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ORIGINAL ARTICLE

The role of biofield energy treatment on psychological symptoms, mental health disorders, and stress-related quality of life in adult subjects: A randomized controlled clinical trial

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Abstract

Background: Western and Eastern cultures have practiced biofield energy therapy for thousands of years, but empirical research on effectiveness of this therapy is relatively nascent. Study was aimed to assess the safety and efficacy of biofield therapy on psychological symptoms and mental health disorders in adult subjects.

Methods: Seventy-seven participants (39 male and 38 female) underwent clinical trial. This trial was simple randomized, placebo-controlled, parallel-group, open-label, and single-center with subjects, who have one or more psychological symptoms. Two sessions of biofield energy attunement were given in-person at day 0 and 90 for 3 min (treatment group, $n = 35$) and others allocated to naive attunement (placebo group, $n = 42$). Subjects were assessed psychological questionnaire scoring using standard scale of assessment and levels of physiological biomarkers in serum were determined by parameter-specific ELISA.

Results: Perceived psychological symptoms/scores (asthenia, sleep disturbances, anxiety, depression, stress, confusion, future fearness, sexual desireness, motivation, confidence, emotional trauma, etc.) were significantly ($p \leq 0.0001$) improved in the treatment group than placebo control group. Furthermore, physiological biomarkers: vitamins (B_{12}, C, and D_3 metabolites), immune biomarker ($CD^{8+}CD^{28-}$), neurotransmitters (acetylcholine, noradrenaline, and dopamine), hormones (oxytocin, 17-β-estradiol, and insulin), and antiaging protein (klotho) levels were significantly ($p \leq 0.001$) increased in treatment group than placebo. Proinflammatory cytokines (TNF-α, IL-1β, IL-6, and IL-8) and oxidative stress biomarkers (isoprostane and oxidized LDL) were reduced in treatment group compared with placebo.

Conclusions: Results suggest that experimenter's biofield energy plays a significant role in information transfer processes that contribute to individual's state of physical, mental, emotional, and spiritual well-being as well as improved overall health and quality of life.

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KEYWORDS
biofield therapy, complementary therapy, mental disorder, physiological biomarker, psychological symptoms

1 | BACKGROUND

Health is a comprehensive and integrative understanding of people that includes many interrelated physical, psychological, and social factors.[1] World Health Organization (WHO) reported that the promotion of mental health and the prevention of mental disorders could help maintain a positive impact on quality of life (QoL), which can be economically beneficial.[2] Various complementary and alternative therapies (CAMs) are commonly used for different diseases/disorders/conditions such as depression, anxiety, fear of tumor recurrence, weak mental health, knee and back pain, and especially cancer patients.[3,4] Biofield therapies, which manipulate hypothesized energy fields surrounding the body, are frequently used to reduce pain, fatigue, and other treatment-related side effects in cancer patients. According to a recent update of biofield therapies, their effects are explored on QoL, fatigue, and physiological well-being in cancer populations.[5] The Trivedi Effect® is a unique and scientifically proven phenomenon in which a healer can harness the inherent intelligent energy from the universal energy field and transmit it anywhere on the planet through neutrinos (biophotons).[6] A renowned religious spiritual healer using biofield energy to transform the characteristics and behavior of living beings and nonliving materials through unique (thought intention) biofield energy transmission process by his physical presence and long-distance (distant healing) to heal the physical body and mind and bring emotional and spiritual balance.[7]

2 | OBJECTIVES

The present study was aimed at investigating (a) the safety and efficacy of a proprietary therapy (blessing treatment) on psychological, emotional, and mental health symptoms in adult subjects compared with placebo; (b) if changes in symptoms correlate with changes in the levels of different functional physiological biomarkers in serum such as vitamins, neurotransmitters, proinflammatory cytokines, hormones, stress marker, and antiaging biomarker, and psychiatric symptoms following blessing in the treatment group.

3 | MATERIALS AND METHODS

3.1 | Study design/sample size

This study involved a randomized, active-controlled, open-label, parallel-group, single-center trial. Simple randomization technique (allocation concealment mechanism) using a random-numbers table was used to generate the random allocation sequence. We have obtained approval for the protocol and consent forms from the Institutional Review Board (or Ethics Committee). A total of 104 subjects were screened, and 80 were enrolled and divided into two groups. Subjects reported to the study site for the following visits viz. visit 1: screening visit (30 days before randomization), visit 2: randomization/baseline/treatment visit (day 0), visit 3: treatment visit day 90 (±7 days), and visit 4: end of treatment day 180 (±7 days). In addition, safety follow-up was conducted for 1 week (±2 days) after visit 4 (Figure 1). Same placebo control data were considered for different manuscripts for comparison of various parameters.[8]

