ISRCTN16377491 https://doi.org/10.1186/ISRCTN16377491

Integrating technology-assisted diabetes foot care in Pakistan

Submission date
27/09/2024

Recruitment status
No longer recruiting

Registration date
01/10/2024

Overall study status
Completed

Last Edited
30/09/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
Ms Nida Khan

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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 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

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital

Study type(s)
Prevention, Screening, Treatment

Participant information sheet
Not available in web format

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2023

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

Age group
Adult

Lower age limit
25 Years

Sex
Both

Target number of participants
A total of 320 patients (160 in each arm) would be sufficient to address the study objectives. The researchers will recruit four districts (i.e., two districts per arm) with two randomly selected health facilities from each district. Average cluster size is assumed to be 40.

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

Sponsor details
House 12, Street 48, Sector F-7/4
Islamabad
Islamabad
Pakistan
44000
+92 (0)51 2611231 3
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Sponsor type
Charity

Website
https://asd.com.pk/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of this study will be published in a peer-reviewed journal. The protocol and project updates will also be available on the Open Science Framework. The study findings will be presented at national and international research conferences. These findings will be disseminated in a workshop to all policymakers, i.e., Directorate General Health Services and NCD Disease Control Programme.

Intention to publish date
01/10/2025

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