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Biofield therapies: Guidelines for reporting clinical trials☆

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ABSTRACT

A set of guidelines has been developed to help improve reporting of clinical trials of biofield therapies. The need for enhanced transparency when reporting trials of this family of integrative health practices, e.g., External Qigong, Healing Touch, Reiki and Therapeutic Touch, has been advocated in systematic reviews of these studies. The guidelines, called **Biofi**eld Therapies: **Re**porting **E**vidence **G**uidelines (BiFi REGs), supplement CONSORT 2010 by including details of the intervention protocols relevant to biofield therapy trials. BiFi REGs evolved through a draft document created by a core group, two rounds of a Delphi process with an international group of subject matter experts and two panels, meeting via Zoom, which included editors of complementary and integrative medicine journals. BiFi REGs comprises a 15-item Intervention checklist. Modifications of two other CONSORT topic areas are also proposed to enhance their relevance to trials of biofield therapies. Included for each item are an explanation, and exemplars of reporting from peer-reviewed published reports of biofield therapy trials. When used in conjunction with all other items from CONSORT 2010, we anticipate that BiFi REGs will expedite the peer review process for biofield therapy trials, facilitate attempts at trial replication and help to inform decision-making in the clinical practice of biofield therapies.

Introduction

Biofield therapies (BFTs) are a related group of integrative medicine interventions in which practitioners use their hands on or above a client's body to stimulate healing and well-being.[1–3] Of the family of BFTs, those with a substantive amount of clinical research are External Qigong, Healing Touch, Reiki and Therapeutic Touch.[4,5] These practices are based on a model in which living systems contribute to, and exist within, a confluence of electromagnetic forces and other less conventional phenomena, called biofields, which complement biochemical regulatory processes.[6–8] Biofield therapists report that they promote the healing response by sensing and directing a form of energy that is not well-described within the biomedical model.[9–11]

As is the case for most healthcare interventions, BFTs have been tested in randomized controlled trials (RCTs) to build an evidence base.[4,12–15] While these reviews include trials with both positive and negative findings for specific BFTs in a range of clinical conditions, the reviewers also caution that drawing robust conclusions regarding efficacy and effectiveness is often limited by incomplete descriptions of experimental details.[4,5,15,16].

The broad issue of inconsistent reporting of RCTs, which is addressed for BFT trials in the present paper, was first brought to the attention of the clinical research community in a formal manner by CONSORT, the **CON**solidated **S**tandards **o**f **R**eporting **T**rials, published initially in 1996[17] and revised most recently in 2010.[18,19] As emphasized in CONSORT, this desired completeness of reporting is of considerable importance for determining which trials contain sufficient information to meet eligibility criteria for inclusion in a systematic review or meta-analysis. Transparency of reporting is also critical for assessing whether intervention X has clinical benefit for condition Y and, thus, has value for informing clinical practice.

The enduring value of CONSORT is its generalizability to a wide

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range of healthcare interventions. This feature was a major contributor to its formal endorsement by numerous multi-disciplinary as well as specialty-focused biomedical journals.[20] Inherent in this generalizability, however, is the non-specificity of CONSORT Item 5, which broadly asks for reporting on.

> "The interventions for each group with sufficient details to allow replication, including how and when they were actually administered."[18]

This limitation led to the creation of several expanded guidelines, focused mainly on CONSORT Item 5, calling for details relevant to specific types of non-pharmacologic treatments,[21] as well as other healthcare practices, including Herbal interventions,[22] Homeopathy,[23] Acupuncture[24] and Yoga.[25] All such reporting guidelines, including formal and informal expansions of CONSORT, are accessible on the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) website.[26,f] The EQUATOR site also contains reporting guidelines addressing randomized pilot and feasibility trials, and research designs other than RCTs.

The present article describes the development of a guidance document, **Biofi**eld Therapies: **R**eporting **E**vidence **G**uidelines (BiFi REGs). The document's aim is mainly to expand CONSORT Item 5 by identifying specific details of BFT interventions whose inclusion will inform quality assessment and facilitate replication of these trials. Procedures used to develop and achieve consensus for the Intervention-related items followed recommended practices.[27] An explanation and exemplars of reporting are presented for each item. BiFi REGs is meant to be used in conjunction with all other CONSORT items and should be consulted when reporting RCTs as well as other clinical trial designs involving biofield therapies.

