

Integrating technology-assisted diabetes foot care in Pakistan

Submission date 27/09/2024	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 01/10/2024	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/09/2024	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of this study is to explore the feasibility of integrating footcare intervention with diabetes patients at the rural health centre (RHC). This study will also inform how beneficial the foot care intervention will be in the prevention and care of diabetic foot conditions that can lead to serious complications such as foot ulcers and amputations. This research will inform how foot care at RHCs can be made better. The participants will be diabetes patients getting treatment at RHC who will be given foot care i.e., screening, treatment, and patient education.

Who can participate?

The RHC at which diabetic patients are receiving diabetes care has been selected to pilot the integration of diabetes foot care in Punjab. All patients who are registered for diabetes care at the RHC will be invited to participate in this study for 6 months. The patients who will be included in the trial will be those who have access to a smartphone i.e., either a personal phone or a phone of a household member. The patients who plan to move out of the RHC catchment population during the study period will not be offered to take part in this study. Only those who provide consent to participate will be included in the study.

What does the study involve?

This research will be conducted at RHCs. As a part of the study, patients will receive foot assessment at the start and end of the study including self-foot care and quality of life assessment. At some RHCs some patients will also receive foot care and digital application during the study period. Written consent will be obtained from the patients who are willing to participate. The patient data will be collected for a period of 6 months. Any foot care will be given and recorded at the regular monthly visit that the patient makes for their core diabetes. The data from assessment tools will also be collected at the start and end of the study only and this will also be made a part of the regular patient visits. No extra visit will be implied for being a part of the research per se if there is no condition identified that needs treatment at RHC. The participants can ask to withdraw themselves from the study at any time.

What are the possible benefits and risks of participating?

There are no foreseeable disadvantages of participating in the study. The patient records collected will be kept safe in lock and all personal data (i.e., data that can identify the patient)

will be removed from the data files. The benefit of taking part in this study is that all patients will get access to foot assessment. Those who receive intervention will also be able to access foot care (i.e., prevention, management, and access to suitable footwear) at the RHC as well. Currently, there is no such facility available at RHC for diabetics. Those getting access to the mobile application will get knowledge about prevention and care and the platform to engage in patient-responsive care by reporting challenges through the app. Additionally, patients in the intervention group will have the reference link for getting diabetic footwear fitted according to patient foot needs. There will be no payment made to the patients for taking part in this research.

Where is the study run from?

The study will be conducted at two randomly selected rural health centres from each of four districts (i.e., eight RHCs) of Punjab, Pakistan.

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

June 2023 to May 2025

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Nida Khan, nida.khan@conted.ox.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Contact details

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Additional identifiers

Study information

Scientific Title

A feasibility cluster randomised controlled trial of technology-assisted diabetes foot care in Pakistan

Study objectives

The primary objective of the study is to assess the feasibility of clinical outcomes of the intervention package versus the routine care.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 03/09/2024, Oxford Tropical Research Ethics Committee (University of Oxford Research Services, Research Governance, Ethics & Assurance Boundary Brook House, Churchill Drive, Oxford, OX3 7GB, United Kingdom; +44 (0)1865 (2)82106; oxtrec@admin.ox.ac.uk), ref: 560-24

2. Approved 11/08/2023, Association for Social Development, Pakistan IRB (House no. 12, Street 48, F-7/4, Islamabad, 4000, Pakistan; +92 (0)51 2611230-3; irb@asd.com.pk), ref: ASD-EAG-23-001

Primary study design

Interventional

Study design

Feasibility randomized controlled trial

Study type(s)

Prevention, Screening, Treatment

Health condition(s) or problem(s) studied

Diabetes

Interventions

Health facilities will be randomized into control and intervention.

Healthcare staff will be enabled to offer enhanced foot care and footwear intervention. The enabling includes contextualized implementation products: a) desk-guide for doctors; flip book for patient education; b) materials for foot care and footwear, e.g., silicone rubber insoles; c) digital mobile app for patient engagement including knowledge content and platform to report social and care challenges.

