

## **PROTOCOL SYNOPSIS**

### **Title of Research Study**

**“A Randomised, Comparative Study to assess the Efficacy of short term Pranic Healing as a Complementary Therapy in Diabetic Foot Ulcer Management in men and women in the age group of 25-75 (COMPDIAM)”**

### **Keywords**

Energy Healing, Pranic Healing, Diabetic Neuropathy, CAM in Diabetic Foot Ulcers

### **Introduction & Literature Review**

#### **Background**

Lifestyle changes and alterations in human behaviour in the last century have resulted in a dramatic increase in the incidence of diabetes worldwide. Diabetes mellitus (DM) is a chronic progressive metabolic disorder characterized by hyperglycemia mainly due to absolute (Type 1 DM) or relative (Type 2 DM) deficiency of insulin hormone. Type 2 diabetes mellitus (hereafter diabetes) is rapidly emerging as a major threat to global human health. The epidemic is chiefly of type 2 diabetes and also the associated conditions known as 'diabesity' and 'metabolic syndrome'. [1]

As per World Health Organization estimates, more than 346 million people worldwide suffer from DM. If there is no intervention, this number is likely to more than double by 2030. [2] Long term complications in Diabetes develop gradually. These complications might be in the form of depression, skin conditions, foot damage, neuropathy, retinopathy, nephropathy, cardio-vascular disease, hearing impairment, and Alzheimer's disease. [3] Other complications might include stress, insomnia, hypertension and many others. Common risk factors for vascular disease in people with diabetes, specifically type 2 diabetes, include hyperglycemia, insulin resistance, dyslipidemia, hypertension, tobacco use, and obesity. [4]

Diabetic foot ulcers (DFUs) are a serious complication of diabetes. DFUs can result in significant morbidity, mortality and healthcare expenditures. Diabetic Foot Ulcers leading to associated mortality is estimated at 5% in the first 12 months and 42% in the first 5-years of development of the Diabetic Foot Ulcer.[5]

As number of Diabetic patients is increasing, different chronic complications of diabetes are also increasing; Chronic Diabetic Foot Ulcer is one of the very important but most neglected complication of Diabetes. Foot ulcers in diabetic patients are not uncommon. Approximately 14% of diabetic ulcers lead to amputation & in most of the cases it is trivial foot ulcer which ultimately leads to amputation. More than 80,000 amputations are performed each year on diabetic patients in the United States, and around 50% of the people with amputations will develop ulcerations and infections in the contra lateral limb within 18 months. An alarming 58% will have a contra lateral amputation 3-5 years after the first amputation. In addition, the 3-year mortality after a first amputation has been estimated as high as 20-50%, and these numbers have not changed much in the past 30 years, despite huge advances in the medical and surgical treatment of patients with diabetes.[6]

Foot ulceration may lead to infections and lower extremity amputations, which are major causes of patient disability and often result in substantial morbidity, extensive periods of hospitalization, and mortality, as well as economic burden. An amputation occurs every 30 seconds throughout the world, and 85% of amputations are preceded by an ulcer. There have been instances of Chinese medicine –oral in the form of herbs and interventional in the form of acupuncture that have helped in treating DFU before the appearance and after the appearance of ulcers.[7 ]

Recent advances in management of DFUs include debridement, use of Hyperbaric Oxygen therapy (HBOT), Vacuum Assisted Closure (VAC), skin grafts, growth factors, gels, low level laser therapy, offloading etc. Metabolic control and vascular maintenance also play an important role in holistic management of the ulcers. [8]

Diabetic Neuropathic Foot Ulcer has been shown to be successfully healed through treatment by low-intensity laser therapy in some cases. The treatment was however not a monotherapy, but a part of holistic management of Diabetic foot ulcers.[9]

Complementary and alternative healthcare and medical practices (CAM) is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. Today, CAM practices may be grouped within five major domains: alternative medical systems, mind-body interventions, biologically-based treatments, manipulative and body-based methods and energy therapies. While the whole medical systems differ in their philosophical approaches to the prevention and treatment of disease, they share a number of common elements. These systems are based on the belief that one's body has the power to heal itself. Healing often involves marshalling multiple techniques that involve the mind, body and spirit. Treatment is often individualized and dependent on the presenting symptoms.[10] Among rural African Americans with diabetes, the most common alternative therapies used are prayer, diet-based therapies, and natural products. The participants' descriptions enhance our understanding of CAM use among rural African Americans with diabetes.