Methods

An initial list of items for reporting clinical trials of biofield therapies was drafted by a core group of three researchers with experience in conducting and evaluating trials of this family of therapies (RH, MS, ALB). The list was based mainly on the CONSORT extension for non-pharmacological treatments, the expansion of CONSORT Item 5 to reflect acupuncture interventions[21,28] and the general guidelines for reporting interventions.[29] Aspects of research design specific to biofield therapy trials were incorporated into several items.

A draft document, formatted as a Google survey, was created as the basis for the first round of the Delphi process, an iterative activity in which a panel of subject matter experts respond to a questionnaire to approach consensus on a complex topic.[30] An international group of 36 subject matter experts, most of whom had authored clinical trials and/or systematic reviews of biofield therapies, were invited to participate in a Delphi process. The 26 respondents (72%) were asked to rate the importance of each item on a 5-point Likert scale. They were also given the options to provide a rationale for each of their scores and to suggest improvements in the wording of the question in the text-box below each item.

All responses from the expert participants were collated. Items receiving mean scores of ≥ 4 on the Likert scale were formatted for a second round of Delphi ratings after the core group reviewed and decided upon any first-round suggested changes in wording. A further culling of items was performed in response to feedback from Delphi participants who suggested that BiFi REGs should focus mainly on Intervention items and not attempt to fine-tune other items that were similar to accepted components of CONSORT. The revised list was emailed to and scored by the subject matter experts in round 2 of the Delphi process; survey results were reviewed and collated as above by the core group. At the conclusion of the Delphi process, each participant was presented with a $50 Amazon gift card.

At this stage, the core group convened a smaller panel of experts who met during two Zoom sessions. Attendees included editors-in-chief of key journals that have published clinical trials of biofield therapies ($n = 4$), and representatives from complementary, integrative and allopathic medicine organizations ($n = 4$).

Following the Zoom sessions, the core group made final edits to the BiFi REGs checklist, provided explanations for each item and identified exemplars of reporting from the published literature on biofield therapy trials.

Results

The BiFi REGs checklist focuses mainly on rendering the generic Item 5 of CONSORT (reporting Interventions) relevant to clinical trials of biofield therapies. As such, BiFi REGs comprises five Intervention items (Rationale, Treatment Protocol, Control or Comparator Procedure, Other Components of Intervention, and Practitioners) expanded into 15 sub-items (Table 1). These recommendations are meant to be applied in conjunction with all other CONSORT guidelines (Table 2). Amendments are also suggested to CONSORT Items 7a (Sample size determination) and 20 (Trial limitations), again with the aim of improving reporting specific to biofield therapy trials (Table 2).

Each of the BiFi REGs sub-items is presented below, together with an explanation for its inclusion and exemplars from published clinical trials of biofield therapies.

BiFi REGs Item 1: Biofield Therapy Rationale

Item 1a. Description of biofield therapy evaluated: name, and sub-type, if relevant, e.g., Usui Reiki.

Explanation. This family of healthcare practices range from those overseen by national and international organizations, often with strictly adhered to lineages, to those practiced idiosyncratically, with relatively eclectic styles.[2] In light of this cultural and stylistic diversity, researchers should provide specific details regarding the type of biofield therapy on which their treatments were based.

- **Examples**
- In this experiment, Korean qi therapy (called ChunSoo Energy Healing) was performed by a qi therapist in Ki Health International.[31]
- The Reiki in the present study was administered by the experimenter who… trained in Usui Reiki to Master-Teacher level… She employed a combination of Reiki techniques, in particular Ascension Reiki, which was developed by Grahame Wyllie in 1998 and involves using Ascension Reiki symbols.[32]
- … registered nurse Therapeutic Touch practitioners… had practiced the method according to the recommendations of Kreiger.[33]

Item 1b. Rationales for choice of biofield therapy and for how treatment was delivered, with literature citations where appropriate.

Explanation. The reasoning should be presented for the type of biofield therapy as well as for key aspects of the treatment protocol, especially why touch, non-physical touch or a combination was selected, why the treatment was standardized or individualized, and why the trial involved in-person or distance treatment. When treatments followed a traditional practice, the source should be stated and referenced.

