Original Article

Pranic Healing as a Complementary Therapy in Diabetic Foot Ulcer Management: A Randomised, Controlled, Double-Blind Trial

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Abstract

Background: Diabetic Foot Ulcers (DFUs), a serious complication of diabetes, have limited solutions in conventional therapies. The condition needs holistic management of blood glycemic levels; foot wounds; and possible regeneration of nerves in the soles of patients.
Objective: To evaluate the efficacy of Pranic Healing as a complimentary therapy in managing Diabetic Foot Ulcers (DFUs).
Methods: Thirty diabetic subjects already on standard therapy for Diabetes, co morbidities and wound care for Diabetic Foot Ulcers were assigned on a 1:1 basis to the trial and control groups. While both groups continued to receive standard therapy, the trial group additionally received Pranic Healing therapy. The Clinician, nursing staff, assessors and patients were blinded. Pranic Healers carried out healing on the trial group remotely, every day for 50 to 60 minute for stress, diabetes, local wound healing, blood cleansing and regeneration of nerves in the soles. The efficacy variables were the mean change from baseline in wound parameters and grade of DFU, overall well-being and HbAIc levels.
Results: At the end of the trial, about 83.33% participants in the trial group demonstrated lowering of size and severity of the ulceration and improved to a lower grade of DFU compared to 44.4% in control group. The trial group reported a significant reduction in wound area and HbA1c levels. The trial group showed better readings for improved sensory perception in the soles through changes in the large fibre dysfunction and damaged nerves as compared to the control group. Approximately 76.9% of participants in the trial group reported lower stress levels compared to 22.22% in the control group.
Conclusions: Pranic Healing intervention can be a safe and effective adjunct in managing Diabetic Foot Ulcers.

Keywords

glycemic levels, neuropathy, complications in diabetes, foot wounds, regeneration of nerves

Background

Lifestyle changes and alterations in human behaviour in the last century have resulted in dramatic increase in the incidence of diabetes worldwide. In specific, Type 2 diabetes mellitus is rapidly emerging as a major threat to global human health.[1] Long-term complications of diabetes might include depression, skin conditions, foot damage, neuropathy, retinopathy, nephropathy, cardiovascular diseases, hearing impairment, and dementia.[2,3] One of the most devastating complications of diabetes is Diabetic Foot Ulcers (DFUs).

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Data Availability Statement included at the end of the article

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DFUs and foot wounds result in lower limb complications that leads to frequent hospitalizations and in many cases, lower extremity amputations, thus creating a severe economic burden on the families and society.[4] Mortality associated with DFUs is estimated at 5% in the first 12 months and 42% in the first 5 years of development of DFUs.[5] A major amputation for patients with infected diabetic foot occurs every 30 seconds and 2500 limbs are being lost every day around the globe.[6] Recent studies also emphasize the very high prevalence of foot ulceration in diabetic patients on dialysis as a result of end-stage renal disease. The mortality in this patient group is higher than for most forms of cancer.[7]

Major risk factors for foot ulceration are Diabetic Neuropathy (DN), peripheral arterial disease, and consequent traumas of the foot.[8] DN is the most common cause in almost 90% of Diabetic Foot Ulcers. Nerve damage in diabetes affects the motor, sensory, and autonomic fibers. More recently, cellular factors derived from the bone marrow also appear to have a strong impact on the development of peripheral nerve pathology.[9] Proper evaluation of the Diabetic Foot Ulcer and appropriate timely management will ensure better prognosis.[10]

The Wagner system of DFU classification assesses ulcer depth and the presence of osteomyelitis or gangrene by using the following grades: grade 0 (pre-or post ulcerative lesion), grade 1 (partial/full thickness ulcer), grade 2 (probing to tendon or capsule), grade 3 (deep with osteitis), grade 4 (partial foot gangrene), and grade 5 (whole foot gangrene).[11]

Preventing the diabetic foot should be the main concern of healthcare workers. Identifying individuals at risk, like those with peripheral neuropathy, peripheral vascular disease, foot deformities, and presence of callus, and educating them about the preventive and treatment measures should be the priority of healthcare workers.[12]

Currently, localized resolutions for DFUs include debridement, offloading, skin grafts, use of growth factors, specialized gels, Platelet Rich Plasma Therapy (PRPT), Vacuum-Assisted Closure (VAC), Hyperbaric Oxygen therapy (HBOT), low-level laser therapy.[13] Optimal management of DN would involve controlling glycemic levels, treating nerve pain and localised resolution of the wounds. This would call for holistic management of the metabolic condition of diabetes, including strict diet control, lifestyle changes, and novel ways of treating the wound and neuropathy.[8-10,12] There is no treatment officially approved for the prevention or reversal of DN until date.[14]

Available literature shows that complementary and alternative therapies have been in use for a long time to treat diabetes, the underlying cause of DFUs. Disseminating information among healthcare professionals about Complementary and Alternative Medicine (CAM), its clinical evidence and efficacy is crucial.[15] Informed decisions and availability of alternate options may help improve patient treatment outcomes.[3,15] While energy therapies are safe and without side effects, during the intervention, catecholamines such as epinephrine and norepinephrine are released by the body, which in turn increase lipolysis and thermogenesis, resulting in potential lowering of blood glycemic levels. Thus, blood glucose should be regularly monitored and alterations made in diabetes medication(s) if blood glucose levels reduce with energy therapies.[16] Some physicians who extensively experimented with alternate healing modalities have described the role of energy healing in diabetes.[17]

Pranic Healing is a specialized science and art of utilizing energy (*prana*) from natural sources to heal the entire physical body of simple, and chronic conditions. It has also been called *medical qigong*, *vitalic healing, therapeutic touch,* and *magnetic healing*.[18] The non-invasive energy healing modality works on the Principle of Life Force or *prana* (chi or ki), the Principle of Self-Recovery and the Law of Correspondence. In general, *prana* or life energy is important for life to exist (Principle of Life Force) and the body is capable of healing itself at a certain rate (Principle of Self-Recovery). In Pranic Healing, *prana* or life energy serves as a catalyst to accelerate the rate of biochemical reactions involved in the natural healing process of the body.

