SECTION A

Proposal ID 2022-1349

Title of the Project: Prediction and Management of Diabetic neuropathy in Urban, Rural and Tribal people of Raigad District, Maharashtra: The Foot-MaP study

State the:

3.1 Major area/ Discipline: Diabetes

3.1 Sub-area / Discipline: Prediction and Management of Diabetic neuropathy

4. Category of project:

5. In case of clinical/ humans-based study, whether statistical calculation was made for sample size calculation or not – Yes

6. Name the person(s) who conceived and planned this project (If any research student other than PI and Co-PI is involved in conceiving, planning or any stage of proposal formulation, kindly enlist his/her name. In case of violation of Intellectual Property Right, PI may be black listed or appropriate action may be taken):

Dr Rajani Mullerpatan

7. Name the person(s) who designed this project (If any research student other than PI and Co-PI is involved in conceiving, planning or any stage of proposal formulation, kindly enlist his/her name. In case of violation of Intellectual Property Right, PI may be black listed or appropriate action may be taken):

Dr Rajani Mullerpatan

8. Name and Designation of:

i) Principal Investigator with complete postal address, Mobile No., Telephone/ Fax No. and Email

Dr. Rajani Prashant Mullerpatan, Professor-Director
MGM Institute of Health Sciences, MGM School of Physiotherapy, Plot no 1 and 2,
Navi Mumbai. Taluka Panvel Raigad, Maharashtra-410209
Mobile no: 9920048476
Email ID: rajani.kanade@gmail.com

ii) Co-Principal Investigator (s) with complete postal address, Mobile No., Telephone/ Fax No. and Email:

1.Professor Ravi. B

IIT Bombay, Powai, Mumbai 400 076, Maharashtra Department of Mechanical Engineering

Email: b.ravi@iitb.ac.in

Phone: 022-25764399

2. Mr Nishant Kathpal, Director

Ayati Devices Private Limited, Indian Institute of Technology Bombay, Centre of Studies in Resources Engineering, CM08, 3rd Floor, Powai, Mumbai, Maharashtra-400076

Mobile no: 8297109010

Email ID: nishant.kathpal@ayatidevices.com

iii) Statistician (Co-PI) with complete postal address, Mobile No., Telephone/ Fax No. and Email (In case of clinical / humans-based study)

Dr. Maninder Singh Setia, Professor

MGM Institute of Health Sciences, Plot no 1 and 2, Navi Mumbai. Taluka Panvel Raigad, Maharashtra -410209

Mobile no: 8976062646

Email ID: maninder.setia@karanamconsultancy.in

9 . State the nature of Host Institute: Private

10. Whether host institute is DSIR certified: Yes

11. Duration of Research Project: 36 months

ii)Period which may be needed for collecting the data: 24 months

iii) Period that may be required for analysing the data: 12 months

12.Amount of grant-in-aid asked for (details are to be furnished in Section B)

SN	Item Head	1st Year (in Rs.)	2nd Year (in Rs)	3rd Year (in Rs)	Grand Total (in Rs.)
1.	Staff	1249680.00	1249680.00	1630680.00	4130040.00
2.	Recurring	2900000.00	877500.00	125000.00	3902500.00
3.	Non recurring (equipment)	2240000.00	76000.00	-	2316000.00
4.	Contingencies	220000.00	200000.00	900000.00	1320000.00
5.	Travel	1000000.00	1000000.00	500000.00	2500000.00
6.	Overhead charges	760968.00	340318.00	315568.00	1416854.00
	Grand Total	8,370,648.00	3,743,498.00	3,471,248.00	**15,585,394.00**

13. Institution responsible for the research project i) Name Postal address ii) Telephone iii) e- mail iv) Fax No.

Name Postal address: MGM Institute of Health Sciences, Plot no 1 and 2, Navi Mumbai. Taluka Panvel Raigad, Maharashtra-410209

Telephone: 02227437866

Email: mgmschoolofphysiotherapy@mgmsopnm.edu.in

14. In case of Inter-sectoral research projects: i. Name(s) of the Institution (s) / Agencies ii. Whether contributed financially iii. Amount / Budget contributed for this project

Ayati Devices Private Limited, Indian Institute of Technology Bombay, Centre of Studies in Resources Engineering, CM08, 3rd Floor, Powai, Mumbai, Maharashtra-400076.

Mobile no: 8297109010

Email ID: nishant.kathpal@ayatidevices.com

15. Is radio tagged material proposed to be used in the project either for clinical trials or experimental purposes? If so, clearance from Nuclear Medicine Committee, Bhabha Atomic Research Centre, Mumbai, indicating should be attached :

Not applicable

16. Projects involving recombinant DNA/Genetic engineering work should be examined and certificate by the Institutional Biosafety Committee (IBSC) to be enclosed. Guidelines for constitution of IBSC can be obtained from Secretary, Department of Biotechnology, CGO Complex, Lodhi Road, New Delhi-110003.

Not applicable

17. The Institution where the study is being done should ensure that there is no financial conflict of interest by the investigators

No Conflict of Interest

18. Whether your institution (private / NGO) is registered with Department of Scientific and Industrial Research (DSIR), Government of India/ Department of Health Research (DHR) as a health research institute. If yes, certificate from DSIR/ DHR should be attached. Yes, attached

19. Details of documents to be submitted for completing of coda formalities:

S.N.	Title of documents to be required	If submitted yes, pleasetick	Details of document
1.	Institutional Ethical Clearance* and projectApproval Certificate (Necessary documents indicating institutional ethical clearance must be enclosed for research involving human subjects as also animal experiments) Guidelines for IEC for animal experiments should follow CPCSEA requirements and for human studies should follow ICMR guidelines). ** Mandatory at the time of submission of proposal*	Yes √	Ref. MGMIHS/RES./02/2022/326
2.	Declaration and AttestationForm	Yes √	Document uploaded on GIA proposal submission site

3.	Undertaking for staff recruitment	Yes √	Document uploaded on GIA proposal submission site
4.	Mandate Form	Yes √	Document uploaded on GIA proposal submission site
5.	Cancelled cheque	Yes √	Document uploaded on GIA proposal submission site
6.	Name of the Statutory Auditor of the Host Institute (Panel number in case of	Yes √	Document uploaded on GIA proposal submission site

MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Accredited by NAAC with 'A++' Grade
Sector – 1, Kamothe, Navi Mumbai - 410 209
Tel 022-27437622, 022-27437607, Fax 022 - 27431094
E-mail :research@mgmuhs.com; Website : www.mgmuhs.com

Proposal ID: 2022-1349

Title of Research Proposal: Prediction and Management of Diabetic neuropathy in Urban, Rural and Tribal people of Raigad District, Maharashtra: The Foot MaP study

Declaration & Attestation

1. We have read the terms and conditions for DHR Research Grant. All necessary Institutional facilities and support will be provided if the research project is approved for financial assistance.
2. We agree to submit within one month from the date of termination of the project the final report and a list of articles, both expendable and non-expendable, left on the closure of the project.
3. We agree to submit audited statement of accounts duly audited by the auditors as stipulated by the DHR.
4. It is further certified that the equipment(s) required for the project have not been purchased from the funds provided by DHR for another project(s) in the Institute.
5. We agree to submit all the raw data (along with descriptions) generated from the project to the DHR within one month from the date of completion/termination of the project. Further, all conditions stipulated in the sanction will be strictly complied with.
6. Actual Date of start of the project as indicated in the Sanction Order or inability to start the project on the specified date will be intimated to DHR positively within one week by registered post/ speed post as well as by email.
7. We hereby certify that the research proposal entitled " rediction and Management of Diabetic neuropathy in Urban, Rural and Tribal people of Raigad District, Maharashtra: The Foot MaP study " was not submitted to even partially to any other funding agency for financial assistance.
8. In case of failure to comply with any of the above said provisions, DHR will have all rights to ban the concerned Principal Investigator(s)/ Institute(s) for future funding from DHR for any specified period.

Signature of the:

(a) Principal Investigator (s): Dr Rajani Mullerpatan

(b) Co-Investigator (s) :Prof Ravi B

Mr Nishant Kathpal

Dr Maninder Setia

(c) Head of the Department:

Date:

Signature of the Head of the Institution with seal

Pro.Vice Chancellor
MGM INSTITUTE OF HEALTH SCIENCES
(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
KAMOTHE, NAVI MUMBAI

Section B

Title of the Project: Prediction and Management of Diabetic neuropathy in Urban, Rural and Tribal people of Raigad District, Maharashtra: The Foot-MaP study

3. Summary of the proposed research project (in only 200 words):

3.1 Background:

Globally, 1 in 10 people have diabetes and 3 out of 4 people live in low-middle-income countries (IDF 2021). Prevalence of diabetes in India is 8.7%(WHO 2019). Diabetes is a major cause of lower extremity amputation(LEA) as a sequel of non-healing foot ulcers following occurrence of diabetic neuropathy. Among people with diabetes, 29.6%-60% present with diabetic neuropathy (2). People with diabetic neuropathy are at risk of foot ulceration because of reduced sensory feedback and vascularisation of foot (2). Therefore, early detection of diabetic neuropathy is of vital importance in prevention of lower extremity amputations because, LEAs are associated with greater morbidity and mortality rates.

3.2 Research question:

- Is plantar tissue stiffness a valid clinical predictor of risk of diabetic foot ulceration.
- Is there a difference in plantar tissue stiffness between people with diabetes with and without neuropathy and age matched healthy adults.
- Is there a minimally detectable change in plantar tissue stiffness among people with diabetes following intervention.

Primary question:

- Is plantar tissue stiffness a valid clinical predictor of risk of diabetic foot ulceration.

3.3 Methodology:

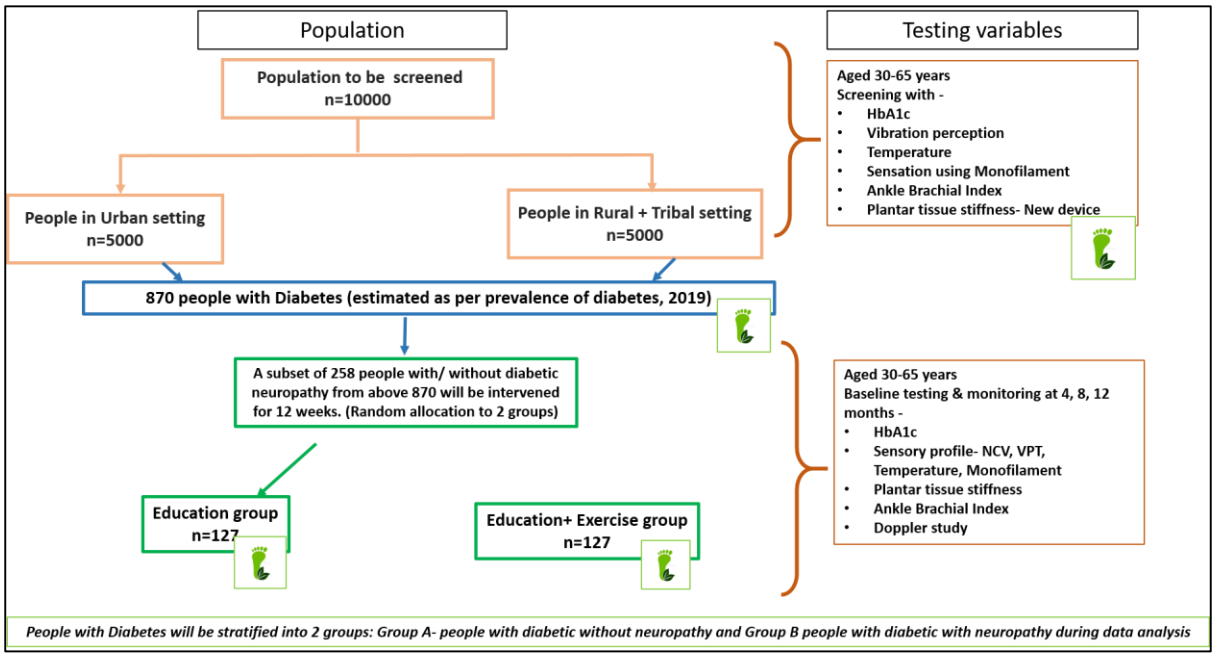


Figure 1:Flow chart of methodology

3.4 Proposed outcome.:

- Plantar tissue stiffness as a novel, single clinical indicator to detect changes occurring in diabetic-neuropathy caused by both reduced sensory and vascular supply.

