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Pilot and Feasibility Studies

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Engagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of Type 2 Diabetes and its Risk factors (EMPOWER-D): protocol for a feasibility cluster randomised controlled trial in urban Pakistan

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Abstract

Background Diabetes is a rapidly growing non-communicable disease globally, with 360 million out of 537 million affected adults residing in urban centres in 2021. In Pakistan, the situation is alarming, with diabetes prevalence alone exceeding 28.3% in urban areas, placing significant strain on the healthcare system exacerbated by limited resources and high management costs. Due to these multidimensional challenges, there is a growing emphasis on large-scale community-based participatory interventions like Participatory Learning and Action (PLA) for the prevention and control of type 2 diabetes mellitus (T2DM) and to improve the health outcomes of people living with T2DM. Building on a successful rural intervention from Bangladesh (D-Magic), our study aims to adapt PLA for T2DM prevention and control in urban settings and assess its feasibility in the urban context of Pakistan.

Methods The EMPOWER-D feasibility trial is a two-arm cluster randomised control trial (cRCT) with embedded economic and process evaluation, to be conducted in the urban setting of Karachi, Pakistan. Six clusters, defined as blocks with a population of 1500, will be randomly allocated (1:1) to intervention and control arms. The intervention arm will participate in an 18-month PLA intervention, which includes monthly community meetings where group members will identify, prioritise, and address issues related to T2DM and its associated risk factors. Recruitment, appropriateness, and intervention fidelity will be assessed, alongside anthropometric, biochemical, and sociodemographic data collection. The trial data will be descriptively reported for the feasibility outcomes.

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Discussion This EMPOWER-D feasibility trial is among the first to implement a culturally tailored PLA intervention to prevent and control T2DM in urban low- and middle-income countries (LMICs). By conducting a feasibility cRCT trial, we aim to generate critical insights into this approach's feasibility in an urban setting, informing the implementation of a future definitive trial. Addressing T2DM aligns with the Sustainable Development Goals for 2030, exploring how community-based research can empower LMICs to tackle local health risks and targets.

Trial registration The trial is registered at Clinicaltrials.gov on 26th August 2024 [NCT06570057].

Trial acronym Engagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of type 2 Diabetes and its Risk factors: Urban Feasibility Trial (EMPOWER-D-UFT).

Keywords Type 2 diabetes mellitus, Feasibility trial, Participatory Learning and Action, Urban, Non-communicable diseases, Prevention, Protocol

Background

Type 2 diabetes mellitus (T2DM) is a growing global health crisis, particularly in low- and middle-income countries (LMICs), where three-quarters of affected individuals now live [1]. Of the 537 million people with T2DM worldwide, 360 million reside in urban areas [2]. Rapid urbanisation and socio-economic shifts, including rising affluence, poor dietary habits, and limited green spaces, are key factors that have contributed to this surge [2]. Consequently, T2DM is now a leading cause of premature death, disability, and rising healthcare costs, contributing 75.3 million disability adjusted life years (DALYs) globally in 2021 [3]. In Pakistan, the situation is even more alarming with diabetes prevalence in urban areas exceeding 28.3%, much higher than the global urban average of 12.1% [4]. This has led to 2.07 million DALYs annually for T2DM in Pakistan [5], and a yearly per-person cost of up to $740.10, including both direct and indirect costs [6]. Recent guidelines for managing T2DM emphasise the importance of multidisciplinary integrated care as a crucial, cost-effective strategy [7]. However, in LMICs, this model places a heavy burden on consumers through high out-of-pocket expenditures [8] and further strains the already burdened healthcare systems [9]. This underscores the need for a sustainable, community-focused participatory approach that more sustainably addresses both personal and systemic factors contributing to T2DM [10].

Community Health Participatory Research (CHPR) originated in the 1970s, is a community centre approach that integrates community engagement, collaboration, and shared decision-making to co-create solutions [11]. Participatory Learning and Action (PLA), a prominent example of CHPR, inspired by Paulo Freire's philosophy [12], empowers communities to engage in health management through collective decision-making and problem-solving, leading to culturally relevant and scalable interventions that alleviate healthcare burdens and improve health outcomes.