An energy body (energetic blueprint of the physical body) and various auras surround and interpenetrate and affect the visible physical body. Any disharmony/imbalance in the energy body manifests as disease in the physical body and vice versa. This is called the Law of Correspondence. Energy flows in the body through energy meridians, similar to blood vessels carrying blood. The energy body, through the whirling energy centres known as "*chakras*" controls and is responsible for the proper functioning of the whole physical body and its parts and organs. When the energy meridians, energy centres (*chakras*), and auras are cleansed of dirty, diseased energy and infused with clean and fresh energy; the energy body is balanced and healed.[18] The major energy centres not only control and energise the internal organs, but also control and affect one's psychological functions.[19] Advanced Pranic Healing involves the use of colour *prana* for cleansing and energising the organs and energy centres. An interesting aspect of Pranic Healing therapy is the power of cellular healing and regeneration of cells/organs.[20] This aspect of regeneration can be exploited to reverse conditions like neuropathy.

The research hypothesis and choice of outcome measures were based on the findings from previous research on DFUs which suggest that DN is not adequately addressed by conventional therapies and needs holistic management of diabetes and possible regeneration of nerves in soles of patients suffering from DN and DFUs.

H0. Pranic Healing intervention as an adjuvant therapy cannot have significant efficacy in management of Diabetic Foot Ulceration.

H1. Pranic Healing intervention as an adjuvant therapy can have significant efficacy in management of Diabetic Foot Ulceration.

Materials & Methods

Objective

To compare and study the efficacy of Pranic Healing in managing Diabetic Foot Ulcers as an adjunct to the conventional treatment methods. The efficacy of Pranic Healing was assessed by measuring progression of wound healing, changes in sensory perception in soles and reduction in glycemic levels and stress.

Ethical Approval and Consent to participate

The Institutional Ethical Committee reviewed and approved the pilot study before the commencement of the trial. **Ref: IEC-KIER 16/14.09.2019**.

All the participants gave their prior written consent for participation, confidentiality, and publication of results. The study included insurance cover for all the participants till 3 months after the completion of the study.

Research Design and Setting

Pranic Healing is used as a complementary therapy alongside the standard treatment for DFUs and diabetes in this study. The research is designed as an interventional, single-centre, double-blind, randomized controlled study, which is the standard methodology used in Pranic Healing clinical studies. The research setting was a super speciality hospital for patients with diabetes and Diabetic Foot complications.

Based on previous literature, the sample size of 26 (13 in each group) was estimated as adequate. With 5% Alpha error and 80% Power; the calculated sample size came to 13 per group.Anticipating for a 10% dropout, we recruited 30 (15 in each group) participants.

Eligibility Criteria for Participants

Inclusion Criteria

- Men and women between 25 to 75 years, already on standard therapy for diabetes and co-morbidities and presenting with DFUs in Wagner Grade1-3.
- A few participants with Diabetic Foot Wounds above the malleoli were included and graded to remove bias in the study.

Exclusion Criteria

- Pregnant women and substance abusers (tobacco/substance/alcohol) were excluded from the study as their energies would be very different from the rest of the population.

The participant flow chart is shown in Figure 1.

The participants were screened and randomized by a concealed allocation of 1:1 to trial group or control group by the investigator using an online sequence generator (RANDOM.ORG).While both the groups received standard therapy for diabetes and wound care; the trial group received additional Pranic Healing therapy for 5 weeks. The clinician, participants, nursing staff, and the assessors were blinded.[1]

Confirming factors were steady dose of medications, constant dietary patterns, no change in lifestyle and physical exercises (or lack of exercises) during the period of study.

We informed the patients about the trial, the modality of energy healing and the study process. Over a period of 15 days (from 18-9-2019), we screened about 50 men and women and recruited 30 participants. They were of Indian ethnicity, aged between 25 to 75 years, and suffering from Diabetic Foot Ulcerations in Wagner Grade 1-3. To avoid bias, we included 2 participants suffering from Diabetic Foot wounds above the malleoli. We excluded pregnant women, smokers and drinkers from the study. On recruitment, the average age was 57.3 yrs, average period of diabetes was 13.07 yrs and average HbA1c level was 9.36%. About 13 participants were on insulin, 13 had co morbidities of vascular and arterial conditions, 1 had Chronic Kidney Disease (CKD), 2 had a history of varicose veins, and 4 had foot deformities. Other than 1 participant, all the participants suffered from peripheral neuropathy.

The demographic characters of the participants at recruitment are shown in Table 1.

Process & Intervention

Qualitative Assessment. On recruitment and end of the trial, the clinician inspected the participants' wound bed and periwound area for discharge, granulation, presence of infection, slough, necrotic tissue and assigned a Wagner Grade. Simultaneously, the clinician decided the requirement of specialized clinical procedures like debridement, offloading, vac application, PRPT, application of specialized gels etc. The healers noted the c*hakral* and overall energetic conditions on recruitment and frequently throughout the trial period. The participants were asked about changes in overall wellbeing, appetite, pain and discomfort levels through a questionnaire at the end of the trial.