Figure 2: Reference band for plantar tissue stiffness to detect risk of ulceration.

- Foot-Map project studies indigenously developed load-cell-based smart, portable, battery-operated device easy to use in Community-Health-Centre to predict, detect and monitor risk of diabetic-foot ulceration.

4.Reason for conceiving the project:

Plantar ulceration still remains the single most common complication that ultimately leads to foot amputation. Diabetic neuropathy leads to stiffness of the plantar surface which can lead to changes in plantar cutaneous sensory thresholds and tissue stiffness. Currently there is no tool to measure plantar tissue stiffness as an indicator of tissue breakdown.

Existing clinical tools available for testing are exclusively designed for detection of sensory threshold and vascular supply. However, the risk of ulceration is modified by a combined effect of reduced sensory and vascular supply which can be measured by measurement of tissue

stiffness. Therefore, we propose to use novel battery operated portable technology to measure tissue stiffness in people with diabetes for early detection of diabetic neuropathy and monitoring diabetic foot. Results of pilot testing (n=404) following ethical approval provided sufficient evidence ($p<0.02$) of preliminary assessment of difference in tissue stiffness among people with diabetes (57.7 yr.) without neuropathy and with neuropathy with reference to healthy age-matched adults

Therefore, a simple, robust model including evidence-based prophylactic measures for the masses are a need of the hour to reduce the burden of diabetic foot complications in India and other similar socio-economic regions of the world.

State the:

i. Novelty of proposed research project (in 100 words and point-wise):

- Foot-Map project studies indigenously developed load-cell-based smart, portable, battery-operated device easy to use in Community-Health-Centre to predict, detect and monitor risk of diabetic-foot ulceration.
- Plantar tissue stiffness is a novel, single, emerging clinical indicator to detect changes occurring in diabetic-neuropathy (Hansen's disease and alcohol toxicity) caused by both reduced sensory and vascular supply.
- Results of pilot testing provide sufficient evidence of preliminary assessment of difference in tissue stiffness among people with diabetes without neuropathy and with neuropathy with reference to healthy age-matched adults.
- Proposed projects weaves together expertise and capacities of health and engineering disciplines and connects to Industry-sector to address rising socio-economic burden of diabetes.

ii. Relevance of proposed research project to public health (in 100 words and point-wise):

- Foot-MaP will control diabetic-foot complications caused by diabetes through early diagnosis, management and follow-up of people with diabetic neuropathy through population-based screening in urban, rural and tribal setting in India and countries facing similar huge burden of diabetes and challenge of constrained human resources and infrastructure for management of diabetes.
- Foot-MaP smart station integrated into clinical care pathway at every CHC in urban, rural and tribal setting to screen people with diabetic neuropathy will contribute to

existing efforts of NPCDCS for prediction, detection and monitoring risk of foot ulceration and help to prevent/reduce occurrence of foot ulceration and ultimately lower-extremity-amputation

- Foot-MaP will control diabetic-foot complications caused by diabetes through early diagnosis, management and follow-up of people with diabetic neuropathy through population-based screening in urban, rural and tribal setting in India and countries facing similar huge burden of diabetes and challenge of constrained human resources and infrastructure for management of diabetes.
- Foot-MaP smart station integrated into clinical care pathway at every CHC in urban, rural and tribal setting to screen people with diabetic neuropathy will contribute to existing efforts of NPCDCS for prediction, detection and monitoring risk of foot ulceration and help to prevent/reduce occurrence of foot ulceration and ultimately lower-extremity-amputation.

iii. Relative importance of proposed research project in a given area (in 100 words and point-wise):

- Current routine clinical practice for diagnosis and management of diabetes in rural-tribal setting focuses on drug therapy for glycaemic control.
- Outcome of Foot-MaP project will shift the paradigm from medical management of diabetes alone to detection of risk of foot ulceration and prevention, management and monitoring diabetic foot complications caused by diabetic neuropathy.
- At the few urban diabetes clinics, which focus on foot care, single test to measure plantar tissue stiffness will replace existing two tests used for detection of protective plantar sensory threshold and foot vascular supply and provide clinicians with combined indication of risk of diabetic foot ulceration.

iv. Applicability of your research project in-

(a)Short term (in point-wise):

- Outcome of proposed Foot-MaP study will hold a huge potential application in augmentation of capacity and enhance the outcome of NPCDCS; which is focused on early diagnosis and management of diabetic foot complications.
- Application of findings will occur at two levels through NPCDCS for prevention of occurrence of diabetic foot ulceration-

- Integration of Foot-MaP station within District NCD Cells and District NCD Clinics in Raigad District.
- Inclusion of measurement of plantar tissue stiffness in the guidelines for detection of rick of ulceration caused by diabetic neuropathy and monitoring diabetic foot to prevent complications.

(b) Long term (in point-wise):

- Integration of Foot-MaP station within District NCD Cells and District NCD Clinics in all districts of Maharashtra state for prevention of occurrence of diabetic foot ulceration.
- Integrate Foot-MaP station at every CHC at all 298 District NCD Cells and 293 District NCD Clinics in 36 States/UTs in India for prevention of occurrence of diabetic foot ulceration.
- Study the impact of early diagnosis on the socio-economic burden caused by diabetic foot complications by measuring the cost of diabetic foot ulcer care and cost of rehabilitation following lower extremity amputations.
- Study the impact early diagnosis and management on prevention of diabetic foot complications among people with diabetes.

