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REVIEW ARTICLE

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A rapid evidence assessment of recent therapeutic touch research

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Abstract

Aim: To synthesize the most recent evidence investigating the effectiveness and safety of therapeutic touch as a complementary therapy in clinical health applications.

Design: A rapid evidence assessment (REA) approach was used to review recent TT research adopting PRISMA 2009 guidelines.

Methods: CINAHL, PubMed, MEDLINE, Cochrane databases, Web of Science, PsychINFO and Google Scholar were screened between January 2009–March 2020 for studies exploring TT therapies as an intervention. The main outcome measures were for pain, anxiety, sleep, nausea and functional improvement.

Results: Twenty-one studies covering a range of clinical issues were identified, including 15 randomized-controlled trials, four quasi-experimental studies, one chart review study and one mixed methods study including 1,302 patients. Eighteen of the studies reported positive outcomes. Only four exhibited a low risk of bias. All others had serious methodological flaws, bias issues, were statistically underpowered and scored as low-quality studies. No high-quality evidence was found for any of the benefits claimed.

KEYWORDS

alternative medicine, complementary therapies, energy-healing, human-biofield, pseudoscience, therapeutic touch

What does this paper contribute to the wider global clinical community?

- Therapeutic touch is widely promoted by nurses internationally, and this paper appraises the quality of the latest research claimed to support the practice.
- Nurses may hold incongruent beliefs regarding the evidence for therapeutic touch, such as knowledge and values regarding scientific versus faith-based practices.
- Nursing research in this field appears pluralistic in nature, supporting underlying beliefs of therapeutic touch as a faith-based approach, while undertaking clinical trials and experiments to confirm efficacy.

1 | INTRODUCTION

Therapeutic touch (TT) was invented by nursing professor Dolores Krieger and clairvoyant Dora Kunz in 1972 as a contemporary interpretation of spiritualism using the theoretical manipulation of a hypothetical human bio-energy field as a complimentary healing method (Krieger, 1979). Since then, it has been widely adopted by nurses, the subject of over 60 research studies, and is often alleged to have a scientific basis. It remains actively taught in many North American Colleges and in contemporary nursing literature and nurse education. A diagnosis of "Imbalanced Energy Field" is also included in the current North American Nursing Diagnosis (NANDA) manual (NANDA International, 2018). Despite numerous studies conducted over the last 45 years to determine the efficacy of TT as an adjunctive therapy, an abundance of poor quality research and replicated work has meant TT has remained an alternative health practice rather than becoming a mainstream therapeutic intervention. Therefore, a rapid evidence assessment (REA) of the pertinent literature published within the last decade was completed in order to evaluate the most current evidence of its value.

This review aims to synthesize the most recent evidence investigating the effectiveness and safety of TT as a complementary therapy in clinical health applications. We sought to answer the following question using the REA method for studies published since 2009: "how well does TT work as an adjunct intervention in the management of clinical conditions?". The following related questions were also considered:

- What is the overall evidence of TT value in the treatment of clinical health issues?
- What is the evidence of a substantive theoretical basis for TT to justify it as a therapeutic intervention?
- What type of TT application (if any) demonstrates the best efficacy?
- What are the adverse effects of TT?

2 | BACKGROUND

The foundational assumption of TT is the existence of a massless human bio-energy field that "extends beyond the discernible mass which we perceive as man…" (Rogers, 1970). The theory of the human biofield energy used in TT is also closely related to the theory of vitalism, the belief that living organisms are fundamentally different from non-living entities and contain some non-physical element or are governed by different principles than are inanimate things. Such theories of metaphysical life forces are prevalent in many cultures (Chinese, Greek, Persian and Indian) and also frequently observed in contemporary pop-culture; the "force" in the Star Wars film series, being a notable example. TT represents another iteration of these ideas, espousing that within each living being's biofield energy there may be balance which produces good health, or there may be an imbalance which may result in illness (Kunz & Peper, 1985; Campbell, 1980; Dossey, 2018). Described as energy healing, TT aims to harmonize, replenish and improve the flow of a human biofield energy by removing blockages of the person's "biofield" but involves no physical contact (Mueller et al., 2019). The practitioner claims to be able to detect and manipulate a client's biofield energy and bring that into better balance, using their hands to stimulate the body's natural ability to heal itself (O'Mathúna et al., 2016).

Human biofield energy therapies remain controversial as these practices are in direct conflict with contemporary physics and biomedical science. In TT, the proposed energy is spiritual in nature and said to exist outside of contemporary physics, chemistry and biology, but has yet to be proven to exist (Stenger, 1995, 1999). Another criticism of the theory is that unlike established biophysiological processes, no underlying anatomical structures or physiology associated with the proposed human biofield energy has been identified.