Quantitative Assessment. We compared the wound area of each participant by taking photographs either through a wound zoom camera or a cell phone and later uploading it to Image J software at baseline and the end of the study. Previous glycemic (HbA1c/FBS) levels were noted at recruitment and tested again at the end of the trial. Neuro Touch™

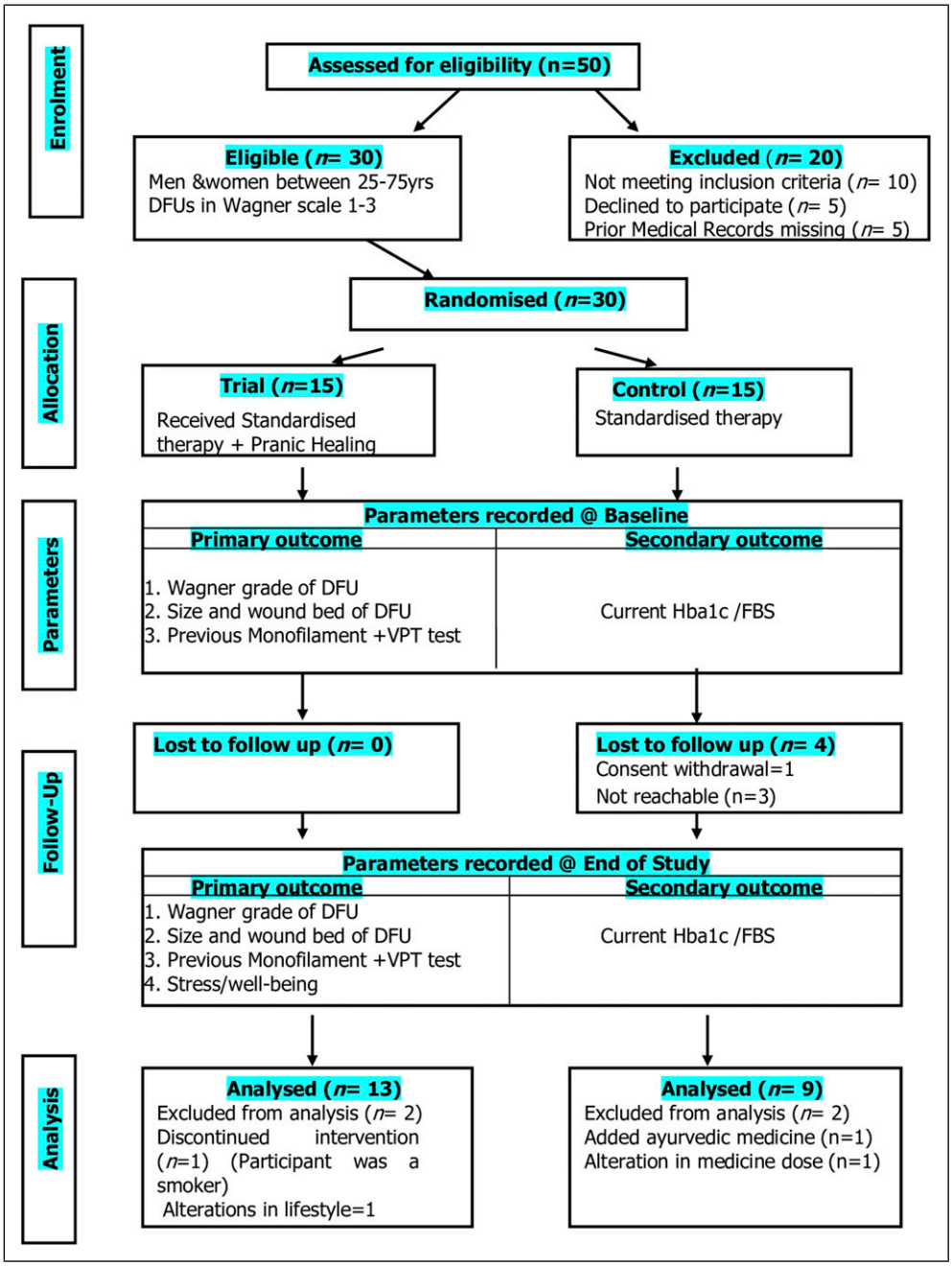

Figure 1. PARTICIPANT FLOWCHART-COMPDIAM.

Table 1. Demographics at baseline.

Characteristics	Statistics	Control N = 15	Trial N = 15	Total N = 30
Gender	Female n (%)	02 (13.33)	03(20)	5(33.33)
	Male n (%)	13(86.66)	12(80)	25(83.33)
Age (Years)	n	15	15	30
	Mean ±SD	62.0 ±8.48	53.07 ±10.39	57.33 ±10.37

multifunctional screening device was used to carry out the graduated Semmes Weinstein Monofilament and Vibratory Perception Test (VPT) on all the participants at the end of the trial. The readings were compared with previous Monofilament and VPT records.

Pranic Healing intervention included application of specialised protocols for "stress,""Type-2 diabetes,""instantaneous healing of fresh wound,""blood cleansing," and "regeneration of nerves." [19](p.54),[20] (p.227-228, 86-87,121,27).

A team of 10 experienced and internationally Certified Pranic Healers from across the globe worked remotely on the 15 participants in the trial group everyday for 5 weeks. Each healer worked on the subject through the relevant energy centres for 50-60 minutes. To ensure uniformity, different healers worked on a subject every day, and each healer carried out healing on every subject at some point in the study.