6.1 International status:

Existing literature informs regarding use of various systems to evaluate diabetic foot like plantar tissue stiffness using an indenter system, vibration perception, sensory threshold and pressure distribution on the foot. Muller M *et al* (2001) conducted a study to determine the difference in plantar tissue stiffness in patients with diabetes (n = 20) and diabetic neuropathy(n = 14) and healthy normal (n = 14) using an indenter system to measure plantar tissue stiffness over first, third and fifth metatarsal, heel of each subject using an indenter system that accurately measures force/displacements. The plantar tissue of patients with diabetes andperipheral neuropathy was stiffer than control population.[9]

Andresa M.C *et al* (2016**)** determined influence of various body positions on vibration perception thresholds (VPTs). VPTs were performed at an atomical locations like heel, first metatarsal head, hallux of theright plantar foot under two randomized conditions: during sitting and standing. The contact force applied to the probe was measured and controlled within the five trials. Contact forces between the probe and the foot

were higher during standing. However, no differences in VPTs were found between conditions which were indicative that VPTs were not different during standing compared to sitting, contrary to our expectations. [10]

Thomas G. *et al* (2006) determined the tactile sensory threshold levels on the plantar surface of the feet in healthy subjects as well as assessing if differences existedbased on gender or between extremities. They observed that plantar tactile sensation did not differ between the left and right feet, but differences did exist between men and women in all regions except the hallux. The heel region tactile threshold was found to be significantly higher than all other regions. The mean tactile sensitivity for both the right and left feet was the 3.61 monofilament. [11]

Alexander N B (1998)*et al* conducted a study on influence of age, rotation direction, angle, and speed on the threshold for sensing foot dorsi- and plantarflexion when standing and bearing weight on the limb. Both age and speed significantly affected the thresholds for sensing foot dorsiflexion and plantarflexion in women. [12]

Mueller M *et al* reported plantar soft tissue thickness at the metatarsal heads, mid-foot and heel using custom built indentor device and an ultrasound machine. Metatarsophalangeal joint extension had profound effect on increasing forefoot soft tissue stif fness and a consistent but minimal effect on reducing soft-tissue thickness. [13] However, a lacuna in literatureregarding comprehensive longitudinal evaluation of plantar tissue stiffness in people with diabetes led to the conception of the current study.

6.2 National status:

The current prevalence of individuals with diabetes in the age group of 20-79 years is 74.2 million and is estimated to rise upto 124.9 million by 2045.Type I Diabetes is the most common type of DM in children and adolescents with a prevalence rate of 229.4 per annum.

In a study done in Punjab reported that 8.3 % had Diabetes, whereas 6.3% of the population were under the pre-diabetic categories. Risk factors were age individuals in the age group of 45-69 years, obesity, family history of diabetes. Only 18 % were diagnosed with known case of diabetes mellitus (DM) and among them only one-third had controlled blood glucose levels. The etiology of diabetes mellitus (DM) in Indian population is multi-factorial which comprises of genetic factors with environmental influences like obesity linked with higher standard of living, rise in urban migration, and changes in lifestyle .

A recent study reported prevalence of 10.5% to 32.2% diabetic neuropathy in various studies across various Indian states.

Plantar tissue stiffness measured using Ultrasound elastography technique in patient with diabetic neuropathy without foot ulcerated revealed diabetic patients with higher plantar soft tissue thickness and lower stiffness at the 1st Metatarsal head area demonstrated an increased risk of diabetic foot ulceration . Thus addition of plantar stiffness and thickness model improved specificity (by 3%), sensitivity (by 14%), prediction accuracy (by 5%) and prognosis strength (by 1%).

6.3 Research gap (in point-wise):

- Existing approach to clinical evaluation of neuropathy largely involves testing touch-pressure sensation using sensory monofilament and vibration sensation using vibrothesiometer. Protective sensory threshold is known for both the sensory variables.
- Both the tools are designed to test sensory impairment; whereas diabetic foot presents changes in the tissues caused by impaired vascular and sensory supply.
- However, currently there is no tool to measure stiffness of the plantar tissue, which is the result of combined effect of impaired vascular and sensory supply occurring in the diabetic foot.
- Pilot results of clinical testing support that plantar tissue stiffness can emerge as a predictor of tissue breakdown.
- Therefore, proposed large population-based study is designed to generate a reference range for plantar tissue stiffness for prediction and monitoring risk of plantar ulceration. Based on the findings a protective threshold value will be generated for detection of risk of plantar ulceration which can be used in strategies adopted by NPCDCS for early diagnosis.

7. Preliminary work already done by the Investigator(s) on this problem, if any.

Existing clinical tools for diabetic neuropathy and risk of ulceration include measuring sensory threshold using vibrothesiometer or measuring vascular threshold using temperature testing.

As risk of ulceration is due to reduction of both sensory and vascular threshold, there was need to evolve a clinical indicator which would measure both sensory and vascular supply.

Figure 3: Device measuring plantar tissue stiffness at 1st metatarsal head and 2nd toe

Tissue stiffness is influenced by sensory and vascular supply. Therefore, a device to measure plantar tissue stiffness was designed at MGM School of Physiotherapy and developed at IIT – Bombay and Ayati devices. The pilot clinical validation of the tool was initiated on a sample of 404 individuals (Diabetes, n=67, age=49.4 yr.; Diabetes with neuropathy, n=60, age= 57.7yr; age matched healthy adults, n= 120, age=46.6yr; Non- age matched healthy adults, n=157, age=31.2 yr.). The preliminary results of the pilot testing demonstrated significant difference in tissue stiffness between diabetes with and without neuropathy ($p<0.02$) over the heel and hallux of the foot which are the maximum weight bearing area during gait.

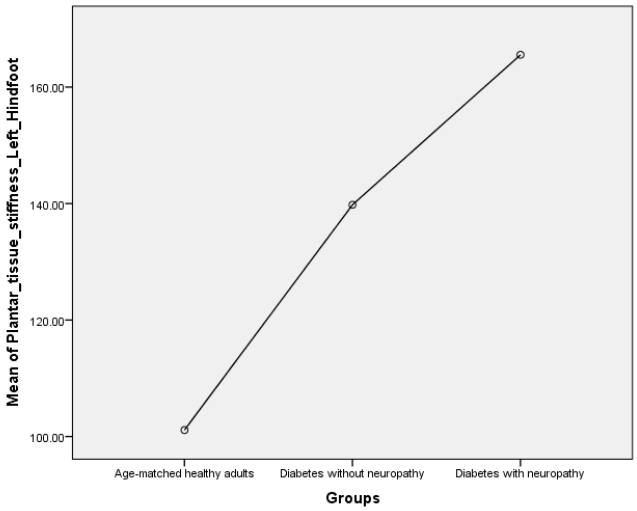


Figure 4: Presents difference in the planter tissue stiffness on hind-foot between 3 groups

Additionally, there was a similar trend noted in agreement between vibration sensation, temperature measurement, and planter tissue stiffness measurement between the groups.