PLA is a transformative approach that drives sustainable community change by addressing local risk factors and solutions [12, 13]. Rooted in CHPR, PLA has successfully tackled health issues, including maternal and neonatal care [13, 14], as a cost-effective, evidence-based intervention (EBI). CHPR enhances community decision-making, enabling local populations to negotiate with external agencies and develop sustainable health strategies [15]. Recently, it has been applied to non-communicable diseases (NCDs), such as the D-Magic intervention (Diabetes Mellitus: Action through Community Groups or mHealth Information for better Control) for T2DM prevention and control in rural Bangladesh [16], health promotion in ruralThailand [17], community-centred interventions for cardiovascular disease in urban Ghana [18], and mental health interventions in Zimbabwe [19]. However, its application in urban settings for NCD prevention, particularly diabetes, remains underexplored, highlighting the need for further research.

In health sciences, disease prevention increasingly focuses on implementing EBIs rigorously evaluated for efficacy and effectiveness. However, resource constraints make feasibility studies essential as an intermediary step for context-sensitive EBIs. These studies assess whether interventions are relevant, sustainable, and suitable for further testing, particularly when community partnerships are needed or research evidence is limited. Moreover, the feasibility studies also guide the adaptation of successful interventions to new contexts [20]. Consequently, this approach optimises resource utilisation, minimises risks, and delivers potentially effective interventions. Hence, the unique challenges of the urban setting, such as greater population density, socioeconomic diversity, and varying levels of access to healthcare, necessitate testing an adapted EBI.

In light of this, under the EMPOWER-D Project (Engagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of type 2 Diabetes and its Risk factors), we aim to test a PLA-based

intervention adapted from the D-Magic Trial for the prevention and control of T2DM in Pakistan. The D-Magic trial was a large cluster-randomised controlled trial conducted in rural Bangladesh to prevent and control T2DM and intermediate hyperglycaemia. It used participatory learning approach, organising community groups that met monthly for 18 months to identify barriers, raise awareness, and plan local solutions such as group exercise and kitchen gardening. The intervention combined regular small group meetings with wider community meetings to share learning and mobilise broader action. The trial demonstrated a significant reduction in diabetes prevalence—by about 48%—showing that community-led, participatory interventions can be highly effective and feasible in low-resource rural settings [15]. While a parallel full-fledged cluster randomised control trial (cRCT) will be adapted for rural Pakistan, we will test the feasibility of this intervention in the urban setting of Pakistan. This feasibility trial will allow us to assess the relevance of this approach by tailoring it to the specific needs, preferences, and varying community engagement of the urban community setting for the prevention and control of T2DM.

Primary objectives

1. To evaluate the feasibility and acceptability of delivering the culturally adapted PLA-based intervention for the control and prevention of T2DM in an urban setting in Pakistan
2. To evaluate the feasibility and acceptability of data collection to assess the potential effectiveness and cost-effectiveness of culturally adapted PLA-based intervention (for the control and prevention of T2DM) for a definitive trial conducted in an urban setting in Pakistan

Secondary objective

1. To estimate the intra cluster-correlation coefficient of outcomes to inform future sample size calculations.

Methods

Study design

The EMPOWER-D feasibility trial is a two-arm cRCT with embedded process evaluation, to be conducted in the urban setting of Karachi, Pakistan. The trial will test the feasibility of an 18-month-long PLA-based *intervention* for the prevention and control of T2DM, culturally adapted from the D-Magic trial delivered in Bangladesh. Trial *assessments* will be conducted at baseline (before starting the intervention) and at endline (at the end of the 18-month-long intervention) which comprises T2DM-based information, anthropometric measurements, and blood sampling as elaborated later in this document.

This protocol has been developed in accordance with the SPIRIT 2013 guidelines for interventional trials. The SPIRIT checklist has been completed and is included as Supplementary file 1 to ensure transparency and completeness in reporting of study design, interventions, outcomes, and data collection procedures.

The flow of the trial is depicted in Fig. 1.

