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Review Article

Nontouch Biofield Therapy: A Systematic Review of Human Randomized Controlled Trials Reporting Use of Only Nonphysical Contact Treatment

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Abstract

Objective and Context: This review was designed to assess the quality and review the outcomes of randomized controlled trials (RCTs) of biofield therapies (external *qigong*, Healing Touch, Johrei, Reiki, and Therapeutic Touch) that report using only nonphysical touch forms of treatment. RCTs of nonphysical contact biofield therapies have the potential to contribute to an evidence base for health-promoting effects mediated through mechanisms outside the present understanding of biomedicine.

Methods: Articles meeting inclusion criteria were identified from database and reference list searches and evaluated for a range of reporting and design items. Data were extracted to determine the range of protocol parameters and treatment outcomes. The final set of included RCTs were evaluated via a modified 5-item Jadad scale as well as by a set of 20 criteria that included items relevant to the early-phase nature of the trials and to the examination of nonphysical touch biofield therapy interventions.

Results: Of 90 RCTs that assessed effectiveness of a biofield therapy in humans, 28 trials involving 1775 participants met additional inclusion criteria (most importantly a clearly reported use of only nonphysical contact treatment). The research designs of these 28 trials revealed marked heterogeneity in regard to condition treated, number and duration of treatments, nature of the control/comparison group, and outcome measures. Finally, 10 trials were excluded on the basis of low quality assessment scores. Twelve of the remaining 18 trials (7 Therapeutic Touch, 3 external *qigong*, 1 Reiki, and 1 Healing Touch) reported at least one primary outcome with statistically significant beneficial treatment outcomes.

Conclusions: The pilot study nature of essentially all the identified nonphysical contact biofield therapy RCTs, as reflected by low sample sizes alone, precludes drawing robust conclusions. Given this perspective, the finding that two thirds of the higher-scoring trials demonstrated at least partial effectiveness favors a continued research effort, especially in light of the translational value of biofield clinical trials for studies exploring the nature and physiologic basis of biofield healing.

Introduction

Biofield therapies (BFTs) are a set of healthcare practices used to stimulate the healing process. They are based on an explanatory model in which living systems contribute to and exist within a confluence of electromagnetic as well as other conventional and nonconventional phenomena, collectively defined as a biofield.[1–6] The potential for affecting health by modulation of the biofield is reflected in its characterization as ''a force associated with a biological system that can cause action at a distance.''[7] This definition has been modified by considering a healer or healer–client dyad as a ''biological system'' and by regarding healing as an ''action.''[8] In clinical practice, BFTs use both hands-on and hands-off (nonphysical contact) procedures.[9,10]

Biofield therapies, most commonly external *qigong*,[11,12] Healing Touch,[13] Johrei,[14] Reiki,[15–17] and Therapeutic Touch,[18] have been frequently tested in randomized controlled trials (RCTs).[19,20] Interpretations of trial outcomes as mediated via the biofield, however, are confounded when the protocol reports use of hands-on or combined hands-on and hands-off procedures. While such protocols are of value

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for testing the real-world practice of these therapies, experimental findings suggesting that light physical touch lessens stress,[21] reduces pain,[22,23] and induces a general feeling of well-being[24,25] may account for at least part of any beneficial effects attributed to BFTs. With the aim of more directly assessing healing via the biofield, the present review identified and evaluated RCTs that report using only nonphysical touch forms of the five BFTs listed above.

One of the challenges for evaluating and interpreting RCTs of BFTs is that, with few exceptions, these trials are designed as pilot studies; as such, they are often replete with limitations inherent in early-phase clinical research.[26] These limitations include small sample size, restricted patient populations, control procedures that have not been adequately validated, and the use of multiple outcome measures to test which ones may be sensitive to the intervention. Such design features of pilot studies are frequently identified in systematic reviews as deficiencies, although considering the nature of early-phase clinical research, ''it is unrealistic to expect that sufficient knowledge exists to permit a fault-free design for [this type of] trial.''[26] Given these design constraints, pilot studies most frequently aim at ''proof of concept'' and seek to generate, rather than test, hypotheses. In this light, the present review aims to (1) evaluate the quality of reporting and degree of adherence to study design features important to early-phase testing of nonphysical contact forms of BFTs and (2) assess the evidence for effectiveness of this form of biofield healing, independent of condition treated or outcomes measured. Conclusions of this systematic review include recommendations for future research. A preliminary version of this review has been presented.[27]

