroup of 18 higher-quality trials revealed that 12 reported significant beneficial effects in at least 1 outcome. However, similar to other reviews, small sample sizes in most studies was noted as a hindrance to drawing definitive conclusions.[22]

For those concerned about "confounding" effects of touch, one approach has been to have "sham" practitioners mimic hands-on as well as hands-off approaches. While the use of sham practitioners may control for effects such as presence, support and attention, touch, skill, and healing intention, this approach may not fully control for actual biofield effects, as electromagnetic emanations exist from all living systems and simple social interactions have been found to produce biofield interaction effects.[51]

As implied above, the study design selection of the biofield therapy and whether to use a hands-on, hands-off, or a combination protocol should depend mainly on the research question. If the focus is on assessing real-world practice, then either an efficacy (sham-controlled) or a comparative effectiveness (usual care comparison) design is appropriate. In this case, the researcher should consult with several practitioners who work with the clinical condition on a regular basis and have known clinical successes with the population of study. The treatment protocol can be guided by what the practitioners have found works best in their clinical practice. On the other hand, if the research focus is more mechanistic and the goal is to determine whether factors such as touch or distance play a role in promoting healing, then the researcher may want to seek biofield therapists who have experience using entirely hands-off (nonphysical touch) treatments in their practice.

Practitioner Selection

A major challenge facing biofield therapy research is how to determine a practitioner's skillset with respect to healing efficacy. Currently, most researchers rely on statements attesting to the practitioner's experience with the clinical condition, how long the practitioner has been in practice, and whether s/he is known to others for his/her clinical expertise. While this is the current process for practitioner selection, it is not optimal for research. What is clearly needed is a procedure to test whether biofield therapists are able to achieve a criterion level of effect in order to be involved in research. While therapy (whether psychotherapy, physical therapy, or biofield healing) can be standardized and manualized for research, the ability to follow and execute a manualized therapy does not necessarily reflect a verifiable level of skill. Tests that might "calibrate" practitioners' ability to interact with the biofield might be useful for prescreening practitioners prior to their participation in a clinical trial.[52]

As a general rule, selection of biofield practitioners depends on the research question. If the researcher seeks to understand whether a local practitioner community (eg, a group of Reiki or HT practitioners who deliver services in a particular hospital or clinic) can affect patient outcomes, a study examining the effectiveness of a specific intervention would be appropriate. For studies designed to examine biofield approaches for a difficult-to-treat or severe clinical condition, studying a practitioner who has demonstrated experience and clinical success in working with that clinical condition may be appropriate.

In summary, questions of dose, type of treatment, and practitioner selection should be guided by the research question and by feasibility of implementation.

CONSIDERATIONS OF MODERATORS, MEDIATORS, AND "MECHANISM"

There has been confusion, by both researchers and funders, regarding the need to include analysis of potential mechanisms in early stage clinical studies of biofield therapies. As with other controversial healing modalities, there is pressure to demonstrate "biologically plausible mechanisms" of biofield therapies. We argue that elucidating mechanisms, while important in helping to understand and even improve upon a therapy's effects, is not essential for conducting rigorous and potentially informative clinical trials of any therapy. It is also the case that clinical trials may be well suited to elucidate treatment moderators (variables that are present in the population prior to the treatment and modify the effects of the treatment on an outcome variable but are not correlated with treatment) and mediators (variables that are part of a causal pathway of effects of the treatment on the outcome variable and therefore modify effects of treatment on the outcome variable).[53] A possible example would be examining whether the gender of the patient significantly predicted outcomes in response to the therapy—ie, whether gender is a moderator of treatment. An example of a mediator would be to examine whether changes in HRV in response to a biofield intervention mediated the effects of the intervention on depression (ie, whether improvements in postintervention depression are fully or partially caused by mid-intervention changes in HRV). Exploration of potential moderators and mediators of treatment may lead to better empirically based hypotheses for testing mechanisms of biofield therapies. In general, clinical trials examining efficacy of biofield therapies as practiced in clinical settings provide important impetus for preclinical research to more clearly examine biologically based mechanisms using experimental paradigms.

A key hindrance to understanding potential mechanisms of biofield therapies is the absence of a reliable measure of the purported biofield emanations from the practitioners. While there have been a few reports regarding emanations from certain practitioners,[54-56] creating a systematic method to examine such bioenergetic signals is a crucial step to better understand the physiological basis of biofield therapy.

The development of systematic methods examining bioenergetic signals from practitioners may help us better understand, for example, whether the efficacy of the healing interaction is directly proportionate to the strength of the biofield emanation, to a particular pattern of biofield emanation, or whether there are other factors apart from or in addition to bioenergetic signaling that significantly contribute to the outcomes of the practitioner/client encounter. As interested engineers and scientists further develop techniques to measure emanations from practitioners at different electromagnetic frequencies, it will be of interest to determine whether specific patterns of bioenergy emanation are predictive of better healing outcomes. At the same time, there are potential pitfalls from assuming that electromagnetic emanations are the sole explanation for the experience and practice of biofield therapies,[50] as they would not account, for example, for the results of distant healing studies carried out in electromagnetically shielded environments (see Radin et al, this issue).[57,58]

Placebo Elements: Main Effects or Moderators?