Research into the nature of TT has developed, with around 30 studies published by 2000 and another 15 studies over the next decade. Within this, there are few basic scientific studies to validate the theory although some pre-clinical work attempting to validate the theory has been undertaken. The most well-known was conducted by Emily Rosa in 1997 to test whether TT practitioners could detect human biofield energy as they claimed. This basic blinded study showed that practitioners could not do so better than chance (Rosa, 1998). Other researchers have attempted to demonstrate that TT had biological effects in vitro (Gronowicz et al., 2015, 2016; Olson et al., 1997; Radin et al., 2015). However, as highly speculative pilot works these studies presented significant design flaws including: unfalsifiable hypotheses, failure to adequately address causality and confounding factors, were statistically underpowered and have been unreplicated.

The majority of research in the field has focused on small-scale clinical studies by TT practitioners and published in alternative health journals. Several reviews of TT research have also been published over the years (Bagci & Yucel, 2020; Chhugani, 2014; Kumarappah & Senderovich, 2016; Monroe, 2009; O'Mathúna, 2000; Senderovich et al., 2016). One problem here is that meta- and systematic analysis is not possible due to the unique nature of trials, and diverse populations where TT has been applied. Interestingly, there is also a clear division in findings between work published in alternative health journals and that published outside of them. Those published in alternative media have been overwhelmingly positive, while those outside critical.

Three independent clinical reviews of TT have been conducted by Cochrane Library researchers and all identified problems with the quality of TT research available. Two which initially indicated some positive findings were later withdrawn due to concerns over the validity of the included studies (Ernst, 2003; O'Mathúna et al., 2016; So et al., 2013). In a review of literature used in TT research in 2000, O'Mathúna noted that "Literature reviews about therapeutic touch often cited only research with favourable findings. When citing

TABLE 1 Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Quantitative, qualitative or mixed methods research studies exploring the use of TT and its benefits for patients in a hospital or community setting • Published in the English language • Published between 2009–2020 (inclusive) • Published in peer-reviewed, academic journals • Available in electronic format	• Narratives and opinion pieces • Theses and dissertations • Articles in grey literature and suspected predatory journals (e.g. journals that that do not support independent peer-review and/or not indexed in a bibliographic health databases) • Grey literature (unpublished research)

studies with contradictory findings, only the favourable findings were usually mentioned. In many reviews, research cited as indicating the efficacy of therapeutic touch indicated it was ineffective. Every review examined had at least one significant mistake concerning how research studies were represented" (O'Mathúna, 2000). In another example, a recent positive review published in an unindexed Greek web journal (Bagci & Yucel, 2020) included a paper from a suspected predatory publication (Beall, 2011; Clarivate, 2019) and omitted two readily available TT research papers with negative results (Madrid et al., 2010; Smith & Broida, 2007).

This reflects the highly problematic nature of TT research to date, which has been diverse and of variable quality. By 2010, a lack of any high-quality evidence of efficacy for the therapy remained, compounded by the fact no scientific evidence supporting the existence of the proposed energy involved had been demonstrated (Robinson et al., 2007).

3 | THE STUDY

3.1 | Design

The REA is an abbreviated form of systematic review useful to determine whether an intervention is feasible, if it is appropriate (ethically or culturally) and can provide a quick summary of potential efficacy, and what is already known about an intervention. REAs use rigorous systematic review methods to search and appraise the literature, but the comprehensiveness of the search and other review stages is more limited (Hemingway & Brereton, 2009). In terms of an evidence hierarchy, an REA falls below a full systematic review in terms of confidence in the findings, but above a scoping review or health technology assessment (Thomas et al., 2013). It has the advantage that it can be undertaken rapidly across a broader range of contexts than a systematic review or meta-analysis or where data are limited. This is useful in this situation, as limited TT research has been applied across a broad range of clinical populations. The UK Civil Service Government Social Research Service (GSRS) established the REA methodology that was adopted in this study (Bevan et al., 2009). Although an REA is not a full systematic review, the PRISMA 2009 checklist for systematic reviews from the Enhancing the Quality and Transparency of Health Research guidelines was used in the preparation of this work (Moher et al., 2009).