Research into CAM use by people with diabetes is limited. Research into the extent of CAM use, why and how it is used, and disclosure of use to healthcare professionals is vital as results could help to improve communication between healthcare professionals and patients and assist in planning better self-management strategies for patients.[11] In the article *Energy Therapies and Diabetes Mellitus*, Diana W. Guthrie, and Maureen Gamble explain how people with diabetes require multiple interventions to reach their glycemic goals. At present, these therapies have few known side effects and many potential benefits. However, as with all unproved therapies, they should be approached with caution. Massage, TT, HT, Reiki, and other types of relaxation therapies, when used in individuals with diabetes, should be accompanied by appropriate blood glucose monitoring and with alterations in diabetes treatment medication(s) when blood glucose levels become lower as pain and discomfort decrease. Catecholamines such as epinephrine and norepinephrine, when released by the body in response to the use of an energy therapy, increase lipolysis and thermogenesis, resulting in increasing energy expenditure and potential for weight change. Clearly, more studies are needed to specifically address the effects of these

various energy therapies on various diabetic populations. Initial research findings and a long history of use in some cultures indicate some measure of safety and promise that energetic approaches may offer the potential for improved healing and for attaining and maintaining a regimen that leads to improved methods and support of glycemic control.[12] It can thus be concluded that the potential for the use of energy-based therapies in T2DM is immense.

Diabetes requires active management of lifestyle, diet, exercise and medication. Energy healing has been shown to aid in stress and lifestyle management, and is also actively being used as a complimentary therapy in various serious conditions. Pranic Healing is an energy healing modality; a no touch, no drug therapy working on the energy centres of the patient to increase the body's chances of self recovery.

Randomized controlled trials (RCTs) have an important place in the assessment of the efficacy of complementary and alternative medicine (CAM). However, they address only one, limited, question, namely whether an intervention has-statistically-an effect. They do not address why the intervention works, how participants are experiencing the intervention, and/or how they give meaning to these experiences. The addition of qualitative research methods to RCTs can greatly enhance understanding of CAM interventions.[13]

Earlier studies in Pranic Healing by Srikant N Jois et al, titled “[Amelioration of mild and moderate depression through Pranic Healing as adjuvant therapy: randomised double-blind controlled trial](#)” have shown that Pranic Healing treatment has a beneficial effect on patients suffering from mild and moderate depression.[14] In another pilot study by the same researcher, Srikant N Jois, titled “*Ameroliation of quality of life and lung function of chronic obstructive pulmonary disease by pranic healing as adjuvant therapy*” the conclusion was that PH as an adjunct to conventional treatment can improve lung function and quality of life of COPD subjects.[15] In another study conducted by Dr B. Chendil Nathan MCh, DNB, FRCS – Neurosurgeon, Apollo Hospitals, Chennai, namely, *Therapeutic Effects of Pranic Healing in Neurosurgery* shows that Pranic Healing enables surgery to be easier for surgeons as well as patients. Pranic Healing reduces pain, blood loss, ICU and hospital stay, faster wound healing, improved neurological outcomes and

overall improvement of daily living/quality of life.[16] In yet another study(Case Study), “*Pranic Healing in Advanced Stages of Cancer: Case Studies*” undertaken by Telma Torres, RN - Sao Paulo Area, Brazil, Integration of Pranic Healing in patients with breast cancer showed a decrease in negative symptoms; (2) Integration of Pranic Healing in patients undergoing chemotherapy with Leukemia showed a decrease in negative symptoms, including weight loss and hair loss; (3) Integration of Pranic Healing in patients with Hodgkins Lymphoma revealed positive outcomes; (4) Integration of Pranic Healing in patients with Non-Hodgkins Lymphoma revealed positive outcomes and possible faster remission rates.“*Pranic Healing in Assisting Couples with Infertility*” was a study carried out by Andrea Rodriguez Roca JD, PhD - Santa Cruz, Bolivia. In this study the integration of Pranic Healing markedly improved positive outcomes in assisting couples with infertility and in pregnant females with high-risk pregnancies.[17]