Methods

Search strategies

Clinical trials and systematic reviews of external *qigong*, Healing Touch, Johrei, Reiki, and Therapeutic Touch were initially identified from searches of PUBMED, CINAHL, AMED, Alt HealthWatch and Cochrane Reviews databases through November 2013. The Boolean search string was (''Reiki'' OR ''Qigong'' OR ''external Qigong'' OR ''Qi therapy'' OR ''Johrei'' OR ''Therapeutic Touch'' OR ''Healing Touch'' OR ''energy healing'' OR ''biofield'' OR ''distance healing'' OR ''remote healing'') AND (clinical trial AND human AND randomized). Supplemental searches were conducted on reference lists from identified systematic reviews of biofield therapy RCTs and from research bibliographies posted on websites of the Center for Reiki Research,[28] Healing Touch International,[29] Qigong Institute,[30] Therapeutic Touch International Association,[31] and British Johrei Society.[32]

Selection criteria

Studies of external *qigong*, Healing Touch, Johrei, Reiki, and Therapeutic Touch included in this review met four criteria: (1) English-language, full articles in peer-reviewed journals; (2) prospective clinical or experimental trials with human participants (healees), using clinical and/or physiologic outcome measures in which the BFT was practitioner delivered; (3) RCTs that compared BFT to an active comparison treatment and/or mimic (sham) therapy or other procedure designed to blind the healees (e.g., healer and healee not in direct line of sight[33]); and (4) clinical or experimental trials in which the BFT in at least 1 group was reported as administered with no physical contact between practitioner and recipient.

Studies were excluded if they were (1) clinical trials of BFTs other than the five therapies listed above; (2) reported in dissertations but not subsequently published in peer-reviewed journals; (3) noncontrolled outcomes trials; (4) trials using an unblinded no-treatment or wait-list control group (because of the possibility of enhanced placebo effects in those knowingly receiving verum treatment or nocebo effects in the no-treatment group;[34] (5) crossover trials in which ''order effect'' was not assessed;[35–37] (6) adjunctive care trials comparing standard or usual care plus BFT versus standard or usual care alone (because of possible enhanced placebo effects in healees knowingly receiving added care); (7) trials reporting use of physical touch forms of BFTs or including physical touch at any point during delivery of the biofield therapy;[38,39] (8) trials in which the BFT was taught to participants for subsequent self-care.[40] In addition, several biofield therapy RCTs[41,42] were excluded on the basis of concerns about the integrity of the lead researcher.[43]

Data extraction

Two investigators independently extracted research design items from each of the trials included in the final group; discrepancies were resolved by consensus. Items chosen for extraction regarding participants, protocol, and control/comparison treatment were similar to those used by Astin et al.[44] to facilitate tracking progress of research in this field. Each study was scored as positive, mixed, or negative*:* *positive* if all or most primary outcome measures were reported as verum treatment more effective than mimic (sham) treatment, or verum treatment at least as effective as comparison treatment; *mixed* if primary outcomes were divided in effectiveness between BFT and control/comparator; and *negative* if all or most primary outcome measures did not show benefit in favor of BFT.

Evaluation Criteria

The methodologic and reporting qualities of the final group of trials were evaluated first by applying a modified form of the five criteria outlined by Jadad and colleagues,[45] defining double-blind as participants/patients and researcher(s). In addition, an expanded set of 20 unweighted criteria (Table 1) were created and applied; these criteria included items proposed for biofield energy healing research[8] and implied in discussions of early phase research.[26] Because the Jadad scale has no specific statistical component, mean scores (total, statistical, and nonstatistical) were computed for the 20 criteria to determine the extent to which our statistical items might provide additional quality assessment information to the Jadad score.

Results

The initial search criteria allowed identification of 90 RCTs that assessed effectiveness of external *qigong*, Healing Touch, Johrei, Reiki, or Therapeutic Touch in humans