[f] In July 2023, attempts to access the CONSORT website were redirected to the EQUATOR website where the following message was posted: *Please note that the CONSORT website is currently unavailable. To access the checklists* via *the original published paper please follow the PubMed links in the full bibliographic reference section of this web page. Or via the GoodReports website at* https://www.goodreports.org/reporting-checklists/consort/.

Table 1
BiFi REGs checklist of information to include when reporting interventions in a clinical trial of biofield therapy*.

ITEM	DETAIL
1. *Biofield Therapy Rationale*	
	1a) Description of biofield therapy evaluated: name, sub-type (if relevant, e.g., Usui Reiki, Chunsoo Korean Qi therapy)
	1b) Rationale for choice of biofield therapy, with literature citations when appropriate
2. *Treatment Protocol*	
	2a) Whether treatment was hands-on (physical contact), hands-off (no physical contact) or both. If hands-off, distance from body surface.
	2b) If practitioner and participant were in separate locations, whether treatment delivery was mediated via phone or video (computer-based) or with other type of contact, e.g., practitioner given photograph of participant. And, whether participant was aware of when treatment was delivered
	2c) Physical posture of practitioner and participant (standing, sitting, supine, prone)
	2d) Whether treatment was structured (predetermined) or individualized (customized)
	2e) Treatment sequence, timing of phases and, if relevant, whether treatment was varied over multiple sessions
	2 f) Number, frequency and duration of treatment sessions
3. *Control or Comparator Procedure*	
	3a) Nature and rationale of procedure in context of the research question, with citations that justify the choice
	3b) Precise description, especially where details differed from the biofield therapy treatment
4. *Other Components of Intervention*	
	4a) Whether communication was allowed between practitioner and participant before, during or after treatment; if allowed, nature of constraints
	4b) Whether a research assistant or anyone other than the practitioner and the participant was in the room during a treatment session
	4c) Whether and how adherence of practitioners to the protocol was assessed
5. *Practitioners*	
	5a) Biofield therapy group: Number and selection criteria, including training and years of experience or minimum required for inclusion
	5b) Control or comparator group: Profession (if different from Biofield Therapy practitioner); number and selection criteria. If delivering sham/mock biofield therapy, how providers were instructed to perform the procedure

* This checklist should be considered in concert with the explanation of each item provided in the main text. These 15 items are designed to replace the generic item 5 of CONSORT[18] when reporting a biofield therapy clinical trial.

- **Examples**
- Therapeutic Touch, an alternative approach based on the theory of energy medicine, has been shown to promote physiological stability in preterm neonates and reduce pain in some adult studies… Although many studies on Therapeutic Touch for pain are fraught with methodological flaws, the conclusion of a Cochrane review is that there is a mild-moderate benefit in favor of it over placebo for pain in adults, and that there is a need for more studies in children.[34]
- During this study, HT [Healing Touch] providers were instructed to not touch the body but to work no closer than 6 in. above the body; touching would suggest to the participant that she was in the HT group and interfere with the attempt to blind the participant to group assignment.[35]
- … results show that Qi might be transferred over short or long distances without touch and transferred with intention or thought in the

Table 2
CONSORT 2010 checklist with BiFi REGs extensions of CONSORT items 7a and 20 for biofield therapy trials.

SECTION/TOPIC	ITEM#	CHECKLIST ITEM*	BiFi REGS ADDITION
TITLE AND ABSTRACT			
	1a)	Identification as a randomized trial in the title	
	1b)	Structured summary of trial design, methods, results, and conclusions; for specific guidance see CONSORT for Abstracts[78,79]	
INTRODUCTION			
Background and objectives	2a)	Scientific background and explanation of rationale	
	2b)	Specific objectives or hypotheses	
METHODS			
Trial design	3a)	Description of trial design (e.g., parallel, factorial) including allocation ratio	
	3b)	Important changes to methods after trial commencement (e.g., eligibility criteria), with reasons	
Participants	4a)	Eligibility criteria for participants	
	4b)	Settings and locations where the data were collected	
Interventions	5)	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	**See**Table 1
Outcomes	6a)	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b)	Any changes to trial outcomes after the trial commenced with reasons	
Sample Size	7a)	How sample size was determined	If no prior studies existed on which to base a sample size calculation, describe how the number of participants was determined, with a rationale for this choice.
	7b)	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
Sequence generation	8a)	Method used to generate the random allocation sequence	
	8b)	Type of randomization; details of any restriction (e.g., blocking and block size)	