3.2 | Method

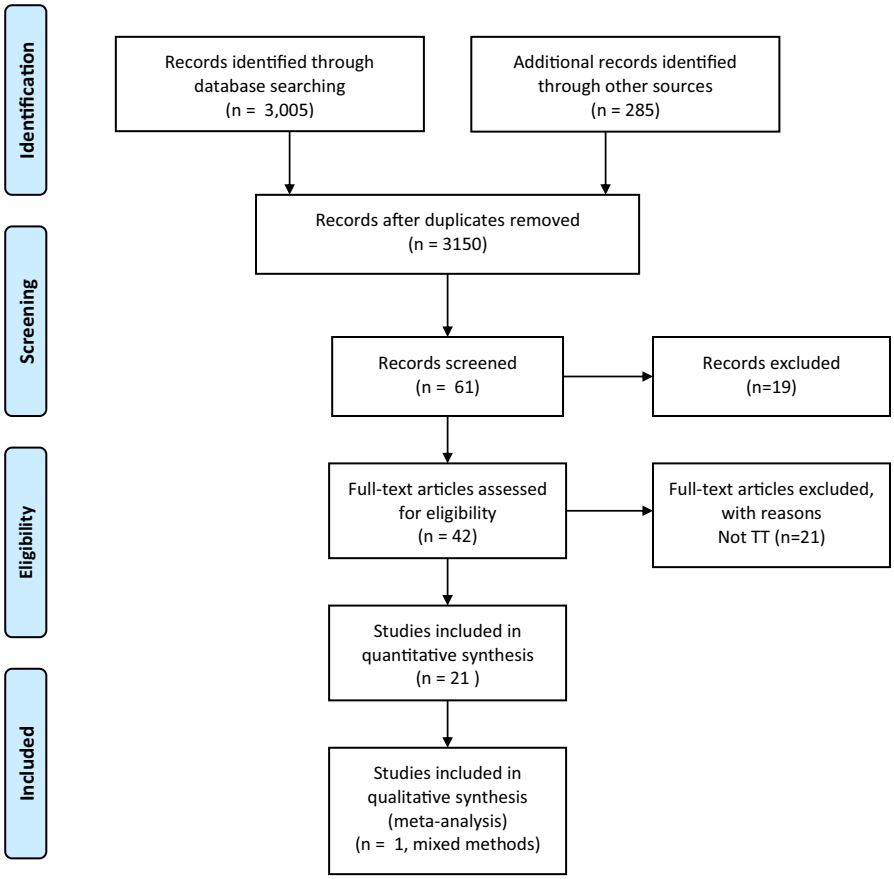
An initial search attempted to identify all relevant clinical studies available in the English language. Bibliographic sources from CINAHL, PubMed, MEDLINE, Cochrane Library databases, Web of Science, PsychINFO and Google Scholar were screened between January 2009–March 2020 for studies exploring TT therapies as an intervention in any clinical condition. The use of the previous decade was selected as a practical REA limitation to cover recent work published after the most recent independent reviews of TT in general use (Ernst, 2003; O'Mathúna, 2000; Robinson et al., 2007). While Google Scholar might yield grey or unreliable literature, it was included in order to allow the literature search to be as comprehensive as possible. Search strings included the following: "Therapeutic Touch", "energy healing," "bio-energy healing/therapy" and "biofield," "bio-field," "bio-energy-field," and "healing/therapy." The initial review of the literature was conducted through both online searches and the manual review of bibliographies within published papers. The REA inclusion and exclusion criteria used are summarized in Table 1.

Once studies had been identified through, they were screened against the inclusion/exclusion criteria. This involved two people who reviewed abstracts independently for decisions on final inclusion. The initial search strategy retrieved 3,290 records. After duplicate and irrelevant articles were removed (mainly secondary sources, narrative pieces or conjecture, not research), a total of 61 titles remained. On further examination of the abstracts, 19 of those records were further excluded as they failed to meet the exclusion criteria. On further investigation of the 42 remaining articles, 21 were also omitted as on detailed examination, did not represent TT therapies (e.g. studies that used massage or Reiki). The study selection and screening process are illustrated in Figure 1.

3.2.1 | Data extraction and assessment of studies

Summary data from all of the selected studies were added into a bibliographic database (Mendeley, Elsevier) and a spreadsheet using a data extraction matrix created from the original research questions, and review tools were based upon the Evidence for Policy and Practice Information Centre's (EPPI) review guidelines for extracting data (The Evidence for Policy & Practice Information and Co-ordinating Centre, 2012). A final determination of the appraisal tools to be used was made after an initial exploration of the results from the data

FIGURE 1 Study selection process



extraction had been undertaken, and after the number and nature of the published work to be included was established. In accordance with the GSRS REA method, the assessment tools used for appraising the quality of research of the studies consisted of the following:

1. The GRSS Weight of Evidence appraisal tool (Gough, 2007), Overall quality was scored as follows: 3 = low, 4–6 = medium and 7–9 = high,
2. The Maryland Scale of methodological quality (Sherman et al., 1998)
   Overall quality was scored as follows: 1 = low, 2–3 = medium and 4–5 = high,
3. The Critical Appraisal Skills Program (CASP) qualitative research appraisal tool (Public Health Resource Unit England, 2006),

Overall quality was scored as follows: low = 1–3, medium = 4–7 and high = 8–10.

3.2.2 | Risk of bias assessment

Risk of bias was also assessed for all included studies using the Cochrane Review Group Risk of Bias (ROB) tool. This instrument is a domain-based tool, which helps the assessor to look for specific bias attributes: selection bias, performance bias, detection bias, attrition bias, reporting bias and other. Although this is not a score-based tool, one point was added for each element of bias identified within the study.