Study setting

The feasibility trial will be conducted in Karachi, Pakistan, a metropolitan city with more than 14 million urban residents [21]. Karachi's administrative structure divides this densely populated city into 7 districts subclassified into 26 towns and 233 Union Councils (UCs), with a further division into blocks. For this feasibility trial, an administrative town in the District Central with a predominantly urban population will be chosen, followed by a convenient selection of the six clusters.

Study clusters

As per Pakistan's 2023 census, the smallest administrative unit, a block, with a minimum population of 1500 will be considered as an eligible cluster for the intervention as well as the assessments. To limit contamination, no two clusters will share boundaries.

Participants and recruitment

Inclusion and exclusion criteria

The participants' eligibility criteria include

For assessments

(i) Adult male and female population (≥30 years) irrespective of their T2DM status.
(ii) Local residents of the area for more than a year
(iii) Ability and willingness to provide informed consent.

For intervention

(i) Adult male and female population (≥ 20 years) irrespective of their T2DM status
(ii) Local residents of the area for more than a year
(iii) Ability and willingness to provide informed consent.

The exclusion criteria for both the assessments and the intervention include (i) pregnant females and (ii) non-local or temporary residents. Recruitment criteria is similar for both the control group and the intervention group.

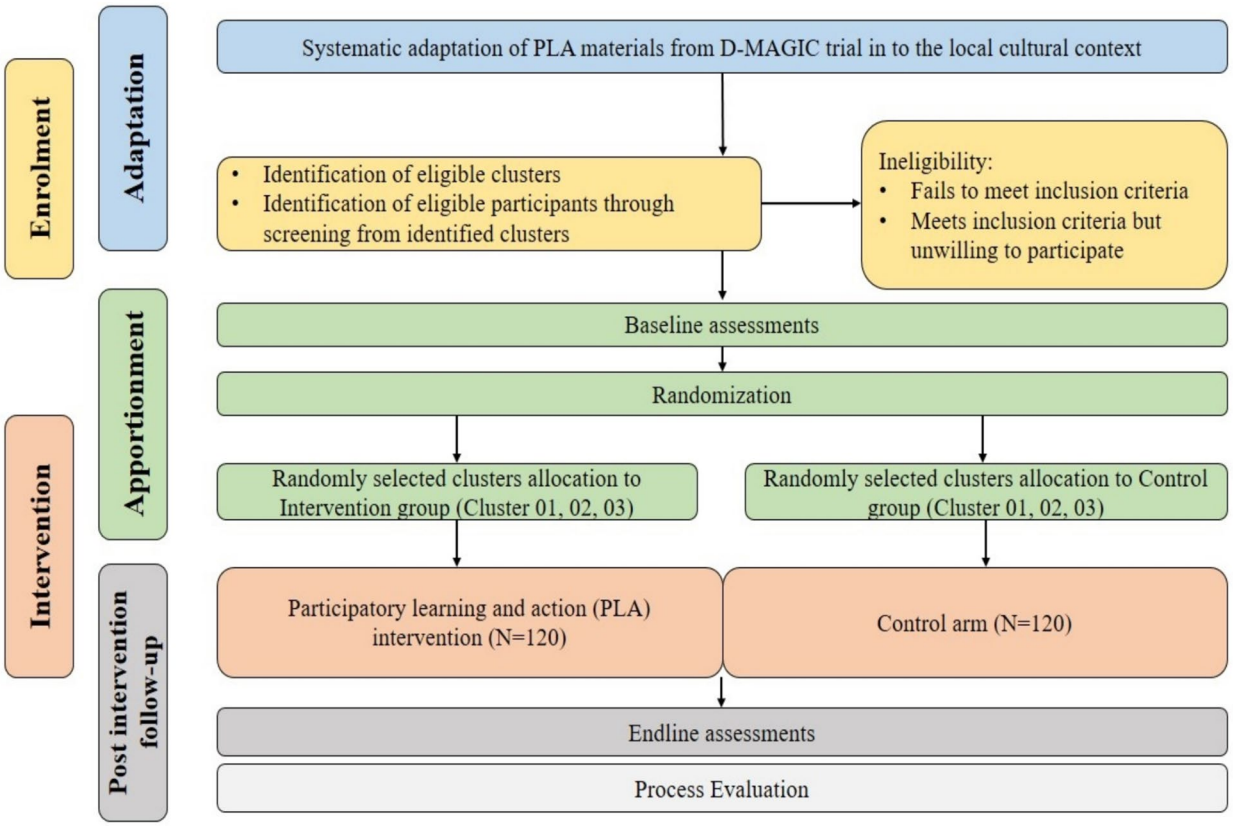

Fig. 1 EMPOWER-D feasibility trial in the urban setting

Identification of eligible participants for assessments

The trial team will obtain maps of the selected clusters from the Pakistan Bureau of Statistics' regional offices to ensure accurate boundaries. For baseline assessments, the line listing of the selected clusters will be done to enlist all eligible households within each cluster i.e., households with at least one eligible participant. Additionally, a list of all eligible participants within each household will be compiled.

Each household will be provided with a unique identification number. During this phase, we will obtain verbal consent from the heads of the households to ensure they are informed about the study in case any member from that household is selected for participation. Once all eligible participants are enlisted, a sample of 40 households will be selected through systematic random sampling with a subsequent random selection of one eligible participant from each household, ensuring equal male and female representation.

Consent and enrollment of eligible participants for assessments

Subsequently, the selected eligible participant and their household head will be again approached to brief them about the project and their role via project information sheets (PIS). The PIS would include the details of the intervention and assessments, their frequency, potential benefits and risks, participant responsibilities, information on how the collected data will be handled and used throughout the study, and contact information of the representative in case they have any queries about the project. The selected participants will be given at least 24 h to review the PIS before providing written consent. Once the enrollment of eligible participants is completed, baseline assessment data will be collected as outlined in the data collection methods section.

Cluster randomization and allocation

After baseline assessment, the selected clusters will be randomised into intervention and control arms in 1:1 allocation. Three of the six clusters will receive the culturally adapted PLA-based intervention while the other three clusters will be usual practice controls.

The Culturally Adapted Intervention (PLA)

Before testing the intervention for feasibility, the PLA-based intervention from D-Magic will be adapted to account for the cultural and contextual factors of urban