(*continued on next page*)

Table 2 (*continued*)

SECTION/TOPIC	ITEM#	CHECKLIST ITEM*	BiFi REGS ADDITION
Allocation concealment	9)	Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10)	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a)	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	
	11b)	If relevant, description of the similarity of interventions	
Statistical methods	12a)	Statistical methods used to compare groups for primary and secondary outcomes	
	12b)	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
RESULTS			
Participant flow (a diagram is strongly recommended)	13a)	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group; for specific guidance see CONSORT for Harms[80]	
DISCUSSION			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Include ways in which the research protocol differed from real-world clinical practice, e.g., practitioner/patient communications; environmental enhancers (treatment room décor, music).
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
OTHER INFORMATION			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (e.g., supply of drugs); role of funders	

* Checklist Items are from the most recent revision of CONSORT[18].

same way as it is by touch. However, there has been no study of the differences in the effects of Qi therapy without touch (QTN) or with touch (QTT).[36]

BiFi REGs Item 2: Treatment Protocol

Item 2a. When practitioner and participant were in the same location, whether treatment was hands-on (physical contact), hands-off (no physical contact) or both; if hands-off, distance from body surface.

Explanation. While the explanatory models of most biofield therapies state that treatment can be effective without physical touch, relatively few clinical trials have directly tested this assertion. Researchers who aim to assess clinical benefit of non-physical touch (off-the body) should be especially thorough in reporting protocol details, as healing at a distance, even when practitioner and participant are in close proximity, is difficult to explain mechanistically.

- **Examples**
- Therapists held both their hands in the classic Spiritist 'passe' position 10–15 cm above the patient's head... The participant's body was touched at no time.[37]
- Four (4) groups received twice-weekly treatment for 8 weeks by either a Reiki master or an actor randomized to use direct touch or no touch (distant therapy)… The first [group received] a generic 30-minute direct contact treatment delivered by a Reiki master in which the participant was lightly touched… The second [received] distant Reiki administered by a master who sat ~2 feet away, maintained hand positions in the "sending" mode, and focused healing intention on the participants. The third was sham direct contact Reiki given by actors. In the fourth arm, actors sat ~2 feet away from participants and mimicked the "sending" position of distant Reiki.[38]
- The Yakson method continued for 15 min with steady touch (5 min: practitioner's palms and fingers kept in close contact so that the infants did not feel pressure), compassionate caressing (5 min: in same hand positions, alternating caressing and resting), and repetition of steady touch (5 min).[39]

Item 2b. When treatment was provided from a remote location, whether practitioners were given information about participants, e.g., name, and/or photograph, and whether participants knew when the treatment was delivered. If treatment involved use of phone or computer (e.g., Zoom), appropriate details of these options should be included.

Explanation. By definition, distance healing from a remote location involves no direct contact between practitioner and participant. It follows that explicit details should be reported concerning the type of information the practitioner was given about the participant, how the treatment was delivered, and whether the participant was aware of the time of treatment. These are important variables that may affect the trial outcome.

- **Examples**
- Distant Reiki sessions were applied the night before the patient's hemodialysis day and lasted approximately 36–40 min. There was no rule that the patients had to follow during the application (such as remaining in a lying or sitting position, sleeping or working, etc.).[40]
- Reiki practitioner [located 8 km away] first undertake [sic] a name of patient and then send the healing energy to the patient.[41]
- If the patient was assigned to the distant reiki group, the research assistant contacted the reiki master with the participant's information.[42]

Item 2c. Physical posture of practitioner and participant, e.g., standing, sitting, supine, prone.

Explanation. The relative physical positions of practitioner and participant should be reported, especially whether the practitioner was in the line of sight of the participant.

- **Examples**
- Participants sat on a chair with palms facing upwards. A healer was used to project prana, or life energy, according to the procedure sitting at a distance of 1 m away and healing the participants.[43]
- The Johrei they provided was … directed towards the participant's back of their head and torso. The practitioner held out his/her outstretched hand not closer than 30 cm from the subject, who was facing away from the practitioner with eyes closed [so that] participants had no external cues as to whether the Johrei practitioner was channeling Johrei or just resting.[44]
- Following each radiation treatment, the study coordinator asked subjects in the HT [Healing Touch] and MT [Mock Touch] groups to lie down fully clothed on a massage table… A 3 × 3-foot opaque screen was placed between their head and body, so they could not see who was providing treatment. The HT [and MT] providers stood and walked around the subject's body.[45]

Item 2d. Whether treatment was structured (predetermined) or individualized (customized).