Table 1. Quality Assessment Criteria

Criterion no.	*Criterion*
Introduction/Background	
1	Are there statements of the specific objectives or hypotheses to be tested?
Design/Methods	
2	Is the nature of the patient/participant population reported? [Including inclusion and exclusion criteria]
3	Is the patient recruitment procedure described?
4	Was informed consent language reported that described the groups to which participants would be assigned?
5	Is the procedure used to generate the random allocation sequence adequately described and appropriate? [e.g., Coin flip or assignment by temporal appearance of PTs are not appropriate. Score ''partial'' if procedure is described but is not appropriate]
6	Was concealment of group allocation described? [Were researchers and PXs unable to (1) predict the group to which a PT would be randomly assigned until the PT was unambiguously enrolled on study and (2) change a PT's allocation after the PT was randomly assigned?]
7	Is there sufficient information on which a subsequent study could base a sample-size calculation? [This could include a sample-size calculation in the present paper.]
8	Is the treatment setting described (e.g., hospital clinic room), and are the physical positions of healer and healee reported (including whether each was standing or sitting, whether PX was in front of or behind PT, and the distance between healer and healee)?
9	Is the biofield therapy treatment protocol adequately described, including the number, duration, and frequency of TXs? [Citation of a prior study for the BFT protocol is acceptable if the cited description is adequate.]
10	Is the control/comparison treatment adequately described or referenced?
11	If a sham/mimic therapy arm was used, was the procedure validated as mimic? [Was it determined by pretesting, *in a preliminary part of the same trial*, hat the sham procedure was indistinguishable from the verum TX (e.g., was an independent panel unable to distinguish between verum and mimic healing, viewed live or on video? Citing a prior study that used such a validation procedure is inadequate.)?]
12	Are the training and experience of the healer(s) reported?
13	Are primary and (if applicable) secondary outcome measures for healees clearly defined and validated? [''Validated'' includes citing references.]
14	Were the researchers who monitored and/or evaluated the treatment outcomes reported as blinded?
15	Was the method(s) of data analysis appropriate to the research question and correctly applied?
Results/Discussion	
16	Are all appropriate baseline demographics and clinical characteristics, for patients actually analyzed, reported by group? [Score ''partial'' if only clinical *or* demographic data are presented.]
17	Was there an investigation of variables, e.g. baseline data, possibly requiring balance in subsequent studies?
18	Are results reported per group and in clinically meaningful units, not just as percentage change?
19	Are the results clearly discussed in relation to the objectives or hypotheses of the trial, and does the abstract adequately represent the contents of the paper?
20	Are the limitations of the study discussed? [If discussed inadequately, score ''partial''.]

Each criterion is scored as yes (1), partial (0.5), no (0) or not applicable. Sum = raw score. Total score = raw score × 100 / [20 − number of criteria scored N/A].

PT, participant; PX, practitioner; TX, treatment; BFT, biofield therapy.

(Fig. 1). Of these trials, 60 met the selection criteria for research design, most importantly that verum therapy be compared to mimic therapy and/or an active comparison treatment. Four trials comparing verum therapy to a no-treatment control procedure were included because the design allowed blinding of participants to their randomization assignment[33,46–48] (e.g., verum and mock treatments were both delivered by a practitioner out of the patient's line of sight). Of the RCTs excluded at this step, the largest number were two-group trials that compared verum BFT to no treatment and did not blind participants to group assignment ($n = 17$).

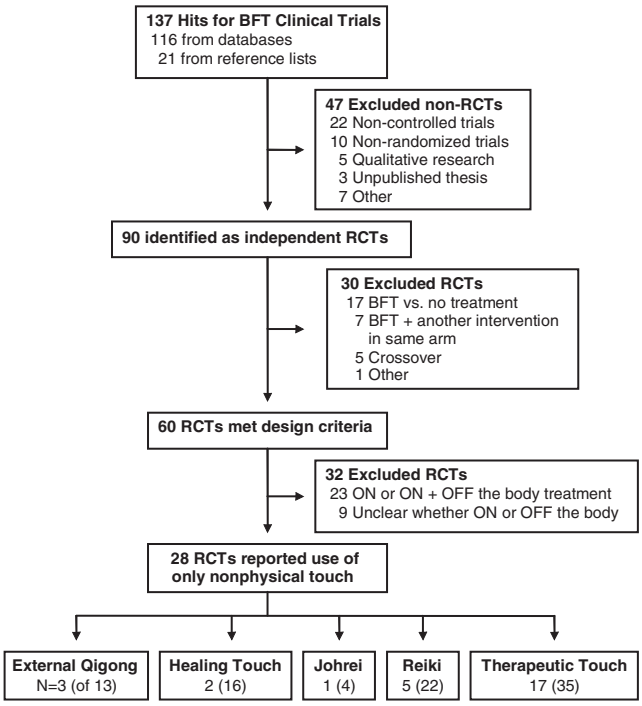

FIG. 1. CONSORT diagram: Article selection process. BFT, biofield therapy; RCT, randomized controlled trial.

Application of the selection criterion most central to the aim of this review, the reported use of only a nonphysical touch form of BFT, resulted in a final set of 28 RCTs (Tables 2 and 3). Among the five BFTs considered, RCTs of Therapeutic Touch—which made up the largest group of included trials at each step of the selection process—contributed 17 to the final group (Table 3). Data from the 28 trials were extracted in four categories: participants (healees) and condition, intervention group, treatment protocol, and results.