3.3 | Analysis

Each of the included studies was each assessed and scored independently by two researcher team members, while a third team member moderated the results. As per the REA methodology, studies were grouped into three categories (high, medium or low quality of evidence) based upon the overall weight of evidence (GSRS) and Maryland Scale scores. Likewise, risk of bias was assessed and categorized as low, medium or high for risk depending on the number of bias issues identified in the five domains.

4 | RESULTS

The clinical conditions where TT was used were highly varied, and the studies and their weight of evidence scores are summarized in Table 2.

4.1 | Types of studies

All but one of the papers identified by the search reported projects using quantitative research methods, and comprised of 15

TABLE 2 Therapeutic touch studies—January 2009–June 2020

Author/Year	Type	Context	Treatment	Ages	Sample	Reported findings	GSRS (3–9)	MSSM (1–5)	CASP (1–10)	ROB (0–7)
Quantitative										
McCormack (2009)	RCT (3 groups)	Pain in postoperative elderly patients	10 min of single session	28–96	90	Positive—decreased pain intensity scores	3	3	N/A	4
Rosales et al. (2009)	RCT (2 groups)	Postnatal complications, and length of hospital stay in preterm infants	Single 20-min of session	<1 month	78	Positive—Decreased length of hospital stay and the presence of complications	3	2	N/A	5
Aghabati et al. (2010)	RCT (3 groups)	Pain and fatigue in cancer patients	30 min × 5 days	15–65	90	Positive—decreased pain and fatigue	3	3	N/A	4
Coakley and Duffy (2010)	Between-subjects experiment (2 groups)	Pain in postoperative surgical patients	20 min of single session	Unclear	21	Positive—decreased pain and cortisol levels	3	3	N/A	3
Madrid et al. (2010)	RCT (2 groups)	Vital signs in patients undergoing cerebral angiography	5–20 min of single session	18–80	40	No difference	5	3	N/A	3
Marta et al. (2010)	Pre/post-test experiment	Pain, depression and sleep in older people with chronic illness	25 min × 8 days	60+	30	Positive—decreased depression and pain, improvement in sleep	3	1	N/A	5
Zare et al. (2010)	RCT (2 groups)	Anxiety in patients undergoing CABG	Single 20 min of session	Adults	44	Positive—Decreased anxiety	3	3	N/A	5
Zolfaghari et al. (2012)	RCT (3 groups)	Anxiety, vital signs and cardiac dysrhythmias during cardiac catheterization	10–15 min, single session	35–65	69	Positive—decreased anxiety, improved stability of cardiovascular vital signs, decreased arrhythmias	4	3	N/A	4
Johnston et al. (2013)	RCT (2 groups)	Pain in preterm infants	5 min of single sessions	Prem. infants	55	No difference	5	3	N/A	2
Ramada et al. (2013)	Pre/post-test experiment	Vital signs and pain in infants undergoing a painful procedure.	Single 20-min session	<1 month	40	Positive—Increased relaxation improved vital signs and basal metabolic rate.	3	2	N/A	5
Younus et al. (2014)	Between-subjects cohort study(2 groups)	Radiation dermatitis	15 × 15–20 min sessions over 5 weeks	18–80	49	No difference	5	3	N/A	3
Vanaki et al. (2015)	RCT (3 groups)	Nausea in chemotherapy patients with breast cancer	Single 15–20-min of session	18–65	108	Positive—decreased nausea	3	3	NA	5
Senderovich et al. (2016)	Retrospective chart review (2 groups)	Geriatric Care (anxiety, pain, function)	Varied	Mean 79	237	Positive—improved well-being	3	1	N/A	6
Tab atabaee et al. (2016)	RCT (3 groups)	Pain in cancer patients	7 × 20 min sessions over 4-weeks	20–65	90	Positive—decreased pain	3	3	N/A	4

(Continues)

TABLE 2 (Continued)

Author/Year	Type	Context	Treatment	Ages	Sample	Reported findings	GSRS (3–9)	MSSM (1–5)	CASP (1–10)	ROB (0–7)
Zaeimi et al. (2016)	RCT (2 groups)	Ventilated patients' cardiovascular vital signs	4 × 20 min × 4 days	15–60	60	Positive—improved stability of cardiovascular vital signs	3	3	N/A	4
Mueller et al. (2019)	Pilot RCT (2 groups)	Back pain in neurological patients	30 min × 4 days	Mean 60	29	Positive—decreased back pain	3	3	N/A	4
Olivares et al. (2019)	Pilot RCT (2 groups)	Rehabilitation in Parkinson's Disease	Unspecified × 1 day	Mean 67	14	Positive—multidisciplinary programme (OT + TT) improved rehabilitation	3	3	N/A	5
Yucel et al. (2020)	RCT (3 groups)	Comfort and anxiety in older people	10 min × 3 days	65–89	30	Positive—decreased anxiety and increased comfort.	3	3	N/A	4
Bagcı and Yucel (2020)	RCT (3 groups)	Sleep quality in older people	10 min × 3 evenings	65+	25	Positive—improved sleep quality	3	3	N/A	4
Alp and Yucel (2020)	RCT (2 groups)	Comfort and anxiety in older people	20 min × 4 days	65+	60	Positive—increased comfort and decreased anxiety	4	3	N/A	4
Mixed methods										
Busch et al. (2012)	RCT (2 groups + interviews	Pain and anxiety in burn patients and nurse interviews	5–15 min TT × 10 days	9–17	43	No difference	5	3	7	2