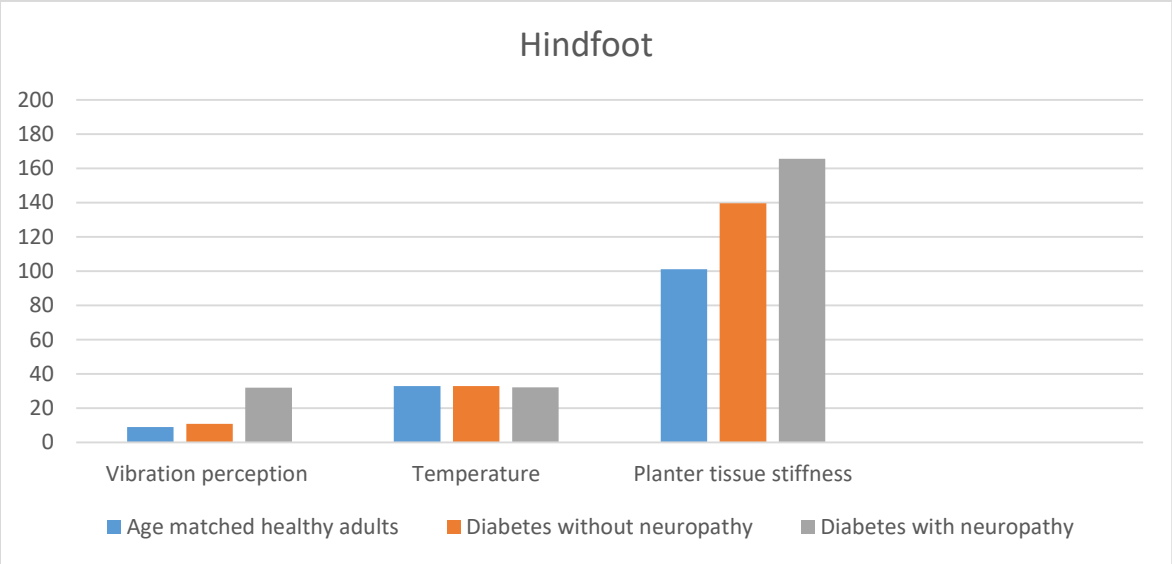


Figure 5:Figure 4: Trend of agreement between vibration, temperature and plantar tissue stiffness among the 3 groups

8. Links with other DHR and ICMR projects (ad-hoc, task force or collaborative).

Not applicable

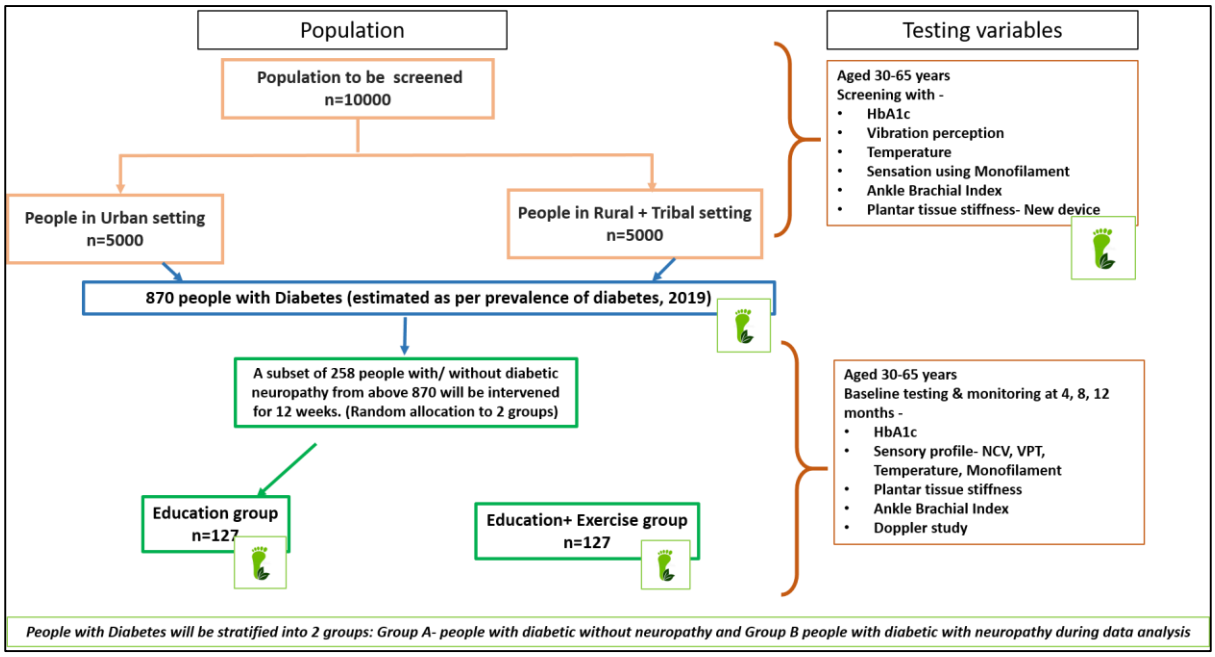
9. Detailed research plan:

9.1 Methodology

The proposed project is approved by Institutional Ethics Committee for Research on Human Subjects (IERC No: Ref.MGMIHS/RES./02/2022/326). Signed informed consent will be sought from all participants. Ten thousand people from urban and rural settings will be screened for diabetic neuropathy using vibration perception sense, touch pressure sensation, temperature, plantar tissue stiffness, ankle –foot vascular supply. All The participants will be tested for HbA1c. Based on findings of HbA1c they will be clinically diagnosed with diabetes.