The healers scanned the energy bodies and energy centres of the subjects with their sensitized hands and determined the imbalances. The healers extracted dirty, diseased energy from the subjects' *chakras* and organs and disintegrated it by discarding it into a salt water solution. Simultaneously, they projected fresh, revitalising *prana* into the relevant energy centres of the subject.

To treat diabetes, the front and back solar plexus *chakras* or energy centres, liver and pancreas were thoroughly treated. The a*jna chakra,* which controls and energizes the pituitary gland was treated. The *meing mein chakra* and kidneys were thoroughly cleansed. Healers cleansed the basic and navel *chakras* and energised them to strengthen the entire body. The heart *chakra* was activated to induce a sense of inner peace. The *chakras* of the throat*,* forehead, crown and back head minor were cleansed and energized to harmonise their functions.

To accelerate wound healing, the affected parts in the soles and the minor *chakras* of the hip, knee and soles were cleansed and energized. Specific colour *prana* was projected on the wound to produce a localized effect; after which other colour *pranas* were used to energise the area. This helped in early closure of the wound and regeneration of the tissue. The forehead *chakra* was treated with the intention of regenerating the nerves in the subject's soles.

The spine, spleen and spleen *chakras* were cleansed. The blood was also cleansed through the lungs.[2] The crown, a*jna,* throat and solar plexus chakras were cleansed and energised to reduce stress and disintegrate feelings of fear, trauma and anxiety.

Primary outcome measures:

- Acceleration of wound healing interpreted through reduction in the size of wound and Grade of DFU
- Reduction in stress levels

Secondary outcome measure

- Stable or lowered glycated haemoglobin (HbA1c) level

Dataset

The dataset(s) supporting the conclusions of this article is available in the figshare repository. https://doi.org/10.6084/m9.figshare.22890758

Statistical Analysis

Statistical analysis was carried out using SAS 9.1, SPSS22.2 and Microsoft Excel software in the present study. Continuous variables were analysed with descriptive statistics such as Mean ± SD/SE. Categorical variables were analysed with descriptive statistics such as count and percentage. Wound size and HbA1c observations were to be analysed for changes from baseline to the end of the trial. As the samples were small, both parametric and non parametric tests were applied. Wound size observations did not show normality, while HbA1c observations showed a normal distribution in the Shapiro-Wilk test. Parametric tests of two tailed Paired Sample T test for intra group and Independent Sample Test for intergroup comparison were applied to analyse variables of wound size and HbA1c at baseline and end of study. Nonparametric tests namely, Wilcoxon signed-rank test for intra group paired samples and Mann Whitney μ test for inter group analysis were applied to compare the trial and control group means at baseline and end of the study.

P values less than .05 were considered as significant. Central tendency was measured by calculating the Mean and Median of the observations. Variability in the samples was measured by Standard Deviation and Standard Error of means.

Results

The summary of clinical results and analysis at the end of the intervention is shown in Tables 2, Figures 2-4.

Wound Size

Complete wound closure was achieved in 4(30.7%) participants in the trial group compared to 1(11.11%) in the control group. (Table 2b).

DFU grade

About 10(83.33%) participants showed lowering of DFU grade in the trial group v/s 4(44.44%) in the control group at the end of the trial. (Table 2b).

The change in wound size in cm^2 of each participants in the trial and control groups is shown in Figure 2.

D1 = Baseline; D35 = End of study

Regeneration of Nerves

About 3(25%) participants showed improvement in the damaged nerves (Monofilament) and 6(50%) in large fibre dysfunction (VPT test) in the trial group, compared to 0% and 2(22.2%) in the control group respectively at the end of the trial. The results of the Monofilament tests are shown in Figure 3(a) (i)and 3a(ii) and Vibratory Perception Threshold test are shown in Figure 3(b) (i), (ii), (Table 2b).

Hba1c

A two-tailed Independent t-test showed that the difference between trial and control groups for change in HbA1c levels was not statistically significant, t(17.06) = -1.78, p = .092, 95% confidence interval [−2.22, 0.19]. (Table 2a(i)).

Similarly, the Mann Whitney μ test used for intergroup comparison of the change in HbA1c levels from D1 to D35 between the trial and control groups did not exhibit a statistically significant change with ($p = 0.208$, z value:?1.313,. (Table 2a (ii)).

Paired Sample T test for the trial group displayed a statistically significant reduction in HbA1c level (t = 2.81; $p = .018$; 95% CI: .301 to 2.607) after intervention with Pranic Healing for 35 days. The control group did not exhibit a statistically significant difference in HbA1clevels between D1 and D35. (t = 0.33; $p = .311$; 95%CI: −0.392 to 1.067). (Table 2a(iv)).

A Wilcoxon signed rank test showed that in the trial group, HbA1c scores were significantly lower after the intervention (Md = 7.55, n = 11) compared to baseline (Md = 9.20, n = 11), z = -25.5, $p+ = .0195$*.HbA1c scores in the control group were not statistically

Table 2a(i). Efficacy of Pranic Healing Intervention: (i) Independent T test for intergroup analysis from D1 to D35.

	Groups	N	Mean	SD	T	*P* value
Wound size Difference of D35 to D1	Intervention	13	3.0229	3.06678	−2.273	.034*
	Control	9	1.8401	6.83889		
HbA1c Difference of D35 to D1	Intervention	12	−1.3417	1.68224	−1.78	.092
	Control	8	−.325	.84473		

*Statistical significance set at 0.05; **n:** Number of samples; **SD:** Standard deviation

Table 2a(ii). Efficacy of Pranic Healing Intervention: Mann Whitney μ test for intergroup analysis from D1 to D35.