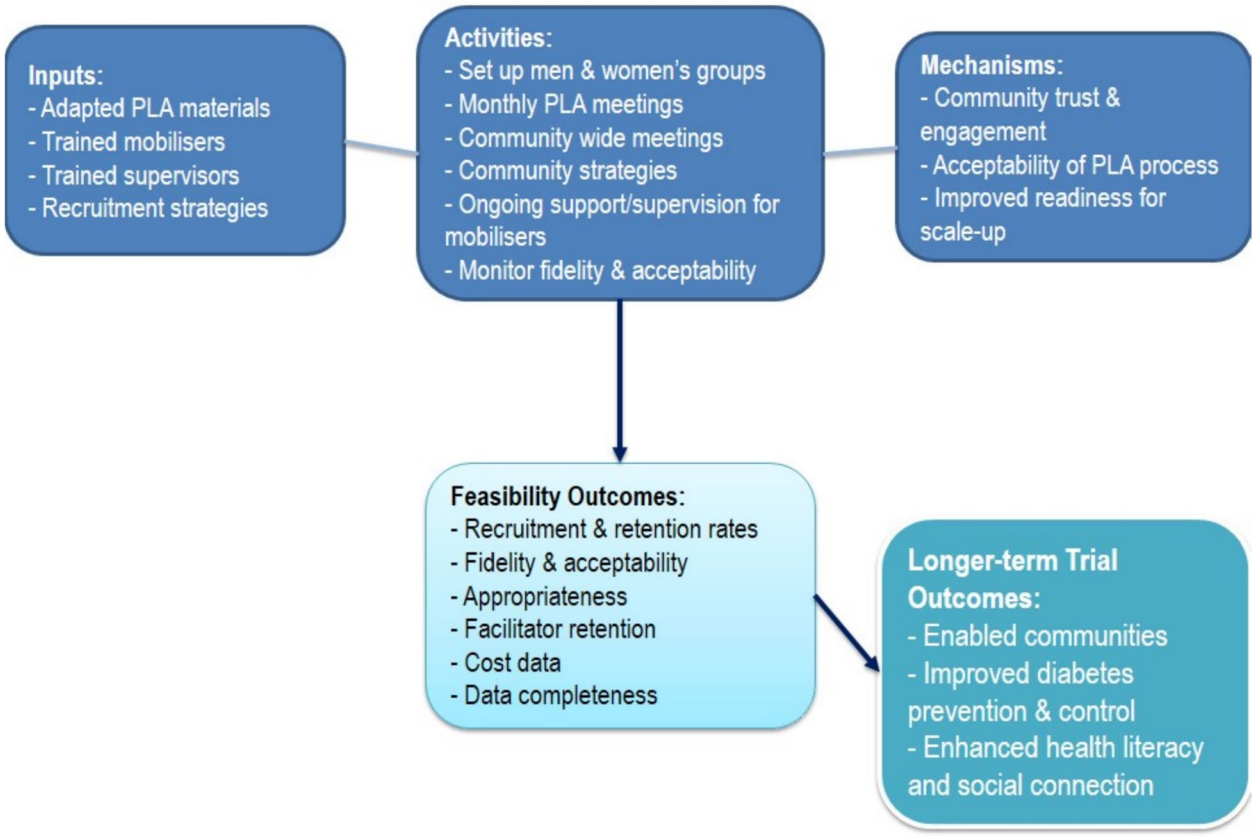

Fig. 2 Logic model for EMPOWER-D feasibility trial in urban Pakistan

settings in Pakistan. The EMPOWER-D adaptation process will be guided by the ADAPT framework and includes systematic steps to ensure cultural and contextual relevance. This involves conducting a qualitative study and a scoping review to identify local barriers and facilitators, followed by co-design workshops with community members, healthcare providers, and other stakeholders to adapt the PLA materials and delivery methods according to the unique sociocultural context. The intervention content, group structures, and facilitation tools are then refined through pilot testing and stakeholder feedback, ensuring alignment with local norms, gender dynamics, and community needs in urban settings of Pakistan.

Intervention—participatory learning and action

The trial intervention is based on the PLA cycles which is divided into four distinct phases [22], i.e., identify and prioritise problems, plan strategies with the community, implement strategies and evaluate and reflect.

Phase 1: identify and prioritise problems The first phase of the intervention will focus on identifying problems in addressing unhealthy behaviours and risk factors for T2DM such as poor diet, physical inactivity, stress, tobacco use, etc.

Phase 2: plan strategies with the community In the second phase of the PLA intervention cycle the community members will plan strategies to address the problems identified in the first phase and how to implement them as per their circumstances.

Phase 3: implement strategies The third phase will involve community members implementing the planned strategies

Phase 4: evaluate and reflect The final phase will focus on evaluating and reflecting on implementing the strategies for improvement and self-reflection.

Intervention logic model

To enhance reproducibility and clarify the hypothesised pathways of change, a logic model has been developed for the EMPOWER-D feasibility trial (Fig. 2). The logic

model illustrates how the adapted PLA cycle is expected to work in an urban Pakistani context. It shows the key inputs (adapted materials, community mobilisers (CMs) supervision ands monitoring structures, and community engagement activities), core activities (monthly men's and women's group meetings, facilitator training, monitoring, and pilot community meetings), and the hypothesised mechanisms (building community trust and engagement, acceptability of the PLA process, and early signals of improved community readiness).

The immediate focus of this feasibility trial is to test whether these mechanisms can be triggered and whether the intervention delivery is acceptable, appropriate, and feasible for scale-up. The logic model also highlights the feasibility outcomes (e.g., recruitment and retention rates, intervention fidelity and appropriateness, facilitator retention, cost, and data completeness) that will inform the design of a future definitive trial for T2DM prevention and control in urban Pakistan.