Explanation. Details of treatment should include whether practitioners were required to follow a set protocol, regardless of their perceived needs of the participant, or whether adjustment of the protocol by the practitioners was permitted. Whether treatment is standardised or adjusted to participant's needs will reflect where the research design lies on the efficacy – effectiveness spectrum[46] and will influence generalizability of the results.

- **Examples**
- The standard script (conversation) with participants and families, centering and balancing of the Reiki practitioners, use of intention, hand positions on the patient's body, and duration of the therapy at each position…were standardized and discussed with all of the practitioners prior to starting participant enrollment.[47]
- Treatment was exactly the same for all sessions. A detailed appendix describes the exact hand positions of practitioner and the time spent on each position.[48]
- Practitioners use ongoing evaluations of the energy field to determine where to work… The provider scanned the participant's field from neck to below the toes to discover any aberrations in the energy field.[35]

Item 2e. Treatment sequence, timing of treatment phases and, if relevant, how treatment was varied over multiple sessions.

Explanation. Sufficient details of the treatment procedure should be included to allow for replication of the trial. Such details include the anatomical or chakra-related regions of the participant's body that were treated and their order of treatment. If more than one treatment session was given, any changes to the original protocol that were made in subsequent treatments should be described.

- **Examples**
- The treatment… was performed for 10 min in a non-invasive, non-contact way… 50-60 cm away from the subject's conjunction of the neck and the occipital region, moved then to the neck region, followed by the vertebral column region, left shoulder blade region, and right shoulder blade region, in this order, every 2.5 min[49]
- The therapist used anatomical hand positions, known as connectors, to examine energy flow, discover trigger points (energy impediments), and restore homeostatic energy flow. Examples of these hand positions include placing both hands over the ears or on the soles of the feet of the participant. The hand positions were gentle contact, not manipulative, forceful, or mechanical, and were maintained for a sufficient duration to relieve the trigger point discomfort as discerned by the Polarity Therapist.[50]
- Therapists held both their hands in the classic Spiritist 'passe' position 10–15 cm above the patient's head…then slowly lowered longitudinally from head to legs with a semi-circular movement. Upon reaching the leg region, the "passe" giver joined the hands together, and repeated the same series of movements for 5 min[37]

Item 2f. Number, frequency and duration of treatment sessions.

Explanation. The *planned* number of treatment sessions, their frequency and duration should be clearly documented. In addition, the *actual* number of treatments given should be reported, including any variation among the participants.

- **Examples**
- Reiki was performed… for 45 min once a week for 6 weeks.[48]
- Patients were studied for a 4-week period (1 week of baseline plus 3 weeks of intervention) while receiving daily radiation treatments. Study treatments (modified massage or Polarity Therapy) were given on either Mondays or Tuesdays. Each treatment… lasted approximately 75 min[50]
- The treatment started with a silent signal from a research assistant to the practitioner and was performed for 10 min… once a day for two consecutive days at as close as possible to the same time of day.[49]

BiFi REGs Item 3: Control or Comparator Procedure

Item 3a. Choice and rationale of procedure in context of the research question, with citations that justify the choice.

Explanation. For RCTs assessing possible benefits of biofield therapy, the control or comparator procedure can be sham (mock) biofield therapy, an active treatment (that could be usual care), a wait list or no treatment. Whereas 'control' is commonly used for an intervention not intended to have major benefit, the term 'comparator' is more appropriate for an active intervention, such as physical therapy, which is expected to be therapeutic.[24] Sources that led to the choice of control or comparator, such as literature or expert opinion, should be reported.

Examples.

Note: Since Item 3a calls for inclusion of citations to justify the choice of control or comparator procedure, the inserted term [ref] in the examples below indicates that a source was reported in the original published study.