Participants, conditions, and outcome measures

The RCTs summarized in Table 2 (external *qigong*, Healing Touch, Johrei, and Reiki) and Table 3 (Therapeutic Touch) make up a wide range of healee populations, sample sizes, conditions treated, and assessed outcomes (subjective assessments or biomarkers). Because participant populations in these trials varied from preterm infants and children to adults and the elderly, and from healthy to chronically ill, there are insufficient numbers of trials to draw conclusions based on healee group. Trials examined BFT effects on in-patients ($n=10$), outpatients ($n=13$), and healthy adults ($n=6$) (1 trial enrolled both in-patients and outpatients). Across the group of 28 RCTs, the number of participants randomly assigned per trial was 63.4 ± 34.5 (mean $\pm$ standard deviation); the median was 58 (range, 15–153), while the number of participants per group was 26.5 ± 14.1 (median, 27; range, 5–54). The number per group was informed by a sample size calculation in 10 trials; most used a convenience sample. Twelve trials assessed conditions for which pain was a major outcome, 9 trials assessed other subjective outcomes (stress or anxiety), while 10 trials examined changes in objective biomarkers: heart rate and/or heart rate variability,[47,49–51] salivary cortisol,[52,53] median nerve latency,[54] and immunologic,[33] or hematological markers.[55]

Interventions

The 28 RCTs reviewed used a variety of trial designs. Twenty of the 28 compared BFT to a mimic (sham) BFT procedure within a 2- or 3-arm design. In 5 of these 20 trials, mimic therapy was performed by the same practitioner who delivered the verum therapy. In the other 15 trials, mimic therapy was performed by nurses, research assistants, actors, or volunteers who were BFT naive and trained to imitate the movements of the BFT practitioners. Five of the 20 mimic therapy–controlled RCTs included a prerequisite to the formal start of the trial that a BFT-naive panel would judge as indistinguishable the verum and mimic procedures, viewed in video or stage presentation.[51,56–59]

Seven RCTs compared verum BFT to usual or standard care, instead of, or in addition to, a mimic BFT control. Of additional interest, 2 of the Reiki RCTs[60,61] and 1 *qigong* RCT[52] compared nonphysical touch BFT to physical touch BFT in separate arms of the same trial.

Protocols

Marked heterogeneity among the trials, as described above for patient population, condition treated, and outcome measures, was also reflected in the number, duration, and frequency of treatments. The 17 RCTs of nonphysical contact Therapeutic Touch, for example, reported a range of 1 to 8 treatment sessions (7 trials used a single treatment) at 5 to 30 minutes per treatment for a total ''dosage'' range of 5 to 180 treatment-minutes. Corresponding numbers for the 5 Reiki trials were 1 to 16 sessions (1 trial used a single treatment) at 20 to 75 minutes per session, for a range of 30 to 480 treatment-minutes. Three of the Reiki trials delivered a dosage greater than the 180 maximum treatment-minutes used in the Therapeutic Touch trials. There was also little consensus on frequency of treatments, with a fairly even divide among the multisession trials, from 1 per day ($n=5$), to 1 every few days ($n=4$), to 1 per week ($n=6$). The decision regarding frequency of treatment was often related to condition studied and ease of access to participants (e.g., postoperative inpatients received BFT daily, whereas oncology outpatients, scheduled for weekly radiation treatments, received BFT after each of their radiation sessions).

Evaluation of trials

Trials were assessed for design and reporting quality by two sets of criteria (Tables 2 and 3). On the 5-point Jadad scale,[45] the 28 BFT trials scored 3.5 ± 1.3 (mean $\pm$ SD). On the 20-item set of criteria, developed for this review, the RCTs scored 64.2 ± 12.2 (of a possible 100 points); the median score was 65.8 (range, 33–89). Mean scores computed separately for statistical criteria (items 7 and 15–18) and nonstatistical criteria were 34.0 ± 17.0 and 73.8 ± 12.7, respectively. Several of the nonstatistical criteria also scored poorly (mean ≤ 0.5), including the reporting of informed consent language (item 4), procedure for generating the random allocation sequence (item 5), concealment of group allocation (item 6), and, in trials where a mimic BFT arm was included, a validation procedure for the mimic therapy (item 11).

Table 2. Randomized Controlled Trials of Nonphysical Contact External *Qigong*, Healing Touch, Johrei, and Reiki