Much has been written regarding both the limitations and misinterpretation of placebo-controlled randomized trials in biofield therapies and integrative medicine in general.[59] While biofield therapies may serve to enhance the "placebo effect,"[48] it does appear that biofield therapies enhance outcomes over and above sham-controlled groups, particularly for pain.[13] However, placebo elements such as belief in receiving biofield therapy (regardless of group assignment) have also been shown to affect clinically relevant outcomes such as quality of life.[30]

To date, studies examining placebo have been designed to examine whether placebo vs verum treatments were more explanatory of outcomes and were not designed to examine whether placebo variables (such as expectation or patient/practitioner relationship) moderated effects of treatment. It is plausible that there is an interactive rather than an "either-or" process for biofield therapies and placebo responses, such that the enhancement of placebo (ie, self-healing) elements would enhance the delivery and the potential outcomes for biofield therapies.

Thus current data suggest it is unlikely that biofield therapies are reducible to placebo responses alone, but like other forms of mind-body medicine interventions and biomedicine in general,[60,61] biofield therapy may intentionally harness the patient's conscious and unconscious expectancies and desires in synergy with the treatment being delivered to enhance outcomes. Such an effect has been hinted at in current studies in other integrative modalities such as acupuncture.[62-64] In order to adequately examine the potential impact and interaction of placebo elements with biofield therapies, additional studies are needed with sample sizes robust enough to allow for testing of moderation effects with placebo elements.

CAPTURING OUTCOMES FOR BIOFIELD THERAPIES: BIOMARKERS, COST-EFFECTIVENESS, AND QUALITATIVE AND WHOLE-SYSTEMS OUTCOMES

In keeping with the notion of "patients as partners in research," a primary goal of outcomes research for biofield therapy is to identify and evaluate outcomes of highest concern to the prospective patient group. In general, biofield therapies are understood to affect the whole person and therefore a broad array of whole-person outcomes is needed to adequately assess their effects. In addition to patient-identified outcomes, there are clear advantages to capturing outcomes across domains, including biomarkers, clinical response, cost-effectiveness, and qualitative data, so that their relative and combined contributions, in keeping with a more biopsychosociospiritual model, can be determined.

Biomarkers

Biomarkers, defined as physiological variables that have significant clinical relevance to the population being studied, may include measures of immune, endocrine, psychophysiological, autonomic nervous system (including skin conductance and HRV), and other neural functions (including electroencephalography, fMRI, positron emission tomography). Biomarkers may indicate which physiological systems are affected by biofield therapy but do not necessarily shed light on the pathways by which these changes occur nor on the transduction events by which practitioner activity is converted to patient responses that initiate the cascade of physiological changes.

In terms of current biofield therapy research, several studies have examined more "global" biomarkers such as HRV and/or single measures of cortisol or natural killer cell cytotoxicity as outcomes either in healthy or specific clinical populations.[12,13,16,18,29,38-41,43,65-68] Such markers were chosen for ease of acquisition/feasibility and potential relevance to the clinical population being studied. Reported changes in these specific outcomes suggest that biofield therapies have positive effects on physiological processes of clinical relevance.

Cost-effectiveness

In order to better integrate biofield therapies into integrative medicine and clinical practice generally, it is important to consider cost-effectiveness.[69,70] While a full cost-benefit analysis is prohibitory for most early-phase clinical trials of biofield therapies, examining cost-effectiveness outcomes such as changes in medication usage, number of days in hospital, days of treatment, or quality-adjusted life years will be highly useful for aiding decision-making in regard to the value of biofield therapy as adjunctive care in a hospital's or clinic's portfolio of services. Thus we strongly recommend, particularly for clinical trials of biofield therapies being conducted with hospitalized patients or ambulatory patients with frequent clinic visits, that cost-effectiveness assessments be designed as a substudy.

Qualitative Outcomes

Nurses, who are often also biofield therapy practitioners, have designed and conducted many of the biofield therapy trials. The rich interest in qualitative research within the nursing profession has led to inclusion of this type of data collection—eg, patient- and practitioner-reported experience—in many biofield therapy trials.[50,71] These qualitative outcomes are of significant importance in helping to understand the immediate as well as the persisting health effects of biofield therapies, including psychospiritual experiences that are often difficult to capture via surveys of outcomes.

Practitioners of biofield therapies can be a valuable resource in guiding both the practice and the science of biofield therapies and could, with collaborative support of researchers, prepare meaningful case reports and even best-case series on their patients. Best-case series have been found to be useful in guiding the science of CAM therapies in cancer.[72] The process of developing and publishing an effective case report is also well documented.[73,74] Practitioners are encouraged to follow the CARE guidelines (http://www.care-statement.org/) to aid in creating case reports on biofield therapy effects in clinical practice.