3.2 | Inclusion criteria

South Asian population (India; male and female) with 20–45 years who meet all the following criteria were included as appropriate participants in the trial such as 20–45 years at the time of written informed consent. Subjects with a complaint with at least one or more of the following symptoms: anxiety/depression/posttraumatic stress disorder (PTSD), asthenia (general weakness/tiredness/fatigue), fear from the future/ongoing negative thoughts, sleep disturbances (poor quality sleep), emotional trauma, stress and confusion, mental restlessness/mind chattering, lack of self-worth, menstrual cycle disorder, and hopelessness/suicidal tendencies. Body mass index (BMI) should be 18.5–30.0 kg/m,[2] calculated as weight in kg/(height in meters). Prior to enrollment, all subjects were screened by the principal investigator, subinvestigator, and physician for eligibility.[8]

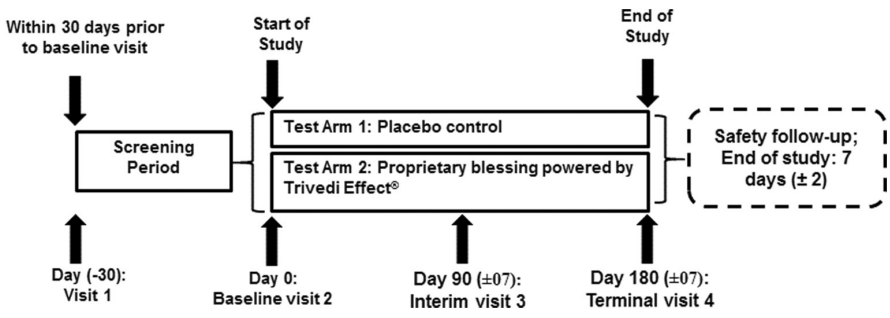

FIGURE 1 Schematic representation of study design.

3.3 | Exclusion criteria

Any participant meeting any of the following criteria was ineligible such as (a) history of allergic responses/hypersensitivity; (b) past history within last 1 year or currently having alcohol dependence or drug abuse; (c) significant diseases or clinically significant abnormal findings in medical history, physical examination, laboratory evaluations, etc., during screening; (d) regular vigorous aerobic/endurance exercise (>3 vigorous bouts/week); (e) known history of positive HIV, HCV, HBsAg, or VDRL/RPR; (f) subjects with nonhealthy, nonhomogenous, damaged over the skin; (g) subjects with birthmarks or excessive hair over the skin; (h) subjects with the usage of self-tanning agents for at least 10 days before screening; and (i) female subjects who demonstrate a positive pregnancy test or currently breastfeeding or planning pregnancy.

3.4 | Withdrawal criteria

Participants were asked to withdraw if they met one of the following criteria: poor compliance (mean compliance <85% at the last estimation) or noncompliance and occurrence of a severe adverse effect.[8] The study discontinuation rate was meager in the blessing group (two subjects), and one subject was discontinued in the placebo group.

3.5 | Biofield energy healing (Trivedi Effect®) attunement method

The eligible subjects were assigned to the blessing group and received two sessions of in-person biofield energy attunements (blessing/prayer) by an experience renowned spiritual experimenter/practitioner on day 0 and 90, under the standard clinical laboratory setting. The healing practitioner had been practicing biofield energy healing therapy for more than 15 years and regularly treats clients. He sat roughly a half meter behind each blessing group participant during all experimental sessions with one participant at a time. Attunement was provided through his unique inherent thought transmission process (channeling universal life force energy) via laying his hands to the blessing group for 3 min/participant, where his palms were positioned about 10–20 cm above the participant's head. The start and end time of blessing therapy was recorded in the electronic case report forms (eCRF). Besides, the placebo control group subjects did not receive any blessing or attunements.

3.6 | Safety assessment

Adverse effects (AEs) were monitored and classified using the Medical Dictionary for Regulatory Activities (MedDRA) terminology to determine safety.[9,10] Investigator performed a physical examination viz. temperature, pulse rate, blood pressure, and respiratory rate at visits 1–4 to evaluate the adverse effects. Before vital signs were taken, subjects were instructed to remain seated for about 5 min. Clinical research coordinators and/or study investigators monitored AEs during day 0, 90, and 180 visits by physical presence and/or phone calls between visits.