Author, year (reference)	*No. of participants and condition*	*Intervention groups*[a]	*Treatment protocol*	*Results*	*P/M/N*[b]	*Jadad score*	*Criteria score (%)*
External *qigong*							
Jung et al., 2006[52]	24 healthy men	1. Nontouch EQ 2. Touch EQ	1 × 10 min TX	Nontouch EQ = EQ: anxiety, mood, cortisol, NK cell activity Nontouch EQ > EQ: neutrophil super-oxide anions; no changes: melatonin	P	5	66
Lee et al., 2005[49]	40 healthy male university students	1. EQ 2. Mimic EQ	1 × 10 min TX	Heart rate ↓, HRV ↑ (LF/HF ↓) in EQ relative to mimic EQ	P	3	66
Smelson et al., 2013[100]	101 recently abstinent cocaine dependent individuals	1. EQ 2. Mimic EQ	2-3 × 15 min TX/wk, 2 wk	EQ > mimic EQ for cue-elicited cravings ($p = 0.06$) and symptoms of depression ($p < 0.05$)	M	5	65
Healing Touch							
Cook et al., 2004[101]	78 women newly diagnosed with gynecologic or breast cancer	1. HT 2. Mimic HT	5 × 30 min (postradiation) weekly TX + 1 × 30 min TX at week 4 follow-up	HT > mimic HT for several measures of health-related QOL	M	5	74
Fitzhenry et al., 2014[78]	41 women undergoing radiation TX for breast cancer	1. HT 2. Mimic HT	5–7 × 45 min (postradiation) weekly TX	Mimic HT > HT (within and between groups) for reported measures of fatigue; no between-group differences in QOL	N	4	73
Johrei							
Laidlaw et al., 2006[33]	33 healthy medical students	1. Johrei 2. Rest	1 × 10 min TX (blinded to condition); crossover at 30 min	Johrei > rest on mood and anxiety following math test stressor; no significant between group differences in IgA, cortisol, or DHEA	M	2	47
Reiki							
Assefi et al., 2008[60]	100 adult outpatients; fibromyalgia	1. Distant Reiki 2. Mimic distant Reiki 3. Touch Reiki 4. Mimic touch Reiki	16 × 30 min TX; 2/wk, 8 wk	No intervention effective for improving pain, fatigue, sleep, well-being, physical or mental function	N	5	83
Bowden et al., 2010[46]	36 healthy undergraduate students	1. Reiki 2. No TX; PX seated behind PT	10 × 20 min TXs, over 2–12 wk	Reiki > no TX in reducing illness symptoms and stress; no between-group difference in anxiety, depression, sleep, or salivary cortisol	M	4	66
Mackay et al., 2004[50]	45 healthy adults	1. Reiki 2. Mimic Reiki 3. No treatment	1 × 30 min TX	Reiki > mimic Reiki for heart rate ↓ and diastolic BP ↓; no between-group differences in systolic BP, cardiac vagal tone, baroreflex, or breathing rate	M	2	43
Shore et al., 2004[61]	45 adult outpatients; psychological depression, stress	1. Distant Reiki 2. Hands-on Reiki 3. Distant mimic Reiki	6 × 60–90 min TX, 1/week	1 = 2 > 3 in reducing depression, hopelessness, and stress	P	4	71
vanderVaart et al., 2011[48]	80 postpartum women who had cesarean delivery	1. Distant Reiki plus usual care 2. Usual care alone	3 × 20 min TX, 1 on each postoperative days 1–3	No between-group differences in Cesarean delivery pain, opioid consumption, or rate of healing	N	5	89

[a]The term 'mimic treatment' has been used in the table for consistency. Other synonyms for 'mimic' in biofield therapy research are mock, sham, and placebo.

[b]P = positive: all or most primary outcomes favored nontouch biofield therapy over control or showed biofield therapy at least equivalent to comparator. M = mixed: primary outcomes were divided between biofield therapy and control/comparator. N = negative: all or most primary outcomes did not show benefit in favor of biofield therapy.

EQ, external *qigong*; TX, treatment; HRV, heart rate variability; LF, low frequency; HF, high frequency; HT, Healing Touch; QOL, quality of life; DHEA, dehydroepiandrosterone; BP, blood pressure.