In a study undertaken by Koji Tsuchiya and Hiroshi Motoyama on a cancer patient, in four Pranic Healing sessions of 60 minutes each, significant changes were observed in the energy levels (38% increase), activity of the parasympathetic nervous system (that is more conducive to the innate healing process of the body to occur), and the immune function capacity in the very first healing session. Chi or energy was measured as electro dermal measurements at specific acupuncture points. [18]

Although energy medicine represents only a small fraction of 1% of the \$2.2 trillion healthcare industry in the US, 6 properties of energy medicine give it strengths that could augment conventional health care models. These include the ways energy medicine (1) can address biological processes at their energetic foundations (reach), (2) regulates biological processes with precision, speed, and flexibility (efficiency), (3) fosters health and prevents illness with interventions that can be readily, economically, and noninvasively applied (practicality), (4) includes methods that can be used on an at-home, self-help basis, fostering a stronger patient-practitioner partnership in the healing process (patient empowerment), (5) adopts non-linear concepts consistent with distant healing, the healing impact of prayer, and the role of intention in healing (quantum compatibility), and (6) strengthens the integration of body, mind, and spirit, leading not only to a focus on healing, but to achieving greater well-being, peace, and passion for life (holistic orientation).[19]

## **Risk Assessment**

### **Known Potential Risks**

Pranic Healing has not been known to have any major potential risks till date.

### **Known Potential Benefits**

Pranic Healing complimentary therapy has been known to aid in the holistic management of various chronic conditions, especially Diabetes.

Immediate potential benefits would be reduced stress levels, better emotional, physical and mental health. Other benefits would include management of Diabetic Foot Ulcers, Blood sugar levels and Hypertension .

Long term benefit potential would include increased ability of the body to heal itself, thus reducing risks of associated conditions and also reducing the blood sugar levels in patients suffering from Diabetes.

## **Objectives and End Points**

The present Pilot project will be undertaken by the researcher to authenticate the findings that short term Pranic Healing intervention (a no touch, no drug, energy based healing modality) can play a complimentary role in managing Diabetic Foot Ulcers, Hypertension, and sugar levels among patients suffering from diabetes. The study would be a randomised, double blind, comparative study among Diabetic patients.

## **Research Question/ Hypothesis:**

*Can short term Pranic Healing intervention play a significant role in providing complimentary therapy for managing Diabetic Foot Ulcers in patients suffering from diabetes?”*

**H0:** *Short term Pranic Healing intervention cannot play a significant role in providing complimentary therapy for managing Diabetic Foot Ulcers in patients suffering from diabetes.”*

**H1:** *Short term Pranic Healing intervention can play a significant role in providing complimentary therapy in managing Diabetic Foot Ulcers in patients suffering from diabetes”*

The goals of the proposed research would include substantiating already known facts about Pranic Healing with empirical data. Pranic Healing is not only an effective, simple, and inexpensive form of healing therapy but is also the safest and the most practical. The mind, emotions and life experiences affect one's constitution. Severe stress or tension, in the long run causes the solar plexus chakra and other chakras to malfunction. The ajna chakra controls the endocrine system. The crown chakra and forehead chakra control and energize the pineal gland. The ajna chakra controls and energizes the pituitary gland. The solar plexus controls and energizes the pancreas. The thymus gland affects the heart, blood pressure, throat, thyroid gland, parathyroid glands and the organs inside the head. Blood pressure can also be lowered by cleansing and energizing the heart chakra and the thymus gland with light whitish green, then ordinary light whitish violet. By working on the invisible energy centres and energy body of the patients, the healer would be able to bring about positive changes in the patients.