3.7 | Psychological symptoms

Perceived changes for psychological and mental health symptoms/complaints were assessed based on Psychological Questionnaire Scoring (PQS). Psychological questionnaire items were used in each category based on the 7-point Likert scale of scoring (1–7). These psychological questionnaire items (ref. Appendix S1) were prepared in-house with few modifications based on the standard scientific literatures, done by renowned experienced psychologists and psychiatrics, who were involved in this clinical trial study. These questionnaires were checked for content validity (content validity ratio was 0.86), reliability, and internal consistency (Cronbach's alpha = 0.89) by statistician and established as in-house PQS document, which has been routinely used in the various clinical trial projects. These psychological questionnaire items were assessed using fourteen (14) category of symptoms (asthenia, sleep disturbances, anxiety/depression/PTSD, stress, etc.), with a seven points scoring scale (1—never, 2—rarely, 3—occasionally, 4—periodic (sometimes), 5—frequently, 6—more frequent (usually), and 7—continuously (every time)). Each subject's scores were calculated, resulting in total symptoms/perception scores in each category. Total scoring in each category of symptom in the treatment group was compared with the placebo control group. Questionnaire-based evaluation of all the symptoms was evaluated at randomization/baseline/treatment visits (day 0, visit 2; day 90, visit 3; and day 180, visit 4).[11–27]

3.8 | Blood sampling and serum preparation

Blood samples were collected at the 0th, 90th, and 180th visits. Serum was prepared using standard method by LabCorp. The collected serum samples were frozen at −20°C until all biomarkers analysis. All biomarkers levels were determined by parameter-specific standard ELISA methods as per the manufacturer's instructions.[8]

3.9 | Physiological biomarkers

Physiological biomarkers were assessed in serum using standard in-house protocol as per the manufacturer's instructions. 17-β-estradiol (CAT#B7K720), vitamin B_{12} (CAT#B7K61E), and 25-OH vitamin D_3 (CAT#B5P020) ELISA-based kits were obtained from Abbott Diagnostics, USA and estimated using Architect ci

4100, Abbott Diagnostics, USA. CD biomarkers ($CD^{8+}CD^{28-}$; CAT#564419), TNF-α (CAT#558273), IL-1β (CAT#558279), IL-8 (CAT#558277), and IL-6 (CAT#558276) ELISA-based kits were obtained from BD Biosciences, USA and estimated by FACS Calibur, BD Biosciences. Vitamin C (CAT#E-EL-0011), 1, 25 dihydroxy vitamin D_3 (CAT#E-EL-0016), oxytocin (CAT#E-EL-0029), insulin, klotho (CAT#E-EL-H5451), oxidized LDL (CAT#E-EL-H0124), isoprostane (CAT#E-EL-0041), norepinephrine (CAT#E-EL-0047), dopamine (CAT#E-EL-0046), and acetylcholine (CAT#E-EL-0081) ELISA-based kits were obtained from Elabscience Biotechnology Inc., and estimated by SpectraMax 190/SpectraMax M2e, Molecular Devices.[8]

3.10 | Statistical analysis

In descriptive analysis of the sample, continuous variables were expressed by using mean, median, and standard deviation (SD) for normal distribution. For the variables with a normal distribution, statistical comparisons between the groups were made by using an independent *t*-test (two-sample *t*-test). The data were represented as mean ± standard deviation/standard error of mean (SEM) and subjected to statistical analysis. Statistical analysis of Psychological Questionnaire Scoring (PQS) was performed, and the level of significance (*p* value) was determined using analysis of covariance (ANCOVA) with 95% confidence interval (CI) of the difference between treatment using SAS®;9.4 (SAS Institute Inc.).

Physiological biomarker analysis, one-way analysis of variance (ANOVA) followed by post hoc analysis by Tukey's test for multiple groups comparison, and for between two groups comparison independent *t*-test was performed using SigmaPlot (v11.0). The $p \leq 0.05$ was considered statistically significant. The authors compared the average variability between the groups and take the ratio of the between mean sum of squares (MSB) to the error (residual) of mean sum of squares (MSE). That is, the *F*-statistic was calculated as $F = \text{MSB/MSE}$. The outcomes of participants, who were randomized and received at least one intervention, were carried out using the intention-to-treat (ITT) analysis. We compared the results of the ITT with that per-protocol (PP) analysis to check whether the results are consistent or not. The statistical results of the ITT and PP population data were the same and considered that the data are reliable. Therefore, the results of the ITT analysis were reported in the manuscript.

4 | RESULTS

4.1 | Subject disposition and demographic characteristics

Total 104 subjects were screened, among which 77 subjects were completed in the study. Among which, 42 (24 male +18 female) subjects were assigned to the placebo control group, and 35 (15 male +20 female) subjects to the Blessing Treatment group and continued at the end of study (Figure 2). Demographic characteristics of study subjects were recorded. There were no clinically significant abnormalities in physical findings like body weight and body mass index values observed between the two groups from baseline to follow-up visit (Table 1).