Based on the prevalence of diabetes (2019), out of 10000, 870 people are estimated to be diagnosed with diabetes. Eight hundred and seventy people will be monitored every 12 weeks for a period of 1 year to detect change in the sensory profile including nerve conduction, vibration perception sense, temperature, plantar tissue stiffness, touch pressure sensation. Additionally, the 870 people will also be assessed for ankle –foot vascular supply using Ankle Brachial Index and Doppler ultrasound

A small subset of 258 people with diabetes will be intervened from the total sample of 870 people with diabetes. Sample size is calculated as per the prevalence of diabetic neuropathy. (2). These people will be stratified into group A (people with diabetes without neuropathy) and control group B (people with Diabetes with neuropathy) during data analysis.



A reference range will be generated for plantar tissue stiffness cutaneous sensory threshold, vibration perception threshold and temperature from the 10000 people using a cross sectional study design.

Plantar tissue stiffness will be monitored in 870 people with diabetes by testing them 4 times at an interval of 12 weeks over a period 1 year. Based on the reference range, these 870people will be categorized as per risk of plantar ulceration into 4 categories (No risk, low-risk, moderate-risk and high-risk. Longitudinal monitoring will enable understanding of change in the plantar tissue stiffness over a period of 1 year among people with diabetes.

Statistical tests will be employed to test level of agreement between the gold standard measures such as nerve conduction, vibration perception sense and Doppler ultrasound and plantar tissue stiffness to establish criterion validity of the new tissue stiffness device.

Out of 870 people, 258 participants will be intervened by dividing them into two intervention groups. Group I -127 patients will be given educational intervention for care of foot and

Group II-127 patients will be given a home exercise program and educational intervention for care of foot.

The intervention protocol will be reviewed and based on finding from the project modification will be done in the intervention and changes will be integrated into a virtual mobile based application for larger dissemination of intervention program.

Inclusion criteria:

- Patients diagnosed with Diabetes with or without peripheral neuropathy.

Exclusion criteria:

- Patient with Diabetes with non-healed Ulcer.
- Acute neurologic disorder affecting sensations such as acute demyelinating polyneuropathy, GBS.
- Peripheral nerve injury involving lower extremity.
- Amputation of lower extremity.
- Fractures, dislocation and soft tissue injuries of lower extremity more than 1 year.
- Congenital and developmental deformities of lower-extremity.

Detection of diabetic neuropathy: Comprehensive evaluation

Demographic details will be recorded. Evaluation in patient with neuropathy will include testing of plantar tissue stiffness, cutaneous sensory threshold, vibration perception threshold, temperature. The foot will be tested on 5 anatomical sites as shown in the Figure

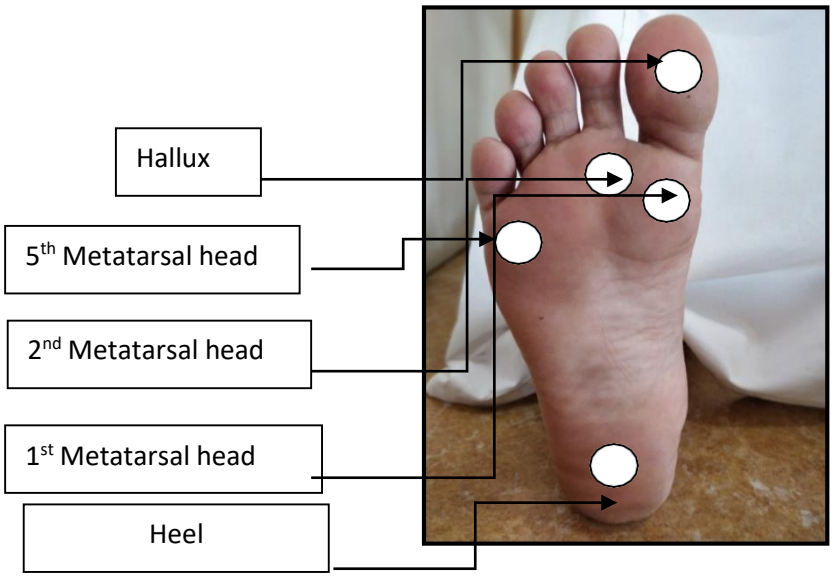


Figure 1: 5 Anatomical sites of plantar tissue stiffness, cutaneous sensory threshold, vibration perception threshold, temperature testing.

Plantar Sensory threshold- The participant will be instructed to be seated in long sitting position with eyes closed. A 10 gm Semmes Weinstein monofilament will be placed at selected sites on plantar aspect of the foot until the monofilament begins to bend. Participant will be asked to report when the monofilament was felt by saying 'yes'. The monofilament will be applied perpendicular to the skin of the foot being tested for a duration of 1–2 s and will be assessed on each foot over heel, medial midfoot, lateral midfoot, medial forefoot, lateral forefoot, and distal end of the hallux. Testing will be always started using the monofilament on the right foot with the subject providing a verbal response. A minimum of 14 touches will be applied to eachplantar region tested using various monofilaments with at least three of the touches.

Vibration perception threshold (VPT) will be measured with a Vibrothesiometer (at 7 different sites i.e. the base of the hallux, 1st, 2nd, 5th metatarsal head and heel. The participant will be seated in long sitting position. The participant will be given a feedback of the vibration prior for appropriate response during the trail. The probe of the vibrothesiometer will be placed at each site respectively. The voltage will be increased from low to high on the base unit until the patient sensed and announced vibration. This reading will be checked and recorded. Three trials of the same will be repeated. [13]

Plantar Tissue stiffness– This device has been developed by team at Bio Engineering and Technology Incubation Centre (BETiC) at IIT Bombay and Dr Rajani Mullerpatan.The MGM Centre of Human Movement Science (MGM CHMS) and BETiC have signed a research MoU which allows us to use this novel device. The device will be used to measure tissue stiffness in 5 anatomical sites of hallux, 1st metatarsal head, 2nd metatarsal head, 5th metatarsal head, canter of heel and center of midfoot.

Plantar tissue temperature assessment will be done using Touch Temp plantar tissue temperature device at 5 anatomical sites of hallux, 1st metatarsal head, 2nd metatarsal head, 5th metatarsal head, canter of heel and center of midfoot.