EDUCATING TO OVERCOME BARRIERS

A key issue in increasing awareness of this area of study is educating healthcare workers and the general public about biofield theory and research. Because biofield therapies do not involve the use of invasive agents like medication, needles, or supplements and because they invoke concepts that are somewhat foreign to many allopathically trained physicians, discussion around stimulating a healing response by working with energy fields often elicits responses that the entire field of study is fraught with pseudoscience. A significant challenge for this field of study is presented by otherwise well-meaning practitioners and advocates who describe or utilize ill-designed scientific methods to "prove" that their method of healing works. These efforts increase barriers to conducting this work. However, in many cases, the barriers are more due to a general lack of conceptual knowledge about biofields and the need to explain hypotheses about biofields in a manner that can be understood and to ensure that people are educated on the state-of-the-evidence and most salient gaps in the research.

In general, a key strategy for increasing interest in biofield science may be to help others understand that "biofields" do not just apply to "biofield therapies" but rather are relevant to the mechanisms by which mind and body interact to promote healing responses. However, in the context of overcoming barriers to successful conduct of biofield therapy research, we suggest the following steps: (1) understand the language of the target audience/stakeholder and speak within their linguistic frameworks wherever possible; (2) highlight the best science in the area and specifically note aspects such as benefit/harm ratios, clinical effect sizes, clinically relevant outcomes, inconsistent findings, gaps in knowledge, and attrition rates for biofield therapies; and (3) provide case examples and possibly actual exercises that allow the audience/stakeholder to potentially experience a sense of the biofield and arouse curiosity.

Funding is a significant challenge in moving forward with biofield research. The National Institutes of Health's National Center for Complementary and Integrative Health (NCCIH, formerly the National Center for Complementary and Alternative Medicine) currently includes biofield therapies in its strategic plan in the mind and body therapies category, an area with funding priority. NCCIH also identified pain research as a priority, so this may be a fruitful avenue to explore for funding for biofield clinical studies. Other organizations such as the Patient Centered Outcomes Research Institute, which supports research, may support studies in biofield therapies, particularly if there is evidence that there is significant public interest. The Department of Defense could also be an avenue for funding, as pain, traumatic brain injury, and PTSD are clinical problems that have been found to respond to biofield therapies. Donations from private foundations have supported previous research in biofield therapy clinical trials and should also be pursued.

Educating program officers and reviewers at funding agencies about the current state of biofield research is an important step the field must take. This may be accomplished by presenting symposia at professional meetings, creating special peer-reviewed journal issues such as this one, and other specific strategies to inform this important set of stakeholders about the area of research and most strategic areas for investment to move the field forward.

An equally challenging task is educating our colleagues and new investigators in the rigorous study designs and optimal approaches necessary to secure funding to build the evidence base for biofield research. Given the controversial nature of this area, those proposing research in biofield research may be well advised to ask a number of colleagues unfamiliar with the field to carefully review proposals before submission.

Finally, much of this work has been conducted through—and likely will continue to be supported by—philanthropy. Finding champions who have an interest in these types of modalities and inquiring whether they would be willing to contribute to a well-designed study is certainly appropriate and will continue to be needed at this juncture.

SUMMARY AND KEY RECOMMENDATIONS

To summarize, the evidence base regarding clinical effectiveness of biofield therapies is strongest in symptom management for pain and cancer, the 2 conditions that have received the most study. Studies are more sparse but evidence is promising for clinical populations with arthritis, dementia, and heart disease. To better assess the impact of biofield therapies and

evaluate their delivery in various settings, we make the following recommendations for researchers planning future clinical trials in biofield therapies:

1. Expand on studies for promising conditions—eg, pain and cancer—with larger efficacy and comparative effectiveness trials. In addition, conduct pilot studies in populations where present evidence is promising but studies are limited (eg, patients with dementia, cardiovascular disorders, osteoarthritis).
2. Design additional biofield therapy trials aimed at elucidating moderators, mediators, and mechanisms that assess clinically relevant biomarkers.
3. Consider conducting pilot clinical trials of biofield therapies where clinical practice suggests beneficial effects but minimal research currently exists (including but not limited to palliative and pediatric populations).
4. Incorporate "dosing" designs and careful decision-making with respect to the dose and type of therapies and/or practitioners selected for the clinical outcome of interest along with developing protocols that allow individualized treatment.
5. Adopt the "patient as research partner" model to incorporate patient-selected outcome measures.
6. Assess the role of placebo elements—eg, patient beliefs and expectations— as potential moderators of biofield therapy effects.
7. Design trials that incorporate a whole-systems approach to outcome variables, including validated survey outcomes, clinically relevant biomarkers, qualitative data, and cost-effectiveness outcomes.

It is our hope that the next decade will bear significant increase in research efforts of sufficient rigor and size to provide a greater understanding of the potential impact of biofield therapies in clinical care.

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