In the current study, 15 male and female patients with Diabetic Foot Ulcers of Wagner Scale 1-3 will be given Pranic Healing treatment remotely along with standardised medical care at Karnataka Institute of Diabetology, Bangalore. Pranic Healing treatment will be provided under the supervision of a qualified medical doctor. Expected outcomes would be Improvement in condition of Diabetic Foot Ulcer, stable or lowered Hypertension, stable blood sugar levels, improved emotional capabilities.

### **Expected Outcomes:**

The outcome measures would be improvement in the condition of Diabetic Foot Ulcer, Blood Pressure recordings, blood sugar and stress levels. The readings of previous two HbA1c will be recorded at the time of recruitment. The participant will be examined for the DFU, Blood pressure and pulse at the beginning and DFU, BP, pulse and HbA1c end of the study.

### **Primary Outcome:**

- Improvement in the size and severity of DFU with stable dose of medicines (diabetic) and optimum dressings and wound care.
- The blood pressure is expected to be stable or even reduce in the experimental population being monitored by the researcher.
- Stress is expected to reduce.
- HbA1c readings would also be expected to be either stable or show a lower reading.
- Other attributes like emotional well-being, physical strength, immunity and general well-being are also expected to improve.

### **End Points**

- 5 % improvement in the size, granulation and depth of DFU with stable dose of medicines (diabetic) and optimised dressing.

### **Secondary Outcomes:**

- Reporting of improved emotional, mental and physical conditions
- Stabilization /improvement in blood pressure levels.
- Stabilization /improvement in blood sugar levels.

### **Methodology:**

**A Randomised, Double Blind Study**



The study will be conducted at Karnataka Institute of Diabetology, Bangalore on 30 patients. Men and women in the age group of 25-75, suffering from Wagner grade 1-3 Diabetic Foot Ulcers will be part of the study group. In addition to the standardized medical care, 15 patients will be given no touch, no drug, Pranic Healing treatment over a period of 4 weeks. Results will be compared with the control group of 15 patients who will not receive Pranic Healing treatment, but will only be on standardised medical care. Regular Pranic Healing treatment will be carried out remotely six days a week for a continuous period of 5 weeks on the randomised experimental group of 15 patients. Pranic Healing sessions of 50 minutes each to address Diabetes, healing of wounds and stress will be carried out distantly at one particular time on every subject in the trial group. A team of 10 healers will work on all the 15 patients, so each healer will carry out healing on every subject at some point in the study. Confirming factors would be constant dietary patterns including constant salt intake and physical exercises (or lack of exercises) during the period of study.

The subjects and the Clinician would be blinded and not know which subject is undergoing the Pranic Healing intervention and which one is not. This will reduce the bias in the results that would otherwise have been influenced by factors not related to the Pranic Healing intervention.