Table 3. Randomized Controlled Trials of Nonphysical Contact Therapeutic Touch

Author, year (reference)	*No. of participants and condition*	*Intervention groups*[a]	*Treatment protocol*	*Results*	*P/M/N*[b]	*Jadad score*	*Criteria score (%)*
Blankfield et al., 2001[54]	21 adult outpatients; carpal tunnel syndrome	1. TT 2. Mimic TT	6 × 30 min TX, 1/wk	No between-group change in median motor nerve latency, pain or relaxation	N	1	53
Eckes Peck, 1997[94]	108 elderly noninstitutionalized patients; arthritis	1. TT 2. Progressive muscle relaxation	6 × 10–33 min TX, every 5–7 d	Pain: ↓both groups; no intergroup difference Distress: ↓both groups; progressive muscle relaxation > TT	N	2	53
Frank et al., 2007[95]	82 women undergoing breast biopsy	1. TT 2. Mimic TT	1 × 10 min TX	No between-group change in pain or anxiety	N	5	78
Gordon et al., 1998[57]	31 adult outpatients; knee osteoarthritis	1. TT + usual care 2. Mimic TT + usual care 3. Usual care alone	6 TX, 1/wk (duration not reported)	TT > mimic TT or usual care alone for pain, well-being, and health status	P	2	50
Hagemaster et al., 2000[96]	15 adult outpatient substance abusers	1. TT 2. Mimic TT 3. No tx	8 × 15 min TX, 1/wk	TT > mimic TT or no TX for social relations and depression; alcohol use ↓in all 3 groups	M	2	33
Hawranik et al., 2008[91]	51 elderly inpatients; Alzheimer's disease	1. TT 2. Mimic TT 3. Usual care	5 × 30–40 min TX, 1/d, 5 d	No TT vs mimic TT differences in aggression or verbal agitation; TT > usual care in nonphysical aggression	M	4	58
Ireland et al., 1998[58]	20 outpatient, HIV-positive children	1. TT 2. Mimic TT	1 × 5–7 min TX	TT > mimic TT for reducing anxiety	P	4	63
Johnston et al., 2013[79]	55 preterm infants (< 30 wk) in NICU	1. TT 2. No TX therapist present	2 × 5 min TX: pre/post heel lance	No between-group difference: premature infant pain or heart rate recovery time	N	5	76
Keller and Bzdek, 1986[97]	60 outpatient adults; tension headache	1. TT 2. Mimic TT	1 × 5 min TX	TT > mimic TT for headache pain	P	3	65

(*continued*)

TABLE 3. (CONTINUED)

Author, year (reference)	*No. of participants and condition*	*Intervention groups*[a]	*Treatment protocol*	*Results*	*P/M/N*[b]	*Jadad score*	*Criteria score (%)*
Lin and Taylor, 1999[53]	95 elderly in- and outpatients; chronic pain, anxiety	1. TT + standard care 2. Mimic TT + standard care 3. Standard care alone	3 × 20 min TX; 1/d, consecutive days	TT > mimic TT > standard care alone (pain and anxiety); mo within-group change in salivary cortisol	M	3	65
McCormack, 2009[98]	90 elderly inpatients; postoperative pain management	1. TT 2. Metronome 3. No TX	1 × 10 min TX	TT > metronome or no TX for pain ↓; no differences in absorption	M	2	58
Meehan, 1993[99]	108 adult inpatients; postoperative pain management	1. TT 2. Mimic TT 3. Pain medication as needed (pain meds)	1 × 5 min TX	Medication > TT > mimic TT for pain; TT > mimic TT, time until pain medications needed	M	4	68
Movaffaghi et al., 2006[55]	86 adult female undergraduates; clinically anemic	1. TT 2. Mimic TT 3. No TX	3 × 15–20 min TX, 1 every 3 d	TT > mimic TT > no TX for hemoglobin ↑; no significant changes in hematocrit	M	3	58
Quinn et al., 1984[56]	60 adult inpatients; post-cardiovascular surgery	1. TT 2. Mimic TT	1 × 5 min TX	TT > mimic TT for anxiety ↓	P	2	68
Quinn et al., 1989[51]	153 adult inpatients; pre–open-heart surgery	1. TT 2. Mimic TT 3. No TX	1 × 5 min TX	No between-group differences in anxiety, heart rate, or systolic blood pressure	N	5	75
Turner et al., 1998[59]	99 burn injury inpatients, age 15–63 y	1. TT + pain medications 2. Mimic TT + pain medications	5 × 5–20 min TX, 1/d	TT > mimic TT on 2 of 4 pain measures and for anxiety; no difference in medication use	M	3	68
Whitley and Rich, 2008[47]	20 preterm infants (< 29 wk) in NICU	1. TT 2. No Tx	3 × 5 min TX, 1/d	TT > no TT on improved heart period variability	P	5	66

[a]The term 'mimic treatment' has been used in the table for consistency. Other synonyms for 'mimic' in biofield therapy research are mock, sham, and placebo.
[b]P = positive: all or most primary outcomes favored nontouch biofield therapy over control or showed biofield therapy at least equivalent to comparator. M = mixed: primary outcomes were divided between biofield therapy and control/comparator. N = negative: all or most primary outcomes did not show benefit in favor of biofield therapy.
TT, Therapeutic Touch; NICU, neonatal intensive care unit.

Trial outcomes

Examination of researcher-reported results of primary outcomes of the 28 RCTs revealed 20 trials (71%) rated as positive or mixed (as defined in footnote to Tables 2 and 3). Effectiveness of nonphysical touch biofield therapy based on higher-quality RCTs was assessed after exclusion of 10 trials with Jadad score of 1 or less or total criteria score of 50 or less or statistical criteria score of 20 or less. Of the remaining 18 trials, 12 (7 Therapeutic Touch, 3 external *qigong*, 1 Reiki, and 1 Healing Touch) reported at least one primary outcome with statistically significant beneficial treatment outcomes.

