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Energy healing intervention as complementary therapy in diabetic foot ulcers

Submission date
09/02/2020

Recruitment status
No longer recruiting

Registration date
18/02/2020

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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:
• Thromobosis/ 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?
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised, double-blind, comparative study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

ROR
https://ror.org/02y4rar07

Funder(s)

Funder type
Research organisation

Funder Name
Pranic Healing Research Institute, New Jersey

Results and Publications

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?
Results article		23/10/2023	18/03/2025	Yes	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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			24/02/2020	No	No