

Energy healing intervention as complementary therapy in diabetic foot ulcers

Submission date 09/02/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/02/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/03/2025	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Nerve damage (diabetic neuropathy), is common in some Diabetic patients suffering from Diabetes for a long time. Nerve damage can lead to numbness, pain and weakness in the affected area of the body. Neuropathy in the soles of the feet is more common than anywhere else. The wounds developed in the soles of Diabetic patients are termed as Diabetic Foot Ulcers (DFUs). Diabetic Foot Ulcers can be treated through conventional methods but might keep recurring due to the loss of sensation in the soles. Diabetic Neuropathy is not easily treated in conventional therapies and needs holistic management of the metabolic disorder itself and possible regeneration of nerves in soles of patients suffering from Diabetic Neuropathy and Diabetic Foot Ulcers.

The objective of the study is to clinically establish the role of energy (Pranic) healing as complementary therapy in the management of Diabetic Foot Ulcers (DFUs) in Wagner classification Grade 1 - 3. Wagner scale classifies the wounds depending on their depth and severity. A lower grade implies a superficial wound and a higher grade implies a wound that had gone deep.

Who can participate?

Diabetic patients (men and women) in the age group of 25 - 75 years, visiting the super-speciality referral centre and presenting with Diabetic Foot Ulcers in Wagner scale 1-3 can enrol for the study. Pregnant women and smokers will be excluded.

What does the study involve?

The study involves Pranic healing treatment as complementary therapy in the management of Diabetic Foot Ulcers (DFUs) in Wagner classification Grade 1-3. Half of the participants recruited will be allocated to the trial group i.e Pranic Healing intervention along with standardised medical care for Diabetes and optimum wound care. The other half will be allocated to the control group; i.e. not receive Pranic healing as a complementary therapy, but only receive medical care for Diabetes and optimum wound care.

Pranic Healing protocols for Diabetes Type-2 and local wound healing and regeneration of nerves in the soles and Psychotherapy for stress will be undertaken for the participants in the trial group.

What are the possible benefits and risks of participating?

The possible benefits of enrolling in the study are accelerated wound healing in terms of size and area of the wound, wound bed appearance, sensory changes in the soles, better glycemic control and reduced stress.

There has been no side effect of energy (Pranic) healing to date.

Risks:

- Thrombosis/ other complications while drawing blood for tests
- Infection of wound, high blood sugar levels, cardiovascular complications
- Patients not following instructions and assuming that the intervention is supposed to replace the conventional treatment

Where is the study run from?

Karnataka Institute of Endocrinology & Research (India)

When is the study starting and how long is it expected to run for?

September 2019 to November 2019

Who is funding the study?

Part funded and under technical support from Pranic Healing Research Institute, New Jersey (USA)

Who is the main contact?

Anuradha Nittur

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A randomised, double-blind, comparative pilot 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

Acronym

COMPDIAM-DFU

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/09/2019, Institutional Ethical Committee, Karnataka Institute of Endocrinology & Research (KIER) (SJICR Campus , Bannerghatta Road, 9th Block, Jayanagar, Bengaluru-560069, India; +918026647222; ieckier2017@gmail.com), ref: IEC-KIER 16/14.09.2019

Study design

Randomised, double-blind, comparative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See <https://drive.google.com/drive/folders/120trMumZMmCHBYtcGAD1z9NPKjfQe5uJ?usp=sharing>

Health condition(s) or problem(s) studied

Diabetic foot ulcers, stress, and nerve regeneration in soles in diabetic patients

Interventions

Pranic Healing protocols for Diabetes Type-2, local wound healing and regeneration of nerves in the soles and Psychotherapy for stress will be followed. Participants will be randomly selected, informed and assigned to the trial or control (no treatment) group as per a computerised random table.

The subjects in the trial group will be provided complimentary healing in the form of Pranic Healing - a no-touch, no-drug energy healing modality every day for 50 - 60 minutes along with standardised wound care and medication for diabetes and co-morbidities for five weeks.

Intervention Type

Other

Primary outcome measure

1. Size and severity of Diabetic Foot Ulcer measured using pictures of the wounds taken on recruitment and at the end of the trial and wound area compared either through the wound zoom camera or using Image J software which will be examined by the clinician and measurements and characteristics noted at recruitment and end of the trial
2. Improved sensation in soles measured through Monofilament and Vibratory Perception Threshold tests using last available reading before the start of the trial and measured at the end of the trial
3. Stress, general well being and appetite measured by means of a questionnaire administered at the end of the trial

Secondary outcome measures

Glycemic level measured through Hba1c or FBS tests using last available reading before the start of the trial and measured at the end of the trial

Overall study start date

08/08/2019

Completion date

16/11/2019

Eligibility

Key inclusion criteria

1. Men and women in the age group of 25 - 75 years
2. Presence of diabetic foot ulcers in Wagner grade 1 - 3

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Total final enrolment

30

Key exclusion criteria

1. Pregnant women
2. Smokers

Date of first enrolment

16/09/2019

Date of final enrolment

12/10/2019

Locations

Countries of recruitment

India

Study participating centre**Karnataka Institute of Endocrinology & Research**

Sri Jayadeva Institute of Cardiovascular Sciences and Research Campus

Bannerghatta Road

9th Block

Jayanagar

Bangalore

India

560069

Sponsor information

Organisation

Center for Pranic Healing

Sponsor details

420 Valley Brooke Avenue

Lyndhurst

New Jersey

United States of America

07071

+1 512-953-7474

info@PranicHealingResearch.com

Sponsor type

Other

Website

<https://www.pranichealingresearch.com/>

ROR

<https://ror.org/02y4rar07>

Funder(s)

Funder type

Research organisation

Funder Name

Pranic Healing Research Institute, New Jersey

Results and Publications

Publication and dissemination plan

Plan to submit the report of the Pilot project for publication as soon as the registration is complete. The report is ready to be submitted in relevant peer reviewed journals.

This will hopefully be followed by a full fledged Clinical Trial.

The results of the pilot project will be shared in relevant medical Conferences and workshops.

Intention to publish date

15/02/2020

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

The details of the participants is available on Mendley datasets (public repository).

COMPDIAM-DFU -patient details - Mendeley Data: <https://data.mendeley.com/datasets/hrtx5gjp5x>

IPD sharing plan summary

Stored in publicly available repository, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			24/02/2020	No	No
Basic results		17/08/2020	17/08/2020	No	No
Basic results	reanalysed results version 2	06/09/2021	06/09/2021	No	No
Dataset			26/06/2023	No	No

[Results article](#)

23/10/2023

18/03/2025

Yes

No