	Groups	N	Mean	SD	Median	Mean rank	Z	*P* value
Wound size Difference of D35 to D1	Intervention	13	−3.02	3.07	−2.87	8.85	−2.304	.021*
	Control	9	1.84	6.84	−0.1	15.33		
HbA1c Difference of D35 to D1	Intervention	12	−1.34	1.68	−0.9	9.08	−1.313	.208
	Control	8	−0.32	0.84	−0.15	12.63		

*Statistical significance set at .05; **n:** Number of samples; **SD:** Standard deviation.

Table 2a(iii). Efficacy of Pranic Healing Intervention: Paired Sample T test for intragroup analysis of change in wound size.

								95% confidence interval of the difference	
		N	Mean	SD	Mean difference	t	*P* value	Lower	Upper
Test group	D1	12	4.25	5.01	2.15	2.916	.014	.52	3.76
	D35	12	2.10	2.7					
Control group	D1	9	10.16	25.07	−1.84	−.807	.443	−7.09	3.41
	D35	9	12.0	31.78					

*Statistical significance set at .05; **n:** Number of samples; **SD:** Standard deviation.

lower at the end of the study (Md = 8.15, n = 8) compared to baseline (Md = 8.90, n = 8), z = –7, $p+ = .3750$. (Table 2a(v)).

The change in HbA1c level of each participant of the treatment and control group is shown in Figure 4.

In the trial group, 10 (76.92%) reported lower stress levels and improved well being a compared to 2(22.22%) in the control group. A third (33.3%) of the control group participants reported feeling worse and facing higher stress levels at the end of the study as compared to 0 in the trial group. (Table 3).

A majority of the trial group participants reported having felt a tingling sensation, corresponding to the movement of energy in the palms and soles during the healing.

Table 2a(iv). Efficacy of Pranic Healing Intervention: Paired Sample T test for intragroup analysis of change in HbA1c levels.

								95% confidence interval of the difference	
		N	Mean	SD	Mean difference	t	*P* value	Lower	Upper
Test group	D1	11	9.86	2.31	1.45	2.811	.018*	.301	2.607
	D35	11	8.40	2.08					
Control group	D1	8	8.78	1.48	.33	1.093	.311	−.392	1.067
	D35	8	8.45	1.67					

*Statistical significance set at .05; **n:** Number of samples; **SD:** Standard deviation.

Table 2a(v). Efficacy of Pranic Healing Intervention: Wilcoxon signed rank test for paired samples D1to D35.

Parameters	Statistics		Control N = 09	Trial N = 13
Change in wound size (cm2)	Baseline (D1)	n	09	13
		Mean ±SEm	10.17 ± 8.36	4.54 ± 1.36
		Median	1.24	3.59
		Min, Max	0.21, 76.87	0.20, 16.27
	EoS (D35)	n	09	13
		Mean ±SEm	12.01 ± 10.59	1.94 ± .76
		Median	1.39	0.55
		Min, Max	0, 96.68	0, 8.17
	CfB	n	09	13
		Mean ±SEm	1.84 ± 2.28	−2.59 ± .81
		Median	−0.10	−0.92
		Min, Max	−2.69, 19.81	−8.10, −.08
		P-value+	0.8438	.0002*
Change in HbA1c level	Baseline (D1)	n	08	12
		Mean ±SEm	8.77 ± .52	9.57 ± .70
		Median	8.90	9.20
		Min, Max	6.50, 11.00	6.40, 13.00
	EoS (D35)	n	08	12
		Mean ±SEm	8.45 ± .59	8.23 ± .60
		Median	8.15	7.55
		Min, Max	6.80, 10.90	6.30, 12.90
	CfB (D35-D1)	n	08	12
		Mean ±SEm	−0.32 ± .29	−1.34 ± .48
		Median	−0.15	−0.90
		Min, Max	−2.00, .70	−3.80, 1.10
		P-value+	0.3750	0.0195*

n: number of subjects in the specified treatment group;
N: Total no. of subjects;
SEm: Standard Error of Measurement;
EoS: End of study; CfB: Change from baseline.
%: Percentage; * significant results.
P-value+: P-value using Wilcoxon signed-rank test.
Change from baseline: EoS (D35) – Baseline (D1).

Table 2b. Efficacy of Pranic Healing Intervention: Efficacy of pranic healing in categorical variables.

Change in Wagner grade	Baseline (D1) n (%)	n	09	13
		G-0	0 (.0)	0 (.0)
		G-1	3 (33.33)	5 (38.46)
		G-2	6 (66.67)	6 (46.15)
		G-3	0 (.0)	2 (15.38)
	EoS (D35)	n	09	13
		G-0	3 (33.33)	5 (38.46)
		G-1	2 (22.22)	5 (38.46)
		G-2	4 (44.44)	3 (23.08)
		G-3	0 (.0)	0 (.0)
Change in monofilament test	n (%)	n	09	12
		Improved	0 (.0)	3 (25.0)
		Status Quo	4 (44.44)	8 (66.67)
		Worse	5 (55.56)	1 (8.33)
Change in Vibratory perception test	n (%)	n	09	12
		Improved	2 (22.22)	6 (50.0)
		Status Quo	3 (33.33)	5 (41.67)
		Worse	4 (44.44)	1 (8.33)
Change in wound bed (approx.)	n (%)	n	09	13
		Improved	5 (55.56)	9 (69.23)
		Status Quo	4 (44.44)	4 (30.77)
Change in stress and well-being	n (%)	n	09	13
		Improved	2 (22.22)	10 (76.92)
		Status Quo	4 (44.44)	3 (23.08)
		Worse	3 (33.33)	0 (.0)

n: number of subjects analysed;
N: Sample size; SD: Standard deviation;
EoS: End of study; %: Percentage;
CfB: Change from baseline: EoS : (D35) – Baseline (D1).