Intervention schedule and facilitation

The intervention would be delivered through 15 monthly group meetings and three wider community meetings. To align with cultural norms, separate male and female groups will be established within each intervention cluster, resulting in three male and three female groups. These meetings will be held once a month and be open to all community members, aged $\geq$ 20 years, residing within targeted clusters. The smaller group meetings will have 20–30 participants per group, whereas the community group meeting will be conducted at the district level involving all gender-based smaller groups.

These meetings will be facilitated by locally hired CMs with a minimum of 12 years of formal education and will be supervised by a trained supervisor. The date, time, and location of the meetings will be determined based on the convenience and consensus of community members. For the first meeting, this consensus will be reached through feedback collected during community mobilisation activities. For subsequent meetings, consensus will be gathered at the end of each meeting regarding the schedule for the next one. All details will be communicated at least 15 days in advance by the CMs, who will also send reminders through text messages and phone calls to ensure everyone's availability and participation.

Intervention training and adherence to the intervention protocol

A community mobiliser's manual will be developed to train the CMs on the content for the PLA meetings. It is a comprehensive step-by-step guide designed to help CMs facilitate PLA meetings. It will begin with an introduction to the project's goals and the mobiliser's role, followed by detailed outlines for 18 themed meetings covering topics such as diabetes awareness, care-seeking, healthy diet, exercise, mental wellbeing, and tackling addictive habits. Each session will provide clear objectives, suggested activities, key discussion questions, and practical tools for engaging local communities. The manual will emphasize interactive learning, community ownership, and culturally relevant solutions, guiding mobilisers from initial awareness-raising to planning, implementation, evaluation, and ultimately handing over leadership to the community.

Additionally, an operational manual will provide executional and logistical guidance for both the CMs and supervisors. The Operational Manual will provide detailed guidance for planning and delivering the community-based PLA intervention. It will cover both the pre-intervention and intervention phases, explaining how to secure approvals, select sites, recruit and train community teams, and organize group meetings. It will outline clear procedures for community mobilization, venue arrangements, consent, record-keeping, supervision, and reporting. The manual will also define roles and responsibilities for supervisors and community mobilisers to ensure smooth coordination and consistency across sites. By combining practical instructions with templates and checklists, it will help the team implement PLA cycle to enable communities to identify problems, plan and carry out solutions, and evaluate progress. A supervisor's checklist will be administered to evaluate the progress of the meetings and monitor the role of the CMs during these sessions.

Control arm

The control arm will follow the usual practice which refers to the absence of any structured community-based intervention or targeted diabetes prevention activities introduced by the research team. These clusters will continue with their regular health-seeking behaviours and access to healthcare as per existing public or private services available in their locality. No participatory group meetings or health education activities will be facilitated by the study team.

All study participants across clusters will receive printed reports detailing the findings of their blood samples. Participants with clinically significant results, as determined by laboratory standards, will be referred to a nearby physician for further evaluation. Additional trial findings will be available to participants upon request.

Trial outcomes

The outcomes of the trial are categorised into feasibility outcomes for assessments and intervention delivery, as outlined in Table 1.