4.2 | Adverse effects

There were no adverse effects (AEs) and/or death reported during physical examination and the entire study period. The hematological and biochemical test results were within the normal range at baseline and follow-up visits (data not shown).

4.3 | Psychological symptoms

The perceived psychological symptoms/scores (asthenia, sleep disturbances, anxiety/depression/PTSD, stress and confusion, mental

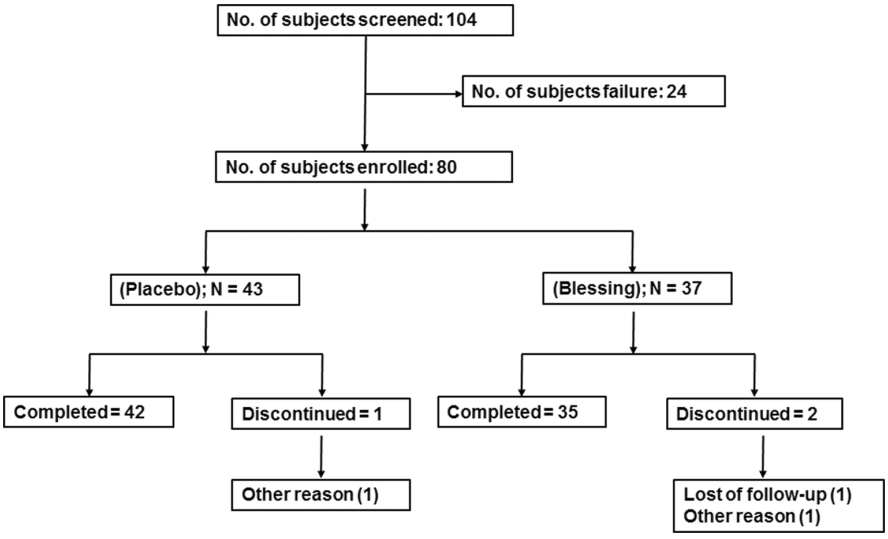

FIGURE 2 Diagrammatic representation of subject disposition.

TABLE 1 Summary of demographic and clinical baseline characteristics.

Demographic and baseline characteristics	Placebo control (*N* = 42)[a]	Biofield energy therapy (*N* = 35)
Age (Years)		
Mean ± SD	34.7 ± 6.42	32.3 ± 6.53
Median	37	34
Min, Max	20, 44	20, 44
Gender [*n* (%)]		
Male	24 (57.14)	15 (40.54)
Female	18 (42.86)	22 (59.46)
Race [*n* (%)]		
Asian	42 (100)	37 (100)
White	0 (0.00)	0 (0.00)
Black or African American	0 (0.00)	0 (0.00)
American Indian or Alaska native	0 (0.00)	0 (0.00)
Native Hawaiian or other pacific Islander	0 (0.00)	0 (0.00)
Other	0 (0.00)	0 (0.00)
Height (cm)		
Mean ± SD	161.0 ± 8.50	158.5 ± 8.46
Median	162.5	156
Min, Max	142, 178	147, 175
Weight (kg)		
Mean ± SD	63.39 ± 10.926	61.75 ± 12.044
Median	61.65	62.2
Min, Max	46.8, 86.0	44.0, 90.1
BMI (kg/m^2)		
Mean ± SD	24.40 ± 3.565	24.43 ± 3.769
Median	24.25	24.7
Min, Max	18.6, 29.8	18.4, 29.7
Marital Status [*n* (%)]		
Married	37 (88.10)	31 (83.78)
Unmarried	5 (11.90)	4 (16.22)
Literacy Status [*n* (%)]		
Literate	40 (95.24)	34 (94.59)
Illiterate	2 (4.76)	1 (5.41)
Substance Usage [*n* (%)]		
Alcohol		
Previous	4 (9.52)	1 (8.11)
Current	4 (9.52)	0 (0.00)
Never	34 (80.95)	34 (91.89)
Cigarettes/Biddies		
Previous	0 (0.00)	1 (2.70)
Current	1 (2.38)	1 (2.70)
Never	41 (97.62)	33 (94.59)
Tobacco		
Previous	3 (7.14)	1 (2.70)
Current	10 (23.81)	3 (13.51)
Never	29 (69.05)	31 (83.78)

Note: Percentages were based on the number of subjects in the specified treatment arm.