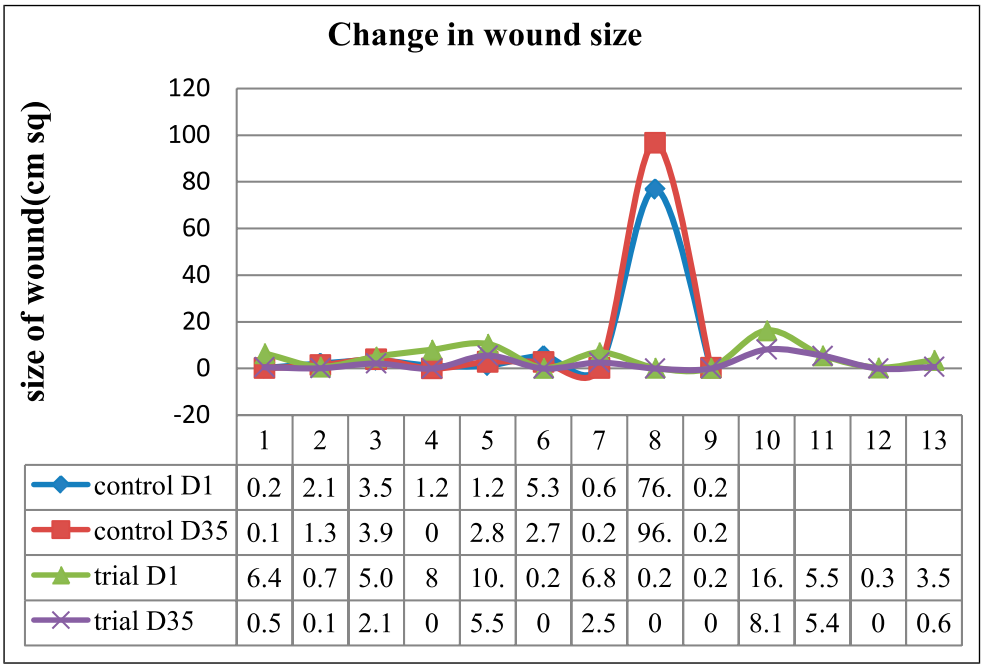

Figure 2. Change in wound size.