randomized-controlled trials (RCTs), four quasi-experimental studies (non-randomized) and one chart review study. Only three identified as being registered trials [with an Iranian clinical trial registration body (Matourypour et al., 2016; Tabatabaee et al., 2016; Zaeimi et al., 2016)]. One mixed methods study was also found, comprised of an RCT and nurse interviews. Studies reported changes in pain, anxiety or comfort self-assessment scores, self-reported nausea scores, clinician assessed pain scores for infants, (Desai, 2018) and vital signs, functional or perceptual changes as outcomes.

4.2 | Types of participants

As there were relatively few studies of similar populations and conditions, the studies were selected to include any use of TT as an adjunctive intervention for any condition where it was being used in clinical practice for both paediatric and adult populations.

4.3 | Types of intervention

The types of interventions employed all involved some version of TT as described in Table 2 with no physical contact. These varied in the stages described and length of application (from 10–30 min). Often the intervention was only vaguely described, and some were combined with other interventions, such as music or occupational therapy.

4.4 | Types of control

Studies that included control subjects used control group in which patients received standard care with no TT. Those that used more than two comparative groups also used sham TT in a third group, described as the practitioners holding their hands further than 6" from the patient, and avoided thinking positive intentional thoughts during the therapy.

4.5 | Outcome measures

Studies used a wide variety of well-validated assessment tools and simple vital signs measurement depending on the population of interest. For adults with pain, most researchers used the visual analogue scale (VAS) and the visual analogue thermometer (VAT) and one study the self-reported Numeric Pain Rating Scale (NPRS) for chronic pain. For infant pain assessment, tools included the Premature Infant Pain Profile (PIPP), and the Neonatal Infant Pain Score (NIPS). Other than pain assessment, the studies exploring anxiety used the Spielberger State-Trait Anxiety Inventory (SSTAI) and for comfort used the General Comfort Questionnaire (GCQ). For assessment of radiation dermatitis, the researchers used the National Cancer Institute Common Toxicity Criteria for Adverse Events (NCIC CTC AE V.3.0) and Breast Cosmetic Rating System (BRS). Other functional assessment tools used included the following: the Standardized Mini Mental State Examination (SMMTE), the Profile of Mood States (POM), the German Quebec Back Pain Disability Scale (QBPDS), the Frontal Assessment battery (FAB), the Unified Parkinson's Disease Rating Scale (UPDRS), the Beck Depression Inventory (BDI), the Parkinson's Disease Quality of Life scale (PDQ39), the Apathy Evaluation Scale (AES), the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C-30), the Pittsburgh Sleep Quality Index (PQSI) and the Palliative Performance Scale (PPSv2).

4.6 | Quality of evidence

The overall quality of evidence was low with over 70% of studies scoring the minimal score possible of three on the GSRS weight of evidence scale. The highest GSRS weight of evidence scores (with a maximum score of 5 out of 9) was found in three RCTs and one cohort study (Busch et al., 2012; Johnston et al., 2013; Madrid et al., 2010; Younus et al., 2014). The studies' results on the MSSM scores also indicated weaker approaches to overall research design. The majority of the studies fell within the 1–3 range out of 5 (see Table 2 for the summary). Of the RCT studies (including the mixed methods study), only two included samples of more than 100 participants and four of them included sample sizes of 30 or less. Although eleven of the RCTs had sample sizes of over 50 participants, these were split by multiple intervention groups with an average group size being 24 people (mode of 30).

The four quasi-experimental studies also mainly demonstrated low-quality evidence with small cohorts of subjects (21–49 participants). The average group size in these studies was 26 participants. However, the breast cancer radiation dermatitis cohort research scored the highest GSRS score of five in this study (Younus et al., 2014). The largest sample reported was in a single retrospective chart review study which examined 237 participants' charts for two comparative groups (TT and no TT) although this study also achieved low quality of evidence scores (Senderovich et al., 2016).

4.7 | Risk of bias

As might be expected where the subject selection opportunity was limited, blinding impossible, comparative group sizes small and the potential for performance bias, the overall risk of bias was high in most of the studies examined. This aspect was particularly problematic in the work. Only four studies exhibited a low risk of bias (with less than three elements present).