- Relaxation Response Therapy [the comparator] teaches subjects to evoke the relaxation response [refs], which helps them replace negative thoughts with less frightening and more positive images (cognitive restructuring). A recent meta-analysis examining autogenic training and self-relaxation demonstrated that each technique had positive effects in patients with tension headaches, coronary artery disease, asthma, pain, Raynaud syndrome, anxiety, depression, or sleeplessness [ref].[51]
- A second arm, purported to induce relaxation but without elements of human touch, included meditative music with tempos slower than normal resting heart rates, known to decrease heart rate, blood pressure, and catecholamines [ref].[52]
- Sham EQT [External Qi Therapy] was administered by the same Qi master… to maintain the consistency of the intervention protocols and to minimize practitioner bias… [In previous studies,] EQT improved psychological states compared with those induced in placebo-treated [sham EQT] controls [refs].[53]

Item 3b. Precise description of control or comparator procedure, especially where details differed from the biofield treatment. If control was sham/mock biofield therapy, describe how practitioners were instructed to perform the procedure.

Explanation. A full description of the control or comparator is essential for readers to evaluate the interpretation of the trial outcome. If the control procedure was a form of sham/mock biofield therapy, it should be specified how practitioners were instructed to perform the procedure, with all details reported as for BiFi REGs Item 2. If the comparator was usual care or another active treatment, all the components should be reported in full detail. This will enable comparison of the usual care provided in the trial with the usual care provided to patients in healthcare settings. If the comparator was waitlist, the period of waiting needs to be specified. While precise description of the control or comparator is fairly straightforward in principle, the more complex the components, the more care is required to describe them.[24]

- **Examples**
- She performed the same movements used by the practitioner during the TT process (the duration was the same as the experimental group). However, instead of centering and holding the intent to help the subject, as the practitioner did in the TT intervention, here, she simply began the treatment and counted back from 100 by serial sevens during the whole treatment.[54]
- In the fourth arm, actors sat ~2 feet away from participants and mimicked the "sending" position of distant Reiki. Actors attempted to minimize unconscious healing intentions by occupying their minds with thoughts unrelated to the participant (e.g., doing mental arithmetic, practicing vocabulary from a foreign language, or rehearsing lines from a play).[38]
- The massage therapists used a modified Swedish massage technique applied over the clothing and without the use of lubricant. Strokes used included compression, light moving touch, and static holds. Areas of the body to be massaged were left to the discretion of the patients and could include back, neck, upper and lower limbs, head, hands, and feet.[50]

BiFi REGs Item 4: Other Components of Intervention

Item 4a. Whether communication was allowed between practitioner and participant before, during or after treatment; if allowed, nature of any constraints.

Explanation. Communication between practitioner and participant may be a confounding variable that complicates interpretation of the results. Such communication might affect the participant's response to the treatment if they perceive the practitioner's voice as either calming or agitating. However, some level of communication may be necessary to explain instructions to the participant, or for the participant to inform the practitioner of discomfort. For these reasons, whether communication was allowed between practitioner and participant before, during or after treatment and the nature of constraints, e.g., adherence to a script, should be reported.

- **Examples**
- The qigong and sham healers followed the same structured protocol…which also included not facing or talking to the subject in order to maintain the blind.[55]
- Throughout the intervention procedure, the therapist remained silent and focused on healing the patient.[37]
- Providers used a standardized script that minimized talking with participants [and] used pre-formulated answers to common questions.[38]

Item 4b. Whether a research assistant, family member or anyone other than practitioner and **participant was in the room during a treatment session.**

Explanation. The presence of a family member, caregiver or other visitor during a treatment session can be a confounding variable if their presence or active involvement with the participant, e.g. holding an infant during treatment, was permitted on an optional basis.

- **Examples**
- In the experiment group, the patients were taken to a quiet room and those accompanying them could also join them.[56]
- The [pediatric] participant could be in either a parent or caregiver's lap or on the bed for the Reiki or sham Reiki therapy. A "Do Not Disturb" sign was placed on the door to the exam room for the duration of the therapy, and no one else was allowed in the room during this time.[47]
- Persons who administered TT and sham asked visitors to leave the room.[57]

Item 4c. Whether and how adherence of practitioners to the protocol was assessed.

Explanation. Biofield Therapy practitioners, who are used to the minimal restrictions of their clinical practice, may find it difficult to comply with the necessary constraints of a clinical trial, such as limiting conversation with the trial participants during treatment and/or complying strictly to a research protocol. Thus, it is important to report how adherence of practitioners to the protocol was monitored.