Along with above measures, clinically evaluation will be performed using validated tools - Ankle Brachial Index, MGM ground level activity, Physical Activity questionnaire, Foot Posture Index, lower extremity strength and nerve conduction studies, pre and post intervention.

Ankle Brachial Index:

The ankle-brachial pressure index (ABPI) or ankle-brachial index (ABI) is the ratio of the blood pressure at the ankle to the blood pressure in the upper arm (brachium). Compared to the arm, lower blood pressure in the leg suggests blocked arteries due to peripheral artery disease (PAD). The ABPI is calculated by dividing the systolic blood pressure at the ankle by the systolic blood pressure in the arm.

Motor NCV for Peroneal nerve

The participant is in the supine position. An active 32 mm disc electrode is placed two-fifths of the distance from the head of the fibula to the tip of the lateral malleolus. The reference electrode is placed 4cm distal to the active electrode over the muscle tendon (Peroneus longus, peroneus brevis, tibialis anterior). Ground electrode is placed over the tibia, 3–4 cm distal to the reference electrode. The first stimulation point(cathode) is placed slightly below the head of the fibula. The anode is proximal. The second stimulation point is placed(cathode) just medial to the lateral border of the popliteal space at the level of the mid-patella, approximately 10 cm proximal to first stimulation point. Standard motor settings are used. Nerve fibres tested are L5, S1, and S2 nerve roots, through the posterior division of the sacral plexus and the sciatic nerve.

Onset latency (msec) Mean S.D. Range Upper Limit of Normal 3.0 0.8 1.7 ± 5.4 4.6

Amplitude (mV) Mean S.D. 5.3 ± 1.7.

Sensory NCV for Sural nerve

The participant is positioned in supine. The recording electrodes **is** felt-tip electrodes with a fixed interelectrode distance of 37 mm were used in the cited study. The active electrode is placed over the dorsolateral surface of the foot at the midpoint of the 5th metatarsal and just lateral to the extensor digitorum brevis tendon of the 5th toe. The reference electrode (R) is placed distal to it. Ground electrode is placed on the dorsum of the foot. The stimulation points The cathode (C) is placed 12 cm proximal to the active electrode behind the lateral malleolus. The anode (A) is placed proximal to it.

Machine settings: Average is used (5–10 stimuli). Sensitivity—5 µV/division, Low frequency filter—20 Hz, High frequency filter—2 kHz, Sweep speed—1msec/division.

Nerve fibres tested are S1 and S2 nerve roots, through the anterior and posterior divisions of the lumbosacral plexus and the tibial and peroneal nerves.

Doppler Ultrasound: Doppler Ultrasonography will be performed using linear head with the mean frequency of 7.5 MHz (range 4-9 MHz). The subject to be tested has to lie in the supine position with the Knee joint bent upto 90^0. B mode assessment will be done to evaluate external

diameter of vessel and vessel wall thickness. Colour doppler imaging will be done to assess the diameter of colour vessel flow. Spectral Doppler imaging will be performed to evaluate the flow spectrum and blood flow parameters- pulsatility index (PI), peak systolic velocity (PSV), end diastolic velocity (EDV), and resistance index (RI). Measurements will be conducted in both lower limbs, in dorsalis pedis artery at the level of the neck of the ankle bone and posterior tibial artery at the level of medial malleolus.[1]

I. Proposed statistical analysis

The normality of data will be ascertained using Kolmogorov–Smirnov test. The descriptive statistics of all variables will be presented as central tendencies and measures of dispersion. The within group, pre and post intervention analysis will be done using appropriate parametric test (paired t test) or non-parametric test based on normality test. Between group comparison will be performed using unpaired t-test or equivalent non-parametric test.

9.2 Time-lines (objective-wise) through graphical representation

Action Plan	**Time Line**			
	0-12 months	**13-27 months**	**28-30 months**	**31-36 months**
1.Recruitment and baseline evaluation				
2.Intervention				
3.Data Analysis				
4. Analysis, Report writing and Submission				

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10. Significance/outcome of proposed work.

10,000 people from urban, rural and tribal setting in Raigad district will benefit from screening for diabetic foot complications.

An estimated 870 people with diabetes, will benefit from comprehensive diabetic foot testing (including, sensory, vascular and stiffness) to detect risk of foot ulceration and prevent/delay occurrence of foot ulceration.

258 people with diabetic neuropathy will benefit from an intervention designed for foot care education and exercise program to reduce stiffness of plantar tissue and make it less prone to risk of ulceration.

Determine minimal clinical detectable size of change in plantar tissue stiffness following an intervention.

Prevention/delay in occurrence of foot ulceration will help to reduce the number of people with diabetic neuropathy developing foot ulceration and ultimately lower extremity amputation.

Although preventable, prevalence of this complication ranges between 4%-27% amongst all diabetic patients. Collateral benefit of exercise intervention will result in improvement in glycaemic control which will also protect people with diabetes from other diabetes related complications such as ischemic heart disease.

Plantar tissue stiffness will emerge as a novel, single, clinical indicator to detect changes occurring in diabetic-foot (Hansen's disease and alcohol toxicity) caused by both reduced sensory and vascular supply.

Booklets and e-education material which can be used for educating both literate and ill-literate people with diabetes in India and countries with similar socio-economic conditions.

Develop a foot evaluation station at each CHC and District NCD Cells and District NCD Clinics within Maharashtra and other states in India and countries with similar socio-economic conditions facing a similar burden of diabetes.

11. Will any technology/ methods/ protocols/ kits/device be developed from the proposed research project?

Yes, the proposed research project will benefit Clinician/ health care workers and patients/ caregivers through development of-

For Clinicians & Healthcare workers:

- Comprehensive sensory and vascular measurement Kit: The project will develop a novel, valid kit measuring plantar tissue stiffness in diabetes and categorise people into no risk to high risk band based on the reference range of plantar tissue stiffness generated from the findings of the project.
- Additionally, the project will validate the novel plantar tissue stiffness measuring device and upgrade it to Technology Readiness Level (TRL) 7 from TRL 5.