5 | DISCUSSION

Work exploring the use TT was reported as positive in 17 of the 21 studies, suggesting TT works effectively in virtually every condition.

This would be a tremendous outcome in terms of health science for any intervention and would also extremely unusual. However, serious methodological and quality issues were evident throughout all of the work examined, making the validity of these outcomes highly doubtful, and without independent substantiation another indication that the reported results should be considered with reserve.

All work started with a confirmatory premise that biofield energies exist and TT was effective. However, they did not conform to typical levels of rigour found with scientific explorations on novel pharmaceutical or practical clinical interventions. Major issues included the level of bias and poor overall methodological quality reflected in study design, implementation and reporting issues. The studies here overwhelmingly presented positive-biased literature reviews and designs that favoured positive outcomes rather than a fair-test (Kimmelman et al., 2014). Most also failed to acknowledge limitations adequately and overstated positive conclusions with insufficient evidence.

It was notable that those studies that scored higher in terms of overall quality and lower in risk of bias were less conclusive than those claiming positive results. For example, three of the studies scoring a 5 in the GSRS (indicating a medium weight of evidence) demonstrated no effect of TT (Busch et al., 2012; Johnston et al., 2013; Madrid et al., 2010; Younus et al., 2014). In the few studies that explored similar populations (pain in preterm infants) in the same year, the higher quality study found no difference using TT (Johnston et al., 2013), while the lower quality study reported positive results (Ramada et al., 2013).

5.1 | Randomized-controlled trials

The majority of RCTs claimed positive results for TT. However, group allocation was generally poorly described, the interventions inadequately described or combined with others, and dissimilar intervention group sizes were encountered. The use of faith-based metaphysical interventions in clinical trials also presents particular problems in terms of scientific epistemology, in that creating a falsifiable hypothesis to test is practically impossible. Similar to faith-healing studies, researchers are employing a theoretical metaphysical intervention that is based on trust in the metaphysical abilities of the practitioner (Hodge, 2007). This introduces considerable scope for experimental error, as in doing so, logically one also has to accept the potential for metaphysical confounding factors.

As the energies involved and their manipulation in TT are unmeasurable, it is impossible to confirm or standardize a treatment, as would be the case in a typical RCT using a drug or physical intervention (Hodge, 2007). An argument used by many supporters of TT is that it is a supernatural intervention that only works when the patient believes in it (Ireland, 1998), in which case the value of undertaking any clinical trial into TT becomes questionable.

Another particular problem in the experimental design of RCT studies that use extra therapeutics compared to standard treatment is that the participants in the additional therapeutic group always tend to do better than those without the intervention (Jain et al., 2015), additionally, for those that used sham TT. Differentiating between sham TT and actual TT has to be accepted on trust that there is actually some meaningful differentiation between therapeutic activities. This makes the use of sham TT in the studies highly problematic, even if performed by an unqualified TT practitioner as it is an unverified differential practice. It was often performed by the same practitioner claiming to use slightly increased physical distance and not thinking positive intentional thoughts. However, there is no verified distance of any claimed effect. The use of TT in combination with other therapeutic interventions (such as massage or music) in an RCT also demonstrates another known problem with experimental design, in that in such cases, isolating the effects of the TT intervention becomes practically impossible (Clark & Mulligan, 2011). Finally, as described below, allocation bias and a lack of meaningful comparative groups in the RCTs also represented a serious problem.

5.2 | Quasi-experimental studies

The quasi-experimental studies all suffered from the same issue of purposeful and non-randomized samples giving rise to a significant risk of bias. Of the two pre/post-test experiments, both were small Brazilian studies. One that examined pain in infants in an intensive care unit (Ramada et al., 2013), and the other TT in chronic pain patients (Marta et al., 2010). Both claimed positive results, and yet provided weak theoretical justification for their hypotheses, used diverse sets of patients and had small sample sizes (less than 40). Neither used control groups, so the identified benefits are speculative at best.

The two between-subjects experiments had similar issues, although did use comparison control groups. One was a US study that examined the impact of TT on cortisol and natural killer cell levels in adults (Coakley & Duffy, 2010) as stress/inflammatory markers, and conflated psychoneuroimmunology theory with the theory of human biofield energy as the justification for the work. It also included only 21 participants in two unbalanced groups (12 in the TT and nine in the control group). The other was a cohort study exploring radiation dermatitis in breast cancer patients (Younus et al., 2014), and while it employed a somewhat more rigorous methodology, it had two unbalanced groups with 17 in the TT cohort versus 32 in the control. With large sample sizes and random allocation some disparity is less significant and can be adjusted for, but with small samples and purposeful sampling, as here, this can distort results significantly, making them unreliable (Faber & Fonseca, 2014).