- **Examples**
- Practitioners met on a regular basis to discuss use of specific techniques and ensure intervention delivery consistency.[58]
- Training and monitoring of the TT and sham treatments was done by one of the investigators, using a written protocol to assure integrity of the intervention.[57]
- All patients were asked to guess the healer's identity [External Qigong or Sham] after the first treatment to examine the quality of blinding procedure.[59]

BiFi REGs Item 5: Practitioners

Item 5a. Biofield Therapy practitioners: Number and selection criteria, including training and years of experience or minimum required for inclusion.

Explanation. Eligibility criteria for the biofield therapy practitioners, and demographics of those selected, should be presented, as these may influence generalizability of the trial results. Differences (if any) in the training and experience of the participating practitioners should be highlighted.

- **Examples**
- Registered nurses who had completed a minimum of level 3 certificate training were recruited to provide the HT treatments. Each practitioner was widely known in the local HT community as an excellent healer. Of the 5 providers for this research, 3 had completed level 3 training, and 2 had completed level 4. Each had a minimum of 1 year of an active HT practice. Two had been in practice for 10 to 15 years. To eliminate the effect of individual practitioner traits, each patient received therapy from at least 3 HT practitioners.[35]
- In total, 199 qualified Johrei practitioners (36 men and 163 women, age range 15 - 87 years, average age: 58.0 ± 13.9) volunteered to participate in this study to provide Johrei healing. They had been trained in Johrei's concepts, objectives, principles, methodology, effectiveness, and practical skills in one of the two religious corporations, Izunome and Toho No Hikari, and were certified as qualified general practitioners and registered as members of either of the two corporations. They each had more than two years of experience administrating Johrei.[49]
- Eight Spiritist healers…take turns in pairs carrying out the interventions. All intervention staff must be over 18 years of age and sign an informed consent form. The Spiritist healers have all completed SP [Spiritist Passe] training proposed by the Brazilian Spiritist Federation… and have at least five years' experience in applying SP at affiliated Spiritist centers.[60]

Item 5b. Control or comparator group practitioners: Profession (if different from Biofield Therapy practitioner), number and selection criteria.

Explanation. Appropriate selection of providers to perform the sham or comparator procedure contributes to the successful performance of a RCT. For providers of the sham biofield therapy, their number, profession, level of familiarity with the biofield therapy being assessed, and other selection criteria should be reported. For those who provided a comparator intervention, their number and selection criteria, including training and experience with the procedure, should be stated.

- **Examples**
- Four (4) actors who were matched to the Reiki masters in age group, gender, race, and general appearance provided control interventions. Additional selection criteria for the actors were no experience with or knowledge of energy medicine, no self-reported natural ability as a healer, and low healing touch potential according to the subjective assessments of the Reiki masters after meeting the actors and feeling their hands.[38]
- The licensed physical therapists (3 females) were local and did not include energy work in their repertoire. All had practiced PT for over 10 years, had their own practices, and were experienced in treating complex medical and physical conditions in a range of traditional PT settings.[61]
- The modified massages were given by 1 of 2 licensed massage therapists with extensive experience in providing massage to cancer patients.[50]

Modifications of CONSORT non-intervention items

In addition to the above described 15 Intervention items, two items from the CONSORT guidelines have been briefly extended to reflect specific aspects of biofield therapy trials that should be reported (Table 2, Items 7a and 20).

CONSORT Item 7a. how sample size was determined

***Modification*: If no prior studies existed on which to base a sample size calculation, describe how the number of participants was determined, with a rationale for this choice.**

Explanation. Many RCTs of biofield therapies are designed as pilot or feasibility studies, which is reflected in part by their relatively low sample size.[5,15,58] While conducting pilot studies as a means to inform more robust subsequent trials is generally recommended, there is no consensus on group size for pilot studies. Thus, convenience samples are frequently used in lieu of formal sample size calculations, although alternative statistical methods have been proposed for estimating appropriate group sizes for early phase trials.[62,63].

CONSORT Item 20. Trial limitations, addressing sources of potential bias, imprecision and, if relevant, multiplicity of analyses

***Modification*: Include ways in which the research protocol differed from real-world clinical practice, e.g., practitioner/patient communications; environmental enhancers (treatment room décor, music).**

Explanation. Research results can best be applied to improve clinical practice (the aim of translational research) if the research protocol conforms as much as possible to the practitioner/client encounter during a clinic session. Given that the requirements of clinical research often constrain how therapies are delivered and received, any aspects of the protocol that differ markedly from clinical practice should be reported.