Abbreviations: BMI, body mass index; *n*, number of subjects in the specified category; *N*, number of subjects in the specified treatment arm; SD, standard deviation.

[a]Data were adopted from ref. [8].

restlessness, future fearness, emotional trauma, hopelessness/suicidal ideation, attention-deficit disorders/attention-deficit hyperactivity disorder (ADD/ADHD), and menstrual disorders) were statistically significantly ($p < 0.0001$) reduced in blessing group at both days 90 and 180 compared with baseline-based placebo group. Furthermore, libido/sexual desireness, inspiration/motivation/enthusiasm, and confidence/willpower/decision-making ability score were statistically ($p < 0.0001$) increased in the blessing group at both days 90 and 180 compared with placebo (Table 2).

4.4 | Functional physiological biomarkers

Tukey's post hoc analysis revealed that the level of isoprostane was significantly ($F_{(2,102)} = 131.524$, $p \leq 0.001$) reduced by 43.74% and 65.84% in the blessing group at day 90 and 180, respectively, with respect to the placebo group. Oxidized LDL was decreased significantly ($F_{(2,102)} = 32.281$, $p \leq 0.001$) by 50.19% (at day 90) and 30.91% (at day 180) in the blessing group compared with the placebo control group. The level of oxytocin was increased significantly ($F_{(2,102)} = 52.535$, $p \leq 0.001$) by 412.71% (at day 90) and 192.4% (at day 180) in the blessing group as compared to the placebo control group. Moreover, 17-β-estradiol level was increased by 38.34% in the blessing group at day 90 compared with the placebo group. The insulin level was increased by 25.78% and 88.93% at day 90 and 180 visits, respectively, in the blessing group compared with the placebo group. The level of vitamin C was significantly ($F_{(2,102)} = 26.236$, $p \leq 0.001$) increased by 81.63% (at day 90) and 57.92% (at day 180) in the blessing group with respect to the placebo group. Vitamin B_{12} was increased by 20.64% (at day 90) and 15.77% (at day 180) in the blessing group than placebo.

The level of vitamin D_3 active metabolite, 25-OH Vitamin D_3 in the placebo control group was 10.91 ± 0.47 ng/mL, which was increased significantly ($F_{(2,102)} = 8.826$, $p \leq 0.001$) by 31.62% (at day 90) and 42.71% (at day 180) in the blessing group compared with the placebo control group. Other metabolite (1, 25-$(OH)_2$ vitamin

TABLE 2 Observation of psychological and mental health symptoms after biofield energy treatment in human subjects, measured at day 90 and 180 visits.

Parameter	Visit (day)	Comparison	Mean ± SD	95% CI	*p* value
Asthenia	90	Biofield energy therapy vs. Placebo control	−4.371 ± 0.930	(−4.82, −3.93)	<0.0001
	180		−5.771 ± 0.871	(−6.19, −5.35)	<0.0001
Sleep disturbances	90		−4.343 ± 1.0269	(−4.84, −3.85)	<0.0001
	180		−6.029 ± 0.9416	(−6.48, −5.57)	<0.0001
Anxiety/depression/PTSD	90		−4.057 ± 1.0249	(−4.55, −3.57)	<0.0001
	180		−5.914 ± 0.9636	(−6.38, −5.45)	<0.0001
Stress and confusion	90		−4.086 ± 0.7664	(−4.45, −3.72)	<0.0001
	180		−6.114 ± 0.7230	(−6.46, −5.77)	<0.0001
Mental restlessness	90		−4.029 ± 0.9130	(−4.47, −3.59)	<0.0001
	180		−5.571 ± 0.8526	(−5.98, −5.16)	<0.0001
Future fear	90		−3.743 ± 1.4219	(−4.43, −3.06)	<0.0001
	180		−5.686 ± 1.3750	(−6.35, −5.02)	<0.0001
Emotional trauma	90		−3.686 ± 1.1935	(−4.26, −3.11)	<0.0001
	180		−4.829 ± 1.1152	(−5.37, −4.29)	<0.0001
Lack of self-worth	90		−3.857 ± 1.1797	(−4.42, −3.29)	<0.0001
	180		−5.743 ± 1.1343	(−6.29, −5.20)	<0.0001
Hopelessness/suicidal ideation	90		−3.457 ± 1.4824	(−4.17, −2.74)	<0.0001
	180		−5.057 ± 1.4216	(−5.75, −4.37)	<0.0001
ADD/ADHD (inability to focus)	90		−3.914 ± 1.1073	(−4.45, −3.38)	<0.0001
	180		−5.314 ± 1.0359	(−5.82, −4.81)	<0.0001
Libido/sexual desireness	90		−3.514 ± 1.3138	(−4.15, −2.88)	<0.0001
	180		−5.229 ± 1.2106	(−5.82, −4.64)	<0.0001
Menstrual/mood disorders symptoms	90		−3.300 ± 1.8224	(−4.49, −2.11)	<0.0001
	180		−5.150 ± 1.7072	(−6.28, −4.02)	<0.0001
Lack of confidence/willpower/inability	90		−3.629 ± 1.2261	(−4.22, −3.04)	<0.0001
	180		−5.629 ± 1.2019	(−6.21, −5.05)	<0.0001
Lack of inspiration/motivation/enthusiasm	90		−3.600 ± 1.1541	(−4.16, −3.04)	<0.0001
	180		−5.200 ± 1.0993	(−5.73, −4.67)	<0.0001