Although there are too few trials to permit assessment of outcomes versus treatment-minutes (tx-mins) as an evaluation of dose-response effects, there was little indication of such a relationship. For example, the 4 ''high-dose'' Therapeutic Touch trials ($\geq$120 tx-min) comprised 2 negative- and 2 mixed-outcome trials, while the 8 ''low-dose'' trials ($\leq$10 tx-min) comprised 3 negative-, 2 mixed-, and 3 positive-outcome trials (Table 3).

Discussion

The initial aim of this review—to identify RCTs of BFTs reporting use of only nonphysical contact procedures—was met in 28 (31%) of the 90 biofield RCTs found from database and reference list searches. An additional 9 of the total RCTs were unclear as to whether practitioners used off-the-body style, on-the-body style, or a combination of both styles of treatment, emphasizing the importance for BFT researchers to include unambiguous language regarding this key variable in their description of the intervention.

As an approach to assigning quality scores to the 28 RCTs, two evaluative instruments were applied in the present review: the 5-item Jadad scale[45] and an expanded scale, created for this review, which includes items relevant to trials of BFTs and to early-phase trials.[26] While the two scales yielded similar mean scores for the 28 nonphysical contact RCTs (3.5 [70%] on the Jadad scale and 64% on the 20-item expanded scale), the value of the expanded scale lies in its ability to identify a specific set of under-reported and/or inadequately designed features of these clinical trials. In particular, two statistical items that scored poorly are important for the appropriate design of a large phase 2 or 3 trial based on results of a pilot study. Results were often not expressed in a manner needed to facilitate a future sample size calculation (item 7), or not corrected for baseline variables that were likely to affect outcomes of larger studies (item 17).

As a key example of the nonstatistical criteria, the lack of reported concealment of group allocation, identified as a major source of potential bias in RCTs,[62] was a commonly identified deficiency among the BFT studies we reviewed. Use of the expanded scale revealed two other low-scoring items: one involving lack of proper randomization procedure and a second regarding inadequate informed consent language. Both findings are of concern as each represents a further source of potential bias.[63] An additional low-scoring item, of particular relevance for RCTs of BFTs, involves validation of a mock or sham therapy procedure. Whether or not the verum and mock treatments are performed in line-of-sight of the patient/healee, or by the same or different practitioners, it seems essential to the development of a credible biofield sham that the two procedures be previewed and found indistinguishable by a BFT-naive panel before onset of the trial.[56] Implementation of a mock therapy procedure solely on the basis of its use in a prior trial is insufficient in the absence of validation of the performance of current practitioners and trainees.

It is also of interest that when mock procedures were delivered, by BFT practitioners or BFT-naive persons, the mock therapists were almost always asked to block their intention of treating/healing the participants. A review of the methods sections of our 28 RCTs found that of the 20 trials that included a mock BFT control group, 16 reported specific instructions to the mock therapists to attempt to ''jam'' their intention (almost always by asking them to perform a mental activity such as counting down from 100 by 7s). However, until an ''intention meter'' is developed and validated, this key aspect of BFT delivery (and arguably of most types of healthcare) remains a confounding variable in terms of the quality of BFT provided, as well as a potential factor accounting for differences in outcomes between BFT and mock treatment.

Examination of only RCTs with quality scores above a set of arbitrarily defined cut-points for the Jadad scale, the total criteria score and the statistical criteria score (see Results) revealed that of the 18 qualifying trials, 12 were among those rated positive or mixed (Tables 2 and 3). Thus, two thirds of the higher scoring trials reported at least one primary outcome with statistically-significant beneficial treatment effects, a strong indication that further, more robust trials of nonphysical touch BFTs should be performed.

The relatively small number and marked heterogeneity of nonphysical contact BFT trials precluded formal analyses of clinical outcome as a function of condition treated, patient/participant demographic characteristics or other design parameters. As one example, the wide range of biofield ''dosage,'' expressed as total treatment-minutes, reflects a lack of consensus on how to test BFTs within the relative confines of a clinical trial. It can also be argued that dosage is not a meaningful variable in many nonpharmacologic interventions (e.g., surgery).

Our findings are not readily comparable to those of prior reviews, which have included RCTs of distant healing and prayer in addition to BFTs,[44] hands-on as well as hands-off BFTs,[19] or either single BFTs across conditions[13,15,18] or single conditions across BFTs.[64] To our knowledge, this is the first systematic review focused on clinical trials of proximally delivered BFTs that report the use of only nonphysical contact.