In addition to these components:

Periodic follow-up screening and response (at RHCs): Patient feet will be screened periodically for foot condition (frequency subject to foot condition). The patients get advised according to their foot condition.

Linkage of suitable footwear: patients in the intervention arm will have the reference link for getting diabetic footwear fitted according to patient foot needs.

The control arm will receive treatment as usual (TAU) as well as footcare screening done by an external evaluator.

The duration of the intervention is 6 months.

Intervention Type

Mixed

Primary outcome(s)

The feasibility of clinical outcomes:

1. Uptake of recommended foot care behavior is measured through Nottingham Assessment of Functional Footcare (NAFF) at baseline and endpoint
2. Quality of life is measured through European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L) at baseline and endpoint
3. Uptake of follow-up footcare visits is measured through non-communicable disease card (NCD) card at every follow-up.
4. Uptake of mobile-app-assisted patient engagement measured through application analytics (such as average time spent) at endpoint
5. Uptake of referral care at DHQ hospital through digital referral application (i.e., number of patients referred and reached DHQ) at endpoint
6. Deterioration in foot condition/stage will be measured through non-communicable disease card (NCD) card at baseline and endpoint
7. Complications during footcare (necrosis, amputation, hospitalization) will be measured through non-communicable disease card (NCD) card at baseline and endpoint

Key secondary outcome(s)

The feasibility of operational and economic outcomes:

Operational outcomes:

1. Patient enrolment – OPD load; diabetes patient load; refusal to participate in footcare intervention will be measured through monitoring reports
2. Patient adherence to footcare follow-up (till endline) will be monitored at every follow-up

Economic outcomes :

Providers' cost of RHC enabling, footcare per patient, desired outcome (of footcare) and additional emergency/catastrophic costs will be measured through program data at endpoint

Completion date

31/05/2025

Eligibility

Key inclusion criteria

1. Aged 25 years or older
2. Registered for diabetes care at the primary health care facility
3. Willing to provide written informed consent
4. Have access to a smartphone (i.e., personal smartphone or access to a smartphone within the household)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

25 Years

Sex

All

Key exclusion criteria

1. Diabetes patients who plan to move out of the RHC catchment area during the study period
2. Refuse to give consent to participate

Date of first enrolment

01/10/2024

Date of final enrolment

07/10/2024

Locations**Countries of recruitment**

Pakistan

Study participating centre

Rural Health Center Chak No. 71/SB Sargodha

Sargodha

Pakistan

40100

Study participating centre

Rural Health Center Chak No. 75/SB Sargodha

Sargodha

Pakistan

40100

Study participating centre

RHC Daira Din Panah, Muzaffargarh

Rural Health Center, Daira Din Pannah

Kot Addu

Pakistan

34050

Study participating centre

RHC Shaher Sultan

Rural Health Center, Shaher Sultan

Jatoi
Pakistan
34050

Study participating centre

RHC Roda

Khushab
Roda
Pakistan
41030

Study participating centre

RHC Mitha Tiwana

Khushab
Mitha Tiwana
Pakistan
41250

Study participating centre

RHC Sarai Sidhu

Tehsil Kabir Wala, Khanewal
Sarai Sidhu
Pakistan
58100

Study participating centre

RHC Abdul Hakeem

Kabirwala Tehsil, Khanewal
Abdul Hakeem
Pakistan
58180

Sponsor information

Organisation

Association for Social Development

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All personal identifiers will be removed from the data file. The anonymized data will be used for sharing if requested. No individual data will be published anywhere. The analysis will be published in a thesis, and research articles and presented in conferences to share learnings. The anonymised patient data may be shared with journals to support publication. All identifiers will be removed; therefore, no individual can be identified from the data set shared with the journal. The research data will be stored for 5 years after the final publication of the study. After 5 years, research data (hard and soft copy) will be discarded. The hard copy of the NAFF and EQ-5D-5L questionnaires and consent forms will be shredded. The soft copy of patient records, questionnaire and application data will also be deleted. Only hard copies of NCD patient records will remain at RHCs as part of routine patient records to be maintained by facility staff.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0		30/09/2024	No	No