For Patients & Caregivers:

- Exercise protocol: A evidence based exercise protocol will be developed through the project which will benefit all patients with Diabetes and help in reduction of occurrence of Ulceration
- Education kit: Protective diabetic foot care education kit will be developed for patients and caregivers.
- The project will develop Mobile based FootMaP application for wider reach of the masses in urban, rural and tribal settings for prevention and management of diabetic neuropathy.

12. Future plan for utilization / application of information to be generated from the proposed research project:

- The outcome of the proposed study will result in several deliverables which will be applicable for diagnosis and management of diabetic peripheral neuropathy to detect risk of ulceration; such as-reference range for plantar tissue stiffness and smart portable battery-operated device to measure plantar tissue stiffness (early diagnosis and monitoring) and Foot-care Education leaflets, Foot Exercise protocol, mobile-based Foot-care Education app (prevention and management).
- All the above deliverables will be packaged in two tool-kits for management of diabetes. The diagnostic toolkit will be used by clinicians working in diabetes along with trained health care workers. The therapeutic tool-kit will be used by clinicians working in diabetes, patients and care-givers.
- It is planned that both the kits will be integrated into the NPCDCS pan India and across other countries with similar socio-economic conditions facing burden of diabetes care.

- It is further planned that these toolkits will become a part of the comprehensive toolkits for diagnosis and management of diabetes and its complications.

13. **Facilities in terms of equipment, etc, available at the sponsoring institution for the proposed investigation.**

The sponsoring Institution is equipped with 1 set of each of the following equipment.

Sr.no	Equipment
1	Vibrothesiometer 1 unit
2	Semmes Weinstein Monofilament Kit 1 unit
3	Temp Touch Temperature probe 1 unit
4	Audio-Video Photography system I unit
5	Stimu Device 2 units – Plantar tissue device

14. Budget requirements (with detailed break-up and full justification):

SrNo	Budget Head	Year 1	Year 2	Year 3	Total cost	Justification
I	**Manpower**					
1.1	Project Associate I (2)	944880	944880	944880	2834640	Project Associates will be required to assist PI in recruitment, screening and intervention for participants from urban and rural areas
1.2	Technician (1)	304800	304800	152400	762000	Laboratory Technician will be responsible performing HbA1c test
1.3	Project Associate II (1)			533400	533400	Project Associate from engineering discipline will be responsible to develop a mobile based app to monitor foot health. The app will integrate information gained from the screening of 10000 people with and without diabetes.
II	**Recurring(Consumables) Contingency**					
2.1	HbA1c blood test	2500000	652500	-	3152500	HbA1c test will help to determine glycemic control of the participants included in the screening. The cost of each test is INR 500.00 at MGM Hospital. The institute is prepared to provide a highly subsidised cost (50% of actual cost) for HbA1C test for the purpose of the project.
2.2	Electrode gel, adhesive tapes, sterilium	250000	75000	-	325000	Electrode gel, adhesive tape and sterilium will be required while performing nerve conduction velocity

						studies while screening 10000 participants
2.3	Maintenance and repair	100000	100000	100000	300000	Stimu software will require annual maintenance and upgradation
2.4	Stationary Print outs	50000	50000	25000	125000	Printed data sheets will be required for survey tool for 10000 participants and evaluation sheets
III	**Non-Recurring Contingency**					
3.1	Laptop 2 units	200000	-	-	200000	Research data will be captured and stored using the laptops which will be carried by researchers to urban and rural areas.
3.2	Portable Hard drive 2	20000	-	-	20000	Data of 10000 participants will be stored in hard drives. Videography education material to be shown to participants will be stored on the drives.
3.3	Education Booklet and Videos	200000	-	-	200000	Education booklet will be prepared in English, Hindi and Marathi languages which will be printed and provided to participants undergoing intervention. Additionally videos will be prepared for foot care intervention which will incur cost of hiring equipment for high quality video capture.
3.4	Article Processing Fee for publication of research findings	400000	-	-	400000	It is expected that the information gained from the project will be disseminated through minimum 2 scientific publications BMC Open Access/Diabetologia/ Diabetes Care/ Nature or other Open Access Journals
3.5	Application Development			500000	500000	Information gained from the survey of 10000 people will be used to develop a reference range which will be used to monitor people with diabetes using a mobile based application. Development of the app will require programming system and cloud storage.
IV	**Equipment**					
4.1	Portable Doppler 2 units	700000	-	-	700000	Portable Doppler will enable precise measurement of Ankle Brachial Index and distal blood flow
4.2	Vibrothesiometer 2 units	100000	-	-	100000	Two units of the equipment will be required to measure sensory perception of people

						with neuropathy at urban and rural areas
4.3	Semmes Weinstein Monofilament Kit 2 units	44000	-	-	44000	Two units of the equipment will be required to measure sensory perception of people with neuropathy at urban and rural areas
4.4	Portable NCV system 2 units	800000	-	-	800000	Two units of the equipment will be required to record nerve conduction velocity of people with neuropathy at urban and rural areas
4.5	Temp Touch Temperature probe 2 units	20000	-	-	20000	Two units of the equipment will be required to record skin temperature of people with neuropathy at urban and rural areas
4.6	Audio-Video Photography system	500000	-	-	500000	The system will be required for developing educational material for people with peripheral neuropathy
4.7	Stimu Device 2units	76000	76000	-	152000	The equipment will be used to record plantar tissue stiffness
V	**Travel**	1000000	1000000	500000	2500000	
VI	**Overhead Charges**	760968	340318	315568	3471248	
	Grand Total					**15585394**

15. List of important publications of last 5 years of the all the investigators in the relevant fields

Publication list Last five years (2016-2022)

1. **Mullerpatan RP**, Bharnuke JK. Differences in Foot Characteristics Between Bharatanatyam Dancers and Age-Matched Non-Dancers. Medical Problems of Performing Artists. 2022 Mar 1;37(1):53-7.
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14. **Mullerpatan R**, Nahar S, Singh Y, Cote P, Nordin M. Burden of spine pain among rural and tribal populations in Raigad District of Maharashtra State of India. European Spine Journal. 2020 Sep 10:1-7.
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