BFT in clinical practice commonly involves both physical touch and nonphysical contact procedures. Mediators of the health-promoting effects of light touch appear to include specialized sensory endings,[25,65] autonomic nervous system,[66] and/or hormone release.[67] In contrast, RCTs using only nontactile forms of treatment have the potential to build an evidence base for health-promoting effects mediated through mechanisms outside the present understanding of biomedicine. Such evidence of subjective and objective changes related to nonphysical contact BFT, as identified in the present review, provides encouragement for ongoing efforts to explore the biophysical and physiologic bases of biofield-mediated effects.[1–6,68]

Limitations of the systematic review

As described above, an initial challenge to this review was the accurate identification of RCTs that used only nontouch forms of BFT. Uncertainties in interpreting description of the intervention may have led the review to be based on fewer than the actual number of published trials that otherwise met the inclusion criteria.

A second limitation to assessing beneficial effects of nontouch therapies was the decision to include only trials with human participants. A considerable number of RCTs have been performed with animals,[69–71] plants,[72] cell cultures,[73–76] and cell-free systems[77] in which BFT has clearly been performed with no physical contact between practitioner and recipient. While inclusion of nonhuman trials would have increased our dataset, such trials would also have considerably increased the heterogeneity of the cohort under review and complicated the creation of quality assessment criteria.

A third limitation is that essentially all 28 RCTs reviewed are in the category of pilot studies (mean group size, 27 participants). While a few trials were designed as partial replications,[51,78,79] none were follow-up studies with increased sample size commensurate with a phase 2 or phase 3 RCT. It follows that conclusions from a systematic review of pilot studies must be considered as far from robust.

A final limitation is the absence of quality assessment items for design and reporting of potentially key but unknown variables affecting BFT trial outcomes. As an example, the need to calibrate biofield therapists has frequently been discussed,[76,80] but no method has been devised and validated to test and quantify, before treating a patient or experimental subject, the ability of a practitioner to perform a BFT. Without such a test, negative and/or variable outcomes may be attributable at least in part to intra- or interpractitioner inconsistency, independent of patient/participant receptivity. Another little-studied potential variable is the electromagnetic or other ambient condition of the clinic or laboratory space in which the BFT is performed.[81,82] Discussion of these and other potential confounders of outcomes of biofield trials (e.g., experimenter effects,[44,83,84]) are beyond the scope of this review, but they remain as challenges to the field.

Recommendations for future research

Numerous suggestions for improving the design and reporting of RCTs of hands-off as well as hands-on forms of healing have been presented in prior reviews.[8,19,20,44] Two of the more important issues, relevant but not unique to trials of BFTs, are the choice of control/comparator group and the use of fixed versus individualized treatment protocols. In the case of BFT RCTs, the use of mock therapy is feasible as a control for nonphysical touch trials to a much greater extent than for trials involving physical touch. As discussed above, it is essential for the mock therapy procedure to be prevalidated on the basis of independent blinded assessment of the performance of therapists who are to provide the verum and mock treatments.[51,56–59] At this still early stage in BFT research, the argument for including, where possible, a mock therapy group holds just as well as the arguments in favor of comparative effectiveness research.[85,86] Trials using control (mock treatment) groups ask distinctly different types of research questions from those using comparator (active control) groups, and one can argue that the most appropriate approach is to design 3-arm trials, randomly assigning participants to verum treatment, mock treatment, or standard care. As found in this review, the question of fixed versus individualized treatment has been answered overwhelmingly in favor of providing all participants with the same number, duration, and frequency of treatments. However, in light of the striking lack of consensus as to what these parameters should be, as well as in the interests of encouraging clinical research to better reflect clinical practice, consideration should be given to protocols in which biofield practitioners are allowed a degree of freedom (within broad parameters) to individualize treatment protocols. This argument has also been framed within the explanatory model of biofield healing: ''[As in clinical practice], a treatment should be ended according to cues from the field rather than the passage of time.''[87]

In addition to the need to improve reporting of biofield RCTs in accord with quality assessment items listed in this and other reviews,[8,20,88] future research needs to further explore the three potential confounders of biofield trials mentioned above. Creative approaches are called for to (1) calibrate practitioners in regard to their ability to generate ''healing presence,''[89,90] as well as to perform BFT;[76] (2) calibrate healing space in regard to initial conditions[81,82] and the possible persistence of field effects,[91] and (3) assess experimenter/observer effects as positive or negative affectors of trial outcome.[44,83,84]

Finally, it would seem of value for research-minded representatives from each of the BFT organizations to convene a workshop with the aim of discussing topics related to clinical trial design. Such a meeting could formalize research guidelines by creating a CONSORT (Consolidate Standards of Reporting Trials) extension for BFT trials, similar to existing CONSORT extensions for RCTs of acupuncture[92] and herbal medicine.[93]

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