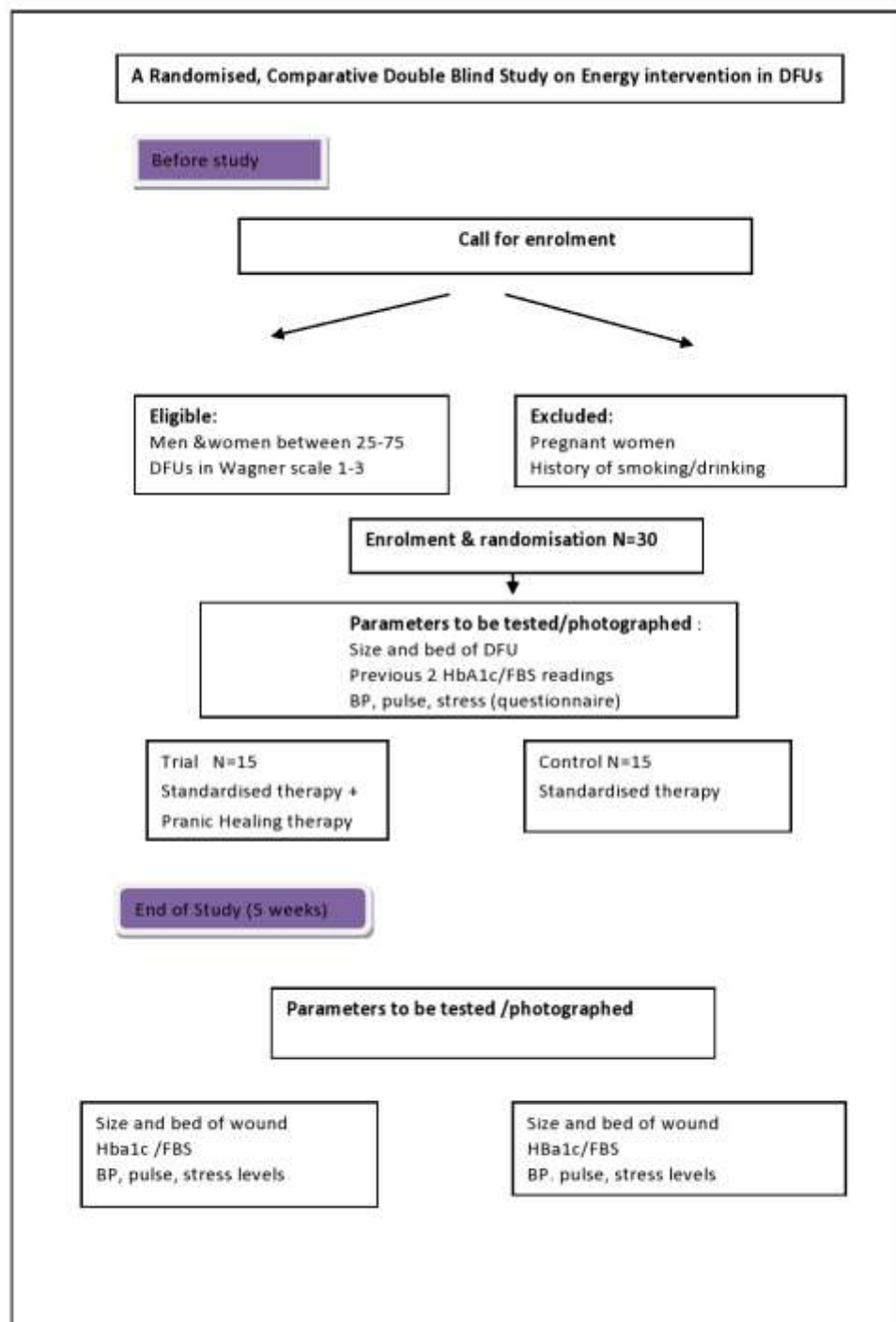


Fig-1 METHODOLOGY- COMPDIAM- A Randomised, Double Blind Study

Changes in major organs and chakras will also be noted during the course of the research. Alterations in the mood/emotions of the patient will also be noted in the standard questionnaire.

The Pranic Healing protocol for treatment of Diabetes and healing of wounds would be a customised one with steps taken from the protocols from the book Advanced Pranic Healing by Grand Master Choa Kok Sui(pg 82-90,225-230). The frequency of healings would be six times a week. The Pranic Healing protocol for stress would be from the book Pranic Psychotherapy by Grand Master Choa Kok Sui page 60,61.

### **Design and Statistical Considerations**

Statistical analysis would be based on Independent t test .

**Study Duration: Two months**

**Participant Duration: Four weeks**

**Timeline: Statement of project start date, key milestones, and completion date.**

Estimated start date of project: September 2019

Estimated Completion Date: November 2019

### **Study Population**

The Study population would consist of males and females –literate or semi-literate, married or single in the age group of 25-75 years, across economic and social backgrounds. Patients willing to participate in the study would be required to fill in the consent forms for screening and participation in the study.

### **Inclusion Criteria**

The selection criteria for patients would be men and women in stable health in the age group of 25-75 yrs, married or single, with DFU in Wagner scale of 1-3.

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and availability for the duration of the study
3. Males and Females aged between 25-7 yrs
4. In general good health as evidenced by medical history.
5. With DFU in Wagner scale of 1-3
6. Willingness to adhere to the Pranic Healing intervention regimen
7. Agreement to adhere to Lifestyle Considerations (see section 5.3) throughout study duration

### **Exclusion Criteria**

Pregnant women and patients in unstable health, including smokers, alcoholic patients and patients with other addictions will be excluded.