5.3 | Retrospective chart review study

The single retrospective TT study was a chart review of older adults in a palliative care (Senderovich et al., 2016). Although this study had the largest sample out of all those examined, it also demonstrated

significant methodological issues and scored the lowest in research quality score and the highest risk of bias. Chiefly, all those who participated in the TT experience self-selected to do so, and outcome measures were based on vaguely described improvements (e.g. relaxation, sleep, gratitude) observed by the actual TT practitioner. Demographic and clinical characteristics between those who did and did not participate in the TT programme and outlines some self-reported efficacy by participating patients and was published in an alternative health interest journal. As a retrospective study, there was no attempt at blinding, and significant selection, allocation, and outcome data/reporting bias, and work that resembled more of a narrative review than an analysis of outcomes between two groups.

5.4 | Mixed methods study

A single mixed methods study was also identified in the REA (Busch et al., 2012). This was one of the higher quality studies and examined the effectiveness of TT when used as an adjunctive therapy for burn patients by measuring anxiety levels, the use of pain medications and cortisol levels (similar to the Coakley et al. study). It involved a two-group RCT that was followed up with interviews with nurses who delivered TT (administered for 10 days, 5–15 min per session). The control group received nursing presence only which appeared to simply involve the presence of a nurse. Fourteen different nurses provided the intervention after they had completed a 3-month TT training course and all had at least 2 years of TT practice experience. As with most work described here, the theoretical justification was weak, but the researchers found no significant differences between TT or nursing presence. The qualitative interviews focused upon the experience of participation in the study. It was reported that none of the interviewed nurses expressed doubts towards TT as a possibly effective intervention, but in practice implementing, it was difficult.

5.5 | Risk of bias

Risk of bias was a significant problem in all of the work examined. Selection bias was highly prevalent. One study was reported as an RCT, but patient allocation was not described and the participants represented a very heterogenous group with widely differing surgical experiences (McCormack, 2009). Convenience sampling was widely used and often allocation appeared by judgement of the clinician, by preference of the participant, or based on the results of tests. Overall, those agreeing to participate in the studies were either self-selecting or accepting of the faith-based intervention as a validated therapeutic approach in advance. It was evident that non-believers were more likely to opt-out (which was acknowledged in some studies) and so the samples were not necessarily representative of the general public. In many cases, group allocation was performed by the researcher who was also the provider of the TT intervention, and in others, details of sample allocation were not adequately discussed. In several, a significant proportion of the participants were illiterate, and it was unclear how informed consent was obtained (Alp & Yucel, 2020; Marta et al., 2010; Vanaki et al., 2015; Yucel et al., 2020). A-priori power calculation used to justify the sample size was often based on an overestimated effect size. Additionally, studies reporting favourable statistical analyses were often based upon inappropriate techniques using inflated effect sizes for power calculations, or parametric statistics where data did not follow a normal distribution.

Performance bias was another significant factor, with all of the studies exhibiting issues with respect to this. The nature of the intervention used varied in the studies, where both researchers and participants had to trust a specific metaphysical intervention was being applied that could not be seen or measured. There was also a lack of standardization of the interventions given across studies (even within individual studies). Exposure also varied from a single session of 10 min, to 15 sessions of 20 min given over 5 weeks. In one of the better reported RCTs, the intervention was a single 15-min application of TT, and the three experimental subgroups were very small (Zolfaghari et al., 2012).

Recruitment of the therapists was also poorly described and treatment groups predominantly received more attention from the researchers than the control group. For example, many studies used TT as an additional therapy; one study used three groups where one received added TT, one received an extra audio stimulus, and the other nothing (McCormack, 2009). In several other studies, TT was accompanied by additional interventions (Bagcı & Yucel, 2020; Olivares et al., 2019; Ramada et al., 2013; Rosales et al., 2009; Tabatabaee et al., 2016). Additionally, blinding was not possible in the RCT and experimental studies that involved control groups with no TT intervention.

Detection bias was an issue in a number of studies. Although most used well-standardized assessment tools, most studies made no attempt to report how outcome assessors were blinded from knowledge of which intervention a participant received. In addition, in several studies the researchers or practitioners collected the data (Alp & Yucel, 2020; Bagci & Yucel, 2020; Marta et al., 2010; Rosales et al., 2009; Senderovich et al., 2016). Likewise, attrition bias was also evident, as it was not described or accounted for in the majority of studies, and some were unclear on when, why or how participants had withdrawn. Only two studies noted issues of participant drop-out (Busch et al., 2012; Mueller et al., 2019). This has also previously reported as an issue with TT research in the literature (Jain et al., 2015; Monroe, 2009).