Note: Data are represented as mean ± SD. Placebo control group ($n = 42$) and biofield energy treatment group ($n = 35$). Data were analyzed, and level of significance (*p* value) was determined by using ANCOVA. At the end of study, subjects present in the placebo group ($n = 42$) and biofield energy treatment group ($n = 35$). (−) sign indicates the mean values are decreased than placebo control group.

Abbreviations: ADD, inattentive deficit disorder; ADHD, attention-deficit hyperactivity disorder; CI, confidence interval; PTSD, posttraumatic stress disorder; SD, standard deviation.

D_3) was also increased significantly ($F_{(2,102)} = 56.590$, $p \leq 0.001$) by 230.21% (at day 90) and 66.58% (at day 180) in the blessing group than placebo. Percentage of cluster of differentiation (CD) biomarker ($CD^{8+}CD^{28-}$) cell count was significantly ($F_{(2,102)} = 4.843$, $p = 0.01$) increased in the blessing participants group by 25.40% at day 180 compared with the placebo control group. The level of antiaging protein (klotho) protein was significantly ($F_{(2,102)} = 158.413$, $p \leq 0.001$) increased by 392.89% and 685.33% at day 90 and 180, respectively, in blessing group than placebo (Table 3).

Tukey's post hoc analysis revealed that serum norepinephrine level was significantly ($F_{(2,102)} = 30.906$, $p \leq 0.001$) increased by 103.54% (at day 90) and 96.48% (at day 180) in the blessing group with respect to the placebo group (4.54 ± 0.14). Moreover, serum concentration of dopamine was significantly ($F_{(2,102)} = 208.064$, $p \leq 0.001$) increased by 334.58% (at day 90) and 422.96% (at day 180) in the blessing group as compared to the placebo group. Serum acetylcholine level was significantly ($F_{(2,102)} = 14.936$, $p \leq 0.001$) increased by 43.25% (at day 180) in the blessing group with respect to the placebo group (3217.36 ± 63.14 pg/mL; Table 3).

Tukey's post hoc analysis revealed that the level of interleukin-6 (IL-6) was significantly ($F_{(2,102)} = 19.408$, $p \leq 0.001$) reduced by 76.86% ($p \leq 0.001$; at day 180) in the blessing group as compared to the placebo group. Moreover, IL-8 level was significantly decreased by 53.67% ($F_{(2,102)} = 12.221$, $p = 0.002$) and 72.04% ($F_{(2,102)} = 12.221$, $p \leq 0.001$) in the blessing group at day 90 and 180, respectively, as compared to the placebo group. Serum concentration of IL-1β was significantly decreased by 47.35% (at day 90) and 94.71% ($F_{(2,102)} = 3.179$, $p = 0.035$; at day 180) in the blessing group

TABLE 3 Measurement of serum biomarkers related to oxidative stress, hormones, vitamins, immunity, aging, neurotransmission, and inflammation after biofield energy treatment in human subjects, measured at days 90 and 180.