### **Lifestyle Considerations**

During this study, participants will be asked to adhere to the following:

- No changes in diet will be allowed during the study period of four weeks. Any change in diet of the participant will be made in consultation with the PI or CI.
- Refrain from additional consumption of red wine, Seville oranges, grapefruit or grapefruit juice, mangoes from the start of study intervention until after the final dose.
- Abstain from joining gym, yoga, zumba, aerobics classes, and strenuous exercise during the period of study. Subjects may participate in light recreational activities during studies (e.g., watching television, reading).

- In case participants are already enrolled in gym, yoga, zumba, aerobics classes or carry out strenuous exercises as a daily routine, they will be asked to continue with the same.
- Minimize interactions with household contacts who may be immunocompromised

### **Screen Failures**

Participants who consent to participate in the clinical trial, but do not meet one or more criteria required for participation in the trial during the screening procedures, will be considered screen failures.

### **Strategies for Recruitment And Retention**

Diabetic subjects visiting the Karnataka Institute of Diabetology regularly will be informed about the possibility of participating in study. Those subjects who are self-referred will also be recruited into the study if they meet the inclusion criteria.

The anticipated number of willing participants to be screened might be twice the actual number to be inducted i.e. 60.

All 30 participants would be enrolled from Bangalore only.

### **Source of participants:**

Karnataka Institute of Endocrinology & Research, Bangalore will be the source of participants. Subjects who are self-referred will also be recruited into the study if they meet the inclusion criteria.

There will be no incentives for participants.

### **Study Intervention**

### **Study Intervention Administration**

### **Study Intervention Description**

Pranic Healing, a no touch, no drug therapy works at the physical, emotional, mental and spiritual levels. It integrates meditations, forgiveness techniques and healing

modalities to bring about a holistic change in the life of the subjects. The treatment/healing process involves removal of used up or diseased energy and infusing fresh revitalizing *prana* readily available from the sun, air and Mother earth to transform, balance and harmonize the body's energy processes.

In the current study, 15 patients with DFU in Wagner scale of 1 and 2 will be provided Pranic Healing treatment along with standardised medical care and 15 men and women with the same conditions will be provided only standardised medical care at Karnataka Institute of Diabetology. Pranic Healing treatment will be given under the supervision of a qualified medical doctor.

### **Dosing and Administration**

In addition to the standardized medical care, 15 patients from the treatment group will receive no touch, no drug, Pranic Healing treatment remotely six days a week for a continuous period of 5 weeks. The control group of 15 patients will not receive Pranic Healing treatment, but only standardized medical care over the period of four weeks. Each Pranic Healing session will last for around 50 min.

### **Measures To Minimize Bias: Randomization**

The participants would be allocated to the group after simple randomization. Computer generated random numbers will be used to allot the group i.e treatment group or control group to the participant. The ratio between intervention and control groups would be 1:1.

### **Study Intervention Compliance**

#### **Concomitant Therapy**

The participants will continue with their concomitant therapy. If the Clinician observes a marked change in any of the parameters during the course of the investigations that are a part of or independent of the study, he will recommend an altered dose of the concomitant therapy. This will be noted in the Case Report Forms.

### **Participant Discontinuation/ Withdrawal**

Participants may withdraw voluntarily from the study or the PI may discontinue a participant from the study.

**Participants are free to withdraw from participation in the study at any time upon request. An investigator may discontinue or withdraw a participant from the study for the following reasons:**

- Significant study intervention non-compliance:
- If any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant
- Disease progression which requires discontinuation of the study intervention
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation
- Participant unable to receive Pranic Healing for more than one week.

The reason for participant discontinuation or withdrawal from the study will be recorded on the Case Report Form (CRF). Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention for more than two weeks, and subsequently withdraw, or are withdrawn or discontinued from the study, shall not be replaced.

### **Lost To Follow-Up**

The following actions will be taken if a participant fails to return to the clinic for a required study visit:

- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record or study file. • Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

### **Study Assessments and Procedures Efficacy Assessments**

The participants will be screened and tested for the following readings as per the attached timeline.