It was also apparent that in a number of the studies researchers had introduced or omitted selective outcome measures in the research or in the publication process, indicating the prevalence of selective reporting bias. This was most notable in the initial literature reviews which almost universally presented TT as an existing proven intervention that was being tested in a new context, rather than an unvalidated or controversial technique. All failed to cite prior studies reporting negative outcomes. In many studies, attrition data were not provided apart from numbers. Descriptive statistics indicating the data distribution were not provided in over 90% of the studies. Typically, simple *t* tests or *F* test comparisons were used, when the

assumptions required to validate the use of these tests were not met (Aghabati et al., 2010; Alp & Yucel, 2020; Coakley & Duffy, 2010; Madrid et al., 2010; McCormack, 2009; Mueller et al., 2019; Yucel et al., 2020; Zaeimi et al., 2016; Zare et al., 2010).

One study initially appeared to be a replication of earlier work, as it was published a year later under a different title, and name of the clinical site, with differing statistical analysis (Matourypour et al., 2016; Vanaki et al., 2015). However, this turned out to be the same study published twice in two different journals.

A number of other forms of bias were also encountered during the review, such as positively selected comparators, confounder bias (ignoring potential confounders) and collider bias (ignoring effects of belief in biofields and of TT upon outcome). Publication bias was also noted, with the majority of studies published in publications that actively supported alternative and complementary therapies, or the institutions involved, and undisclosed conflicts of interest were observed with many primary investigators being active TT practitioners.

5.6 | Applicability of evidence

The majority of studies examined were undertaken in countries with large religious majorities and more recently here has been a surge in TT research activity in the Middle East, where one research group published its papers in a religious journal (Alp & Yucel, 2020; Bagcı & Yucel, 2020; Yucel et al., 2020). This would support the notion that overall TT remains a belief-based intervention, much like prayer, and currently, there is little to differentiate TT from other forms of faith-healing.

In terms of personal autonomy, it is important that patients are able to select whatever therapies they wish as complimentary therapies, as long as they are safe and do not interfere with other therapies. TT is certainly safe, but there are other concerns that should be considered for practice. Currently, practitioners charge around $120/hr for their services. This does introduce a financial burden on those purchasing the services, and as an alternative healthcare activity, this is usually borne by the patient. Nevertheless, this does represent an additional care cost with dubious clinical benefits. Additionally, other forms of relaxation and anxiety-reducing therapies can be practiced at no cost. There is also a concern that patients utilizing TT may have been given unrealistic expectations of efficacy. Although TT promises enhanced well-being using a method that sounds simple, wholesome, and without harmful side effects, there remains no evidence of any significant clinical value better than placebo or other relaxation methods.

5.7 | Adverse effects and outcomes

No adverse effects or incidence in any of the studies to date has been reported, and overall, it seems that TT has minimal risk with regard to safety and any side effects.

5.8 | Limitations

In all of these studies, a wide variety of TT implementations were involved in a wide variety of contexts, so comparison by subgroup subgroups was not feasible as direct comparisons would not be reliable as the populations and therapies used were not directly comparable. The REA methodology itself is also a limitation as it provides a narrative quantitative review and is not a meta-analysis with limited breadth and depth of searching and analysis. Finally, the restricted dates used in this REA also represent another limitation.

6 | CONCLUSION

After 45 years of study, scientific evidence of the value of TT as a complimentary intervention in the management of any condition still remains immature and inconclusive:

- Given the mixed result, lack of replication, overall research quality and significant issues of bias identified, there currently exists no good quality evidence that supports the implementation of TT as an evidence-based clinical intervention in any context.
- Research over the past decade exhibits the same issues as earlier work, with highly diverse poor quality unreplicated studies mainly published in alternative health media.
- As the nature of human biofield energy remains undemonstrated, and that no quality scientific work has established any clinically significant effect, more plausible explanations of the reported benefits are from wishful thinking and use of an elaborate theatrical placebo.

6.1 | Implications for practice and research

Given the deficiency of quality research evidence, it remains somewhat puzzling why nursing organizations and textbooks continue to support TT (e.g. Carpenito-Moyet, 2014; NANDA International, 2018) as no other faith-based interventions have gained similar traction in nursing literature. The support of poor quality and biased research is clearly problematic and could affect the wider scientific credibility of the profession. Without basic research, further clinical studies will present similar issues, and given the resources expended to date with no tangible evidence, similar work would seem unjustified. It is, of course, possible that human biofield energy exists, but future research efforts would be better applied to pre-clinical work to establish a validated theoretical framework. Achieving that would support a massive paradigm shift. Therefore, it is recommended that future research is best focused on rigorous studies to demonstrate theoretical validity before further clinical work is undertaken. As the claims TT practitioners make for, and their ability to detect a human biofield energy field can easily be tested with well-controlled practical experiments (as Emily Rosa

attempted to do in 1998), it appears at best inept, and at worst disingenuous that this has not occurred to date.

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CONFLICT OF INTEREST

The authors do not have any competing interests or conflicts of interest with regard to this paper, or the journal.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as a review no new data were created or analysed in this study.

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