Parameter	Placebo control[a] (mean ± SEM)	Biofield energy therapy	
		Day 90 (mean ± SEM)	Day 180 (mean ± SEM)
Oxidative stress biomarker			
Isoprostane (pg/mL)	1088.27 ± 46.38	612.31 ± 16.33***	371.70 ± 24.81***
Oxidized LDL (pg/mL)	963.55 ± 43.17	479.91 ± 35.47***	665.72 ± 49.09***
Hormones			
Oxytocin (pg/mL)	88.05 ± 6.39	451.44 ± 32.93***	257.46 ± 27.62***
17-β-estradiol (ng/mL)	97.08 ± 10.14	134.3 ± 17.52	100.25 ± 12.12
Insulin (mU/L)	11.79 ± 3.18	14.83 ± 2.66	22.28 ± 4.33
Vitamins			
Vitamin C (μg/mL)	17.42 ± 0.74	31.64 ± 1.33***	27.51 ± 1.95***
Vitamin B_{12} (pg/mL)	176.5 ± 19.78	212.93 ± 26.28	204.34 ± 26.54
25-OH Vitamin D_3 (ng/mL)	10.91 ± 0.47	14.36 ± 0.84***	15.57 ± 1.03***
1, 25 Dihydroxy Vitamin D_3 (pg/mL)	124 ± 2.85	409.46 ± 21.66***	206.56 ± 25.82**
Immune biomarker			
$CD^{8+}CD^{28-}$ Cell count (%)	14.72 ± 0.80	16.20 ± 0.69	18.46 ± 1.04**
Antiaging biomarker			
Klotho (pg/mL)	2.25 ± 0.04	11.09 ± 0.39***	17.67 ± 0.99***
Neurotransmitters			
Norepinephrine (ng/mL)	4.54 ± 0.14	9.24 ± 0.57***	8.92 ± 0.57***
Dopamine (pg/mL)	382.44 ± 6.47	1662.02 ± 102.25***	2000 ± 0.00***
Acetylcholine (pg/mL)	3217.36 ± 63.14	3055.76 ± 238.1	4608.72 ± 292.8***
Inflammatory cytokines			
IL-6	2.55 ± 0.18	2.34 ± 0.29	0.59 ± 0.25***
IL-8	18.24 ± 3.19	8.45 ± 0.62**	5.10 ± 0.94***
IL-1β	2.83 ± 1.17	1.49 ± 0.56	0.15 ± 0.11*
TNF-α	7.92 ± 3.00	2.22 ± 0.90	0.34 ± 0.26*

Note: Data were analyzed using one-way ANOVA and post hoc analysis performed by Tukey's test. At the end of study, subjects present in the placebo group ($n = 42$) and biofield energy treatment group ($n = 35$).

Abbreviations: CD, cluster of differentiation; LDL, low-density lipoprotein.

[a]Data were adopted from ref. [8].

*$p \leq 0.05$, **$p \leq 0.01$ and ***$p \leq 0.001$ versus placebo control group.

as compared to the placebo group. Furthermore, level of tumor necrosis factor-alpha (TNF-α) was significantly decreased by 71.97% (at day 90) and 95.70% ($F_{(2,102)} = 4.732$, $p = 0.011$; at day 180) in the blessing group with respect to the placebo group (7.92 ± 3.00 pg/mL; Table 3).

5 | DISCUSSION

The present study results revealed that treatment group participants reported significant improvement in overall psychological symptoms. Among them, attention-deficit/hyperactivity disorder (ADHD) is a common, chronic neurobehavioral disorder related to clinically significant levels of inattention, hyperactivity, and/or impulsivity.[28] In Table 2, authors summarized the effects of the Trivedi Effect® on ADHD and other psychological symptoms. The subjects who received this therapy exhibited either nil or minimal score of psychological symptoms after 180 days of the treatment. Satisfaction with sexual desires, inspiration, willpower, self-confidence, and motivation scores were higher in the blessing group compared with the placebo. In addition, there was significantly reduced menstrual disorder symptoms in blessing group than placebo.

F2-isoprostane is one of the important oxidative stress biomarkers in vivo in the pathogenesis of human disease.[29] Oxidized LDL

plays a vital role in neurological disorders associated with oxidative stress in patients with ADHD. It induces neuronal death and reactive oxygen species in Alzheimer's disease.[30] Here, practitioner's blessing has significantly reduced the level of stress biomarkers (isoprostane and oxidized LDL) in treatment subjects in both time points, which could be helpful to the stress/depressed patients. The plasma levels of oxytocin and β-estradiol were correlated with perceived measures of mood, well-being, libido, inspiration/willpower, and motivation. Blessing group showed elevated levels of oxytocin and β-estradiol compared with placebo (Table 3). Oxytocin helps to increase trust behavior in a money-transferring game, increases the ability to interpret mental states, and improves social cognition.[31,32] In this trial, practitioner's blessing sessions significantly increased the level of lovemaking neurohormone oxytocin in serum in adult subjects (female), which might be responsible for improving psychological symptoms like mood alleviation, calmness of mind, cognition, and mental strength.