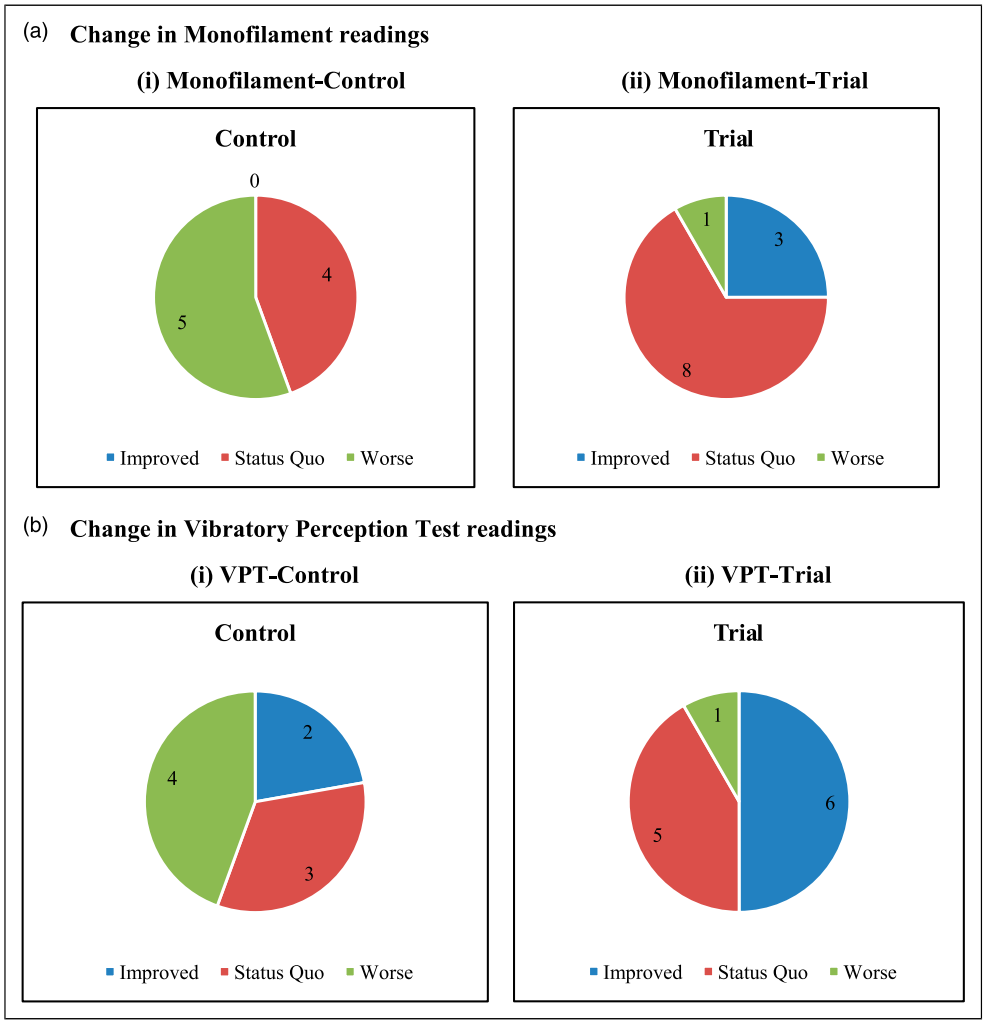

Figure 3. Change in sensory perception. a. change in Monofilament readings. 3a.(i) Monofilament-Control 3.a.(ii) Monofilament-Trial. 3b. Change in Vibratory Perception Test readings. 3b. (i) VPT-Control 3b.(ii) VPT-Trial.

Withdrawal/Lost to follow-up

There was one voluntary withdrawal from the study in the control group. The lost to follow up in the control arm was higher than the trial arm.

Discussion

Prior studies have noted the need for novel solutions for holistically managing DFUs and reversing DN. The current study provides evidence of Pranic Healing offering a solution for holistically managing DFUs and reversing DN. The results suggest that Pranic Healing could help in accelerating wound healing, lowering DFU grade, reversing DN, reducing stress and HbA1c levels when administered as an adjunct.

Results show a statistically significant reduction in the mean area of the wound in the trial groups compared to the control group that demonstrated an increase in the mean area of the wound at the end of the trial. More trial group participants showed reduction in size and severity of the ulceration and moved to a lower DFU Grade as compared to the control group. Even though the wounds had closed or improved to a lower Grade of DFU for 2 participants in the trial group, they were not assigned a lower grade at the end of the trial due to pre-existing bone deformity in the foot that could cause recurrence of the ulcer. A higher number of the trial group participants demonstrated improvement in sensory perception in the soles as compared to the control group. More participants reported reduction in stress and improvement in well-being and appetite in the trial group as compared to the control group. Average lowering of HbA1c was higher in the trial group as compared to the control group at the end of the trial.

During the course of the intervention, the energy bodies, meridians and *chakras* (energy centres) of the

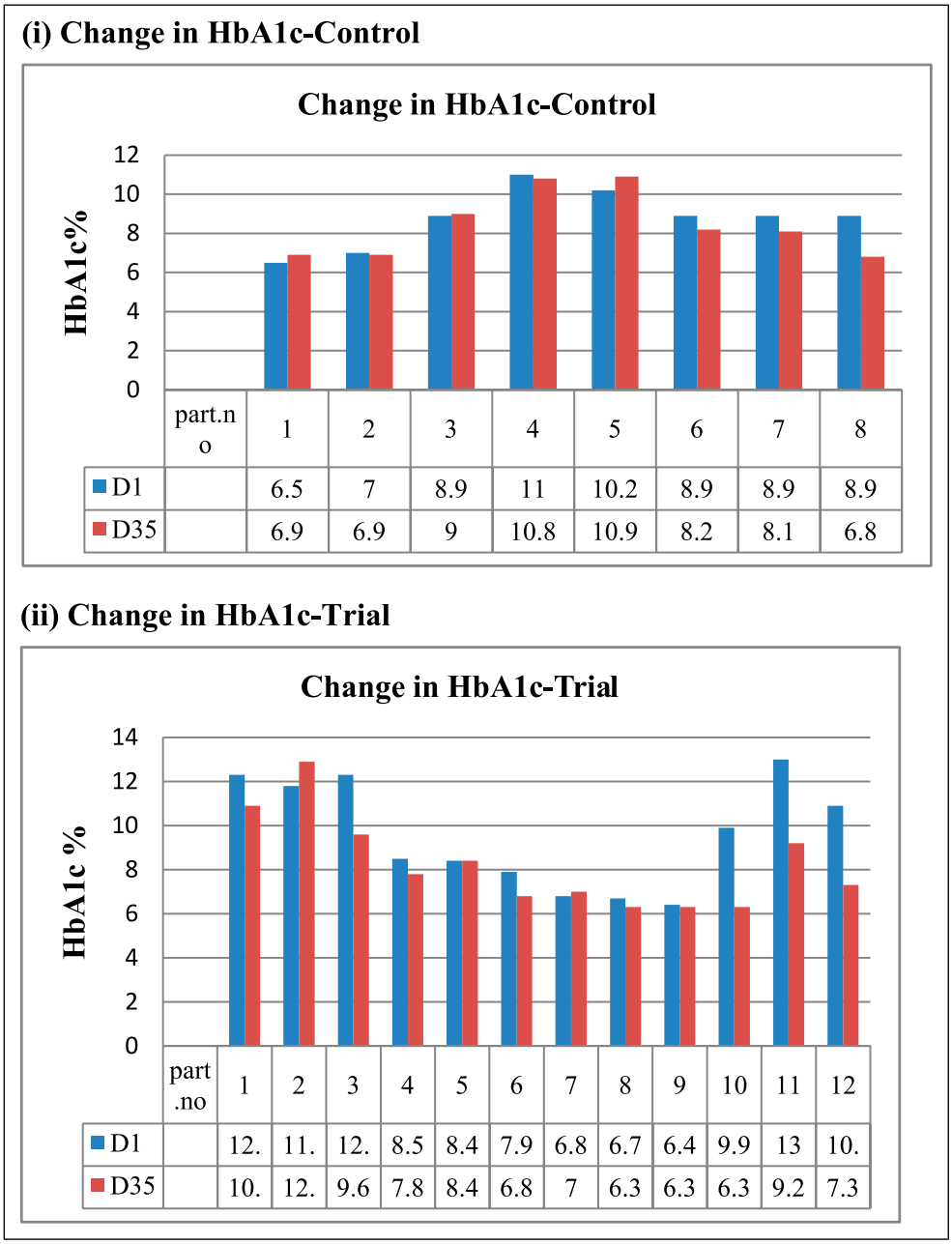

Figure 4. CHANGE in HbA1c LEVELS. 4(i) change in HbA1c-Control. 4(ii) change in HbA1c-Trial.