Discussion

A set of guidelines for reporting clinical trials of biofield therapies, BiFi REGs, is presented that focuses mainly on intervention-specific items, thereby enhancing the relevance of CONSORT (the prototype guidance document) for these particular practices. Other integrative healthcare practices, such as Acupuncture,[24] Herbal Therapies,[22] Homeopathy[23] and Yoga,[25] have already amended CONSORT items to better reflect their specific applications. Additional reporting guidance documents that authors of clinical trials of biofield therapies are likely to

find useful include TIDieR, the Template for Intervention Description and Replication,[29] and the group of guidelines focused on the type of trial design, including equivalence, non-inferiority and pragmatic trials, all of which can be accessed via the EQUATOR website.[26]

Reasons for encouraging transparent and thorough reporting of clinical trials include facilitating peer review, expediting systematic review preparation, informing clinical decision-making and facilitating attempts at trial replication.[24,64] Trial replication is of additional interest in light of current concerns about reproducibility of research results in general[65,66] and studies of biofield therapies in particular.[67,68].

When reporting biofield therapy trials a major challenge is to describe how the clinical research protocol may have differed from, and potentially compromised, aspects of real-world clinical practice. If this issue is not adequately addressed, a reader, reviewer, and/or clinician may make incorrect assumptions about the applicability and value of the trial's results. An example of potential differences between research and practice is the amount of practitioner/participant communication allowed in clinical trials. The free verbal interaction during clinical practice is often curtailed in research settings for the sake of minimizing protocol variability. BiFi REGs addresses this example directly in Item 4a (Table 1) and as part of a broader addendum to CONSORT Item 20 (Table 2) related to Trial Limitations.

Future directions

A category of items that may contribute to a future revision of BiFi REGs can be considered as *known-unknowns*[g], defined as a set of experimental variables likely to influence the results of biofield therapy trials but which, as yet, have not been adequately described or measured. One example involves the selection criteria for biofield therapy practitioners. While their training and experience can affect the trial outcome, it seems of additional importance to establish a pre-screening procedure to assess how well practitioners perform the intervention under conditions of the trial, e.g., how strong is their 'intention[69]; how well do they generate a 'healing presence'.[70,71] 'Calibration' of practitioner ability can involve the use of surrogate markers. Studies have assessed the ability of biofield therapists to affect bacterial growth,[72] alter biophoton release,[73,74] modulate the output of random event generators[75] and affect a wide variety of endpoints in cultured cells.[76]

A second such *known-unknown* is the extent to which the ambient condition of the research space (the 'energy in the room') may influence clinical results. Biofield therapy treatments are postulated to include 'field effects' that may accumulate and persist beyond the designated treatment time.[75] Such speculations are based in part on statistically significant changes detected in the output of random event generators present in the research space during a treatment.[8,75,77] In practical terms, this could mean that the effectiveness of a sham biofield therapy procedure may be influenced by the lingering influence of a biofield therapy treatment previously performed in the same space.

A final consideration for future directions is that the present guidelines for reporting RCTs of biofield therapies limit their focus to clinical trials with human subjects/participants. BiFi REGs should be expanded to include trials assessing effects of biofield therapies on animals, plants, cell cultures and cell-free systems.[8,16,76].

Conclusions

Our rationale for developing BiFi REGs was to improve the accuracy and transparency in reporting biofield therapy trials. This aim can be achieved by addressing the intervention details outlined in Table 1 within the full menu of other CONSORT items listed in Table 2. Inclusion of a CONSORT diagram,[18] which presents the flow of participants from enrollment through each phase of the trial, is also strongly recommended.

As with initial formulations of similar reporting guidelines, BiFi REGs is a work-in-progress that is likely to be updated. Accordingly, we invite researchers, peer reviewers and all other users of this document to submit feedback and suggest improvements by visiting the BiFi REGs comments page on the Consciousness and Healing Initiative website (www.chi.is/biofieldreporting).

Our hope is that BiFi REGs, and the clinical trial reporting it supports, will help to strengthen the evidence base for biofield therapies as well as increase their usage as stand-alone practices and as complementary therapies within mainstream healthcare.

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Declaration of Competing Interest

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[g] This term was popularized in 2002 by then U.S. Secretary of Defense, Donald Rumsfeld, in a quite different context.

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