Vitamin C protects the neuron against oxidative stress, alleviates inflammation, regulates neurotransmission, affects neuronal development, and controls epigenetic function.[33] Both vitamin C and B_{12} can markedly improve depressive symptoms, play a vital role, and have a strong association with mental well-being. $CD^{8+}CD^{28-}$ T-lymphocyte cells play an important role for immunological pathogenesis of influenza infection. There was a reduction in the number of peripheral $CD^{8+}CD^{28-}$ T cells in the acute phase of influenza infection.[34] Current trials indicate a significant increase in the levels of vitamin C, B_{12}, and $CD^{8+}CD^{28-}$ T cells count (Table 3), which might be beneficial for the improvement of immunity in immune-deficient subjects, psychiatric population, and mental health disorders. Vitamin D deficiency in psychiatric disorders is due to a lack of proper brain development, synaptic plasticity, neuronal development, and protective factors against oxidative stress.[35] In this trial, practitioner's blessing sessions significantly increased levels of vitamin D_3 metabolites in serum (Table 3), which might be responsible for the improvement of psychological symptoms like depression, cognition, and mental restlessness.

The researchers reported that low level of klotho could contribute to anxiety and depression through cellular, molecular, and neural pathways that causes stress and depression.[36] Our findings suggest that the levels of klotho protein and more bioavailable active vitamin D_3 metabolites in serum significantly increased in the blessing subjects (Table 3). The higher level of antiaging protein klotho and vitamin D_3 metabolites might be helpful for the improvement of cognition, memory, and overall physical stamina/energy and QoL in adult subjects.

Neurotransmitters are the crucial neuromodulators that control vital brain functions and affect brain states, vigilance, action, reward, mood, sleep, memory, learning, concentration, and motor control.[37,38] Acetylcholine plays a critical role in brain circuits mediating motor control, attention, learning, and memory.[39] This trial showed that the blessing treatment significantly increased the levels of neurotransmitters (norepinephrine, dopamine, and acetylcholine) in serum (Table 3), which might benefit in the depressed populations and mental health disorders. Cytokines can modulate various psychiatric symptoms such as sickness behavior, agitation, cognitive impairment, disorientation, delusions, and hallucinations, which are induced by TNF-α, IL-2, and IFN-α.[40] Clinical trial literature reported that levels of proinflammatory cytokines (IL-6 and TNF-α) were higher in depressed patients compared with placebo.[41] Here, healer's biofield energy therapy (blessing) has shown a significant reduction in proinflammatory cytokines (IL-6, IL-8, IL-1β, and TNF-α) in blessing subjects compared with placebo (Table 3), which might support common mental disorders (CMDs) such as anxiety, insomnia, depression, and stress-related symptoms and chronic inflammatory disorders viz. osteoporosis, arthritis, obesity, and diabetes.

5.1 | Limitations of the study

Apart from positive outcomes of this trial, few limitations include single-center and the mechanisms of energy transmission to effect were observed not been fully revealed. Therefore, it would be necessary to conduct details mechanistic studies on a larger populbetween the groups and take the ratio ofation to examine the benefits of biofield therapy on mental health. Further verification of these findings will require a double-blind experiment under well-controlled conditions. Unfortunately, because of limited funding, we did not fulfill these limitations at this juncture.

6 | CONCLUSIONS

This proof-of-concept clinical study found that biofield energy therapy was safe, tolerable, and free of any untoward adverse effects for long-term use in adult subjects. Healer's blessing significantly improved psychological symptoms and mental disorders in the treatment group compared with the placebo control group in both day 90 and 180 visits. Furthermore, there was a statistically significant improvement of different functional physiological biomarkers' levels in serum that lead to improve the overall health benefits and quality of life in the treatment group compared with the placebo. This novel treatment approach may help to design and conduct clinical trial study with specific symptoms/diseases/disorders that could be more beneficial in the management of both psychological and mental health well-being.

AUTHOR CONTRIBUTIONS

M.KT. and S.J. contributed to the study conception, designing, planning, execution, monitoring, and data interpretation. S.M. and D.T. wrote the first draft of the manuscript. A.B. and S.J. contributed related to review and editing. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

MKT, AB, and DT were employed by Trivedi Global, Inc. SM and SJ were employed by Trivedi Science Research Laboratory Pvt. Ltd.

DATA AVAILABILITY STATEMENT

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

ETHICAL APPROVAL

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Review Board (or Ethics Committee) of Sangini Hospital Ethics Committee, Gujarat, India (Reg. No. ECR/147/Inst/GJ/2013/RR-16) with (protocol code CRLIV051823 and date of approval Dec 11, 2018).

PATIENT CONSENT STATEMENT

Written informed consent was obtained from all individual participants included in the study.

CLINICAL TRIAL REGISTRATION

Reg. No. ECR/147/Inst/GJ/2013/RR-16.

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SUPPORTING INFORMATION

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