participants in the trial group grew cleaner, brighter and balanced. As the *chakras* were healed, the affected organs started functioning better e.g. organs in proximity to the solar plexus chakra ie, heart, liver, pancreas showed improved function; a cleaner a*jna chakra* ensured better regulation of insulin and cleaner sole *chakras* led to improved blood circulation in the soles. The DFUs improved with respect to size and nature of granulation tissue. There was reduction in periwound maceration, slough and discharge in the DFUs. The edges neared approximation, resulting in reduced wound size or closure of the wound. These improvements were interpreted through visual appearance and measurement of wound. Improved readings in both monofilament and Vibratory Perception Threshold test in the trial group suggest successful regeneration of nerves in the soles. Reduction in stress levels and improved well-being were assessed through a questionnaire.

Clinical evidence of the efficacy of Pranic Healing as a complementary therapy has been presented for regeneration of cells,[21] cancer,[22,23] musculoskeletal pain,[24] respiratory ailments[25] and depression.[26] Medical practitioners, who use Pranic

Healing as a complementary therapy, have provided scientific evidence of its benefits in areas of neurosurgery,[27] pain management in emergency department and acceleration of wound healing.[28] As early as 1988, evidence has been presented at various conferences about the benefits of *medical qigong* (energy) in healing carcinoma, immune functions, fractures, stress, psychosomatic, and other emotionally rooted disorders.[29] There is a need for proven cost-effective resources for diabetic care and its complications under standard clinical practices.[30] The results of the current study are in line with the previous studies and can serve to augment the clinical evidence of the efficacy of Pranic Healing as a cost-effective resource for diabetic care and its complications.

There were no adverse events in the study.

Strengths and Limitations of the Study

This study is the first Pranic Healing trial on diabetic subjects suffering from neuropathy. Strength of the study was that presence of co morbidities like cardiovascular conditions, chronic kidney disease, and varicose veins in many participants did not significantly affect the results. A limitation was the presence of bone deformities in the trial group participants, which might have slowed down the wound healing process to some extent.

Conclusions

Pranic Healing intervention as an adjuvant therapy can have efficacy in management of Diabetic Foot Ulceration. *If Pranic Healing techniques can be integrated into the holistic treatment of Diabetes and Diabetic Foot Ulcers, it can save many minds, pockets, limbs and lives.* The project is easily replicable and further large-scale clinical trials and continuous healing until neuropathy is completely reversed, should help in augmenting the results obtained in this study.

Data Availability Statement

(i) The dataset(s) supporting the conclusions of this article is available in the figsharerepository, Anuradha Nittur(2023): COMPDIAM Rawdata. figshare. Dataset. https://doi.org/10.6084/m9.figshare.22890758. (ii) The original protocol is available at ISRCTN17141223 https://doi.org/10.1186/ISRCTN17141223.

Appendix

List of Abbreviations

CAM	Complementary andAlternative Medicine
COPD	Chronic Obstructive Pulmonary Disease
CKD	Chronic Kidney Disease
CVD	Cardiovascular Disease
DFU	Diabetic Foot Ulcer
DN	Diabetic Neuropathy
DPN	Diabetic Peripheral Neuropathy
HBOT	Hyperbaric Oxygen Therapy
PAD	Peripheral Arterial Disease
PRPT	Platelet Rich Plasma Therapy
VAC	Vaccum Assisted Closure
VPT	Vibratory Perception Test

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Author's Contribution

The corresponding author and Principal Investigator Anuradha Nittur was responsible for the conceptualisation, design, and execution of the project.

The co-author Dr Pavan Belehalli, Clinician and Specialist Surgeon, helped in designing the study and identifying the outcome measures, assessment of wound bed, classification of wounds according to Wagner Scale and performed specialized clinical procedures on the participants and advised them to adhere to medical supervision.

Dr Raghavan Ganapathy, Certified Pranic Healer & Certified Pranic Healing Instructor, supervised the healings closely, suggested customised protocols and helped create the manuscript.

Mr Vinod Kumar Dorai took the photos in wound zoom camera and a cell phone and helped in measuring the size of the wounds in Image J software. He also helped in statistical analysis and representation of the data in graphs.

Mr Shivam Singhal, Independent Researcher paid the ISRCTN registration fee and helped in overall research and documentation.

Declaration of Conflicting Interests

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Ethical Approval

Ethical Committee approval was obtained from the IEC-KIER (Karnataka Institute of Endocrinology and Research) before the commencement of the trial. Ref: IEC-KIER 16/14.09.2019.

Informed Consent

Informed consent was obtained from all the participants in writing before including them in the study. Participants' approval/consent has been obtained for publication of results.

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Notes

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2. When specific colour prana are projected on the lungs, they are absorbed by the blood passing through the lungs, thus cleansing the blood, the blood vessels and the entire body.

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