1. Physical Examination- to include BMI, BP, Pulse.
2. Wagner Scale grading of DFU
3. Pre/prior Medical Records – record of medical history + medication in last 2 years.
4. Administration of questionnaires for patient-reported outcomes, such as a daily diary.

### **Expected Study Outcomes**

1. Accelerated wound healing and change in grade of wound on Wagner scale
2. Overall well being and reduction of stress
3. Improved sensation in soles
4. Lowered glycemic levels

### **Referral and recruitment process**

As Karnataka Institute of Endocrinology and Research/ Karnataka Institute of Endocrinology & Research has well-established clinical referral services, subjects will be recruited from Karnataka Institute of Diabetology. Diabetic subjects visiting the Centre regularly will be informed about the possibility of participating in the study. Those subjects who are self-referred will also be recruited into the study if they meet the inclusion criteria. Participants will also be recruited through established community connections of Karnataka Institute of Diabetology.

### **Permissions and Consent forms:**

Informed consent of the patients enrolling in the study project would be obtained after explaining the benefits and the modality of Pranik Healing. Their consent would also be obtained for using the analysed data for research purposes.

### **Adverse Events**

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)).]

#### **Serious Adverse Event**

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.



### **Classification of Adverse Events:**

- ✓ Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- ✓ Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- ✓ Severe – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.
- ✓ Serious - " if, in the view of either the investigator or Clinician, the event results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

### **Relationship to study intervention**

- ✓ Related – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE
- ✓ Not Related – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.
- ✓ Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event,

including an abnormal laboratory test result, occurs in a plausible time relationship to study intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study intervention (dechallenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory rechallenge procedure if necessary.

- ✓ Probably Related – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event, including an abnormal laboratory test result, occurs within a reasonable time after administration of the study intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfill this definition.
- ✓ Potentially Related – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after administration of the trial medication). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as “possibly related” soon after discovery, it can be flagged as requiring more information and later be upgraded to “probably related” or “definitely related”, as appropriate.
- ✓ Unlikely to be related – A clinical event, including an abnormal laboratory test result, whose temporal relationship to study intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study intervention) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- ✓ Not Related – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician.]

In case of any adverse event, the participant will be referred to the OPD at Karnataka Institute of Diabetology and provided consultation.

In case of Severe Adverse Event (SAE), the participant will be referred to either of the following, where Dr Pawan Belehalli is a Consultant:

1. Karnataka Institute of Endocrinology and Research
2. Sri Jayadeva Institute

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution. Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

The study clinician will immediately report to the PI any serious adverse event, whether or not considered study intervention related, including those listed in the protocol or investigator brochure and must include an assessment of whether there is a reasonable possibility that the study intervention caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship.

In that case, the investigator must immediately report the event to the sponsor. All serious adverse events (SAEs) will be followed until satisfactory resolution or until the site investigator deems the event to be chronic or the participant is stable.

### **Unanticipated Problem Reporting**

- Unanticipated Problems that are serious adverse events (SAEs) will be reported to the IRB within 24 hrs of the investigator becoming aware of the event.
- Any other UP will be reported to the IRB within 48 hrs of the investigator becoming aware of the problem.

### **Expected Timeline for Enrolment: 2 months**

### **Role of Principal Investigator:**

The Principal Investigator, Anuradha Nittur will be responsible for overall conceptualization, preparation and presentation of the proposal, coordination of the project and publication in various journals. Areas of Expertise include Writing, Editing, Research, Ideating new ways of spreading Pranic Healing. Pranic Healing qualifications include Basic, Advanced, Pranic Psychotherapy, AOHS, AY prep, Crystal, PSD, ACPH, Kriyashakti.

The Co investigator, Dr Pawan Belehalli, is an experienced Surgeon and Podiatrist with 10+ years of experience in treating patients with Diabetic Foot Ulcers. He also has extensive experience in Consultation, Teaching and Research. He will be the Consultant Doctor and attend to and help document any adverse event, Severe Adverse Event and Unanticipated problem in the Pilot project.

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