Table 1 Feasibility outcomes of the trial with progression criteria

Outcomes/timepoints	Description of assessment/tools	Progression criteria*
Assessments		
Recruitment rate**	The proportion of eligible participants who are successfully recruited to participate	Green—≥ 75% of eligible participants successfully recruited Amber—60–74% of eligible participants successfully recruited Red—< 60% of eligible participants successfully recruited
Follow-up rate for IHG$	The percentage of identified individuals with IHG who are successfully followed up after the baseline assessment, up to the endline assessment	Green—≥ 75% of identified individuals with IHG at baseline successfully followed up until the endline assessment Amber—60–74% of identified individuals with IHG followed up until the endline assessment Red—< 60% of identified individuals with IHG followed up until the endline assessment
Data completeness**	Data will be evaluated for completeness to check the acceptability and feasibility of data collection methods, and to identify any issues and areas of improvement	Green—≥ 75% of collected data is complete Amber—60–74% of collected data is complete Red—< 60% of collected data is complete
Intervention		
Intervention fidelity$	Assessing the content delivered during the intervention, adherence to the trial protocol and manual guidelines, engagement and retention of meeting attendees during the intervention, and any interruptions or deviations from the planned activities through intervention meeting records and stakeholder interviews	Green—≥ 75% adherence to the intervention content and schedule, high engagement and retention rates (e.g., ≥ 80% of attendees present throughout) Amber—60–74% adherence, moderate engagement and retention rates Red—< 60% adherence, low engagement and retention rates
Appropriateness of the intervention delivery$	Reviewing whether the intervention was delivered in a manner that aligns with the needs, preferences, and context of the target population, ensuring it is suitable and relevant for participants	Green—the intervention delivery is highly appropriate, with positive feedback from participants indicating that the intervention aligns well with their needs and preferences—judged strongly through qualitative data Amber—the intervention delivery is moderately appropriate, with some areasneeding improvement Red—the intervention delivery is inappropriate, with significant concerns raised by participants regarding its relevance and suitability
Retention of facilitator$	The proportion of facilitators retained in the study throughout the intervention	Green—≥ 75% retention rate of facilitators throughout the intervention period Amber—60–74% retention rate of facilitators throughout the intervention period Red—< 60% retention rate of facilitators throughout the intervention period
Cost of intervention (including development and delivery)$	Financial records including invoices and receipts	Green—costs within estimated budget with detailed records maintained Amber—costs slightly exceed budget with documentation mostly complete, but the intervention remains manageable Red—costs significantly exceed the allocated budget, indicating high costs of implementation and challenges with sustainability

* Green—proceed with a definitive trial; amber—proceed with changes; red—do not proceed unless changes are possible

** Baseline and endline assessment

$ Endline assessment (process evaluation)

Table 2 Assessment-based measures for the trial

Assessment measures	Description of measures/tools used
Sociodemographic information	Age, sex, religion, marital status, education, occupation, and socioeconomic status
Knowledge of T2DM	Questions in the CRF adapted from DMagic Trial [16] including knowledge on causes, symptoms, complications, and management of T2DM
Health and medical history	Related to cardiovascular diseases, hypertension, and T2DM
Health-related behaviours and risk factors (diet, physical activity, and tobacco)	Food Frequency Questionnaire [23] for diet, International Physical Activity Questionnaire [24] for physical activity, and smoking history
Quality of life	World Health Organization Quality of Life Brief version [25]
Mental health (depression and anxiety)	Patient Health Questionnaire 9 [26]for depression and Generalised Anxiety Disorder 7 [27] for anxiety
Diabetes healthcare resource utilisation	Modified Client Service Receipt Inventory capturing medications, clinical appointments, and hospital services [28]
Anthropometry	Height (cm), weight (kg), blood pressure (mmHg), waist circumference (cm), hip circumference (cm), total body fat%, and visceral fat%
Glycated haemoglobin (%)	Venous sample
Fasting plasma glucose (mg/dl)	Capillary blood sample (finger prick) via Glucometer
Complete blood count	Venous sample

Data collection methods

Data will be collected from participants in their households using Research Electronic Data Capture (REDCap) software. During the first visit, trained CMs will record survey-based information on the Case Report Form (CRF) and conduct anthropometric assessments, as detailed in Table 2. A follow-up visit will be scheduled by the CMs within three working days to collect blood samples, with participants instructed to fast overnight. If participants are unavailable or data is incomplete during the scheduled visit, the CM will remind them on days 3, 7, and 14 to reschedule the visit.

The same process will be followed for endline assessments, independent of the baseline cohort. However, participants identified with intermediate hyperglycemia (IHG) at baseline will be followed throughout the trial to monitor their progression to T2DM, and this cohort will be assessed alongside the endline sample.

All outcomes will be assessed at baseline and endline of the trial.

Sample size

As the study is a feasibility trial, a formal sample size is not calculated. For each of the three intervention clusters, a minimum of one female and one male group will be formed. If we assume that we identify 20 eligible participants for each sex in each cluster this provides 120 female and 120 male eligible participants, distributed as 40 participants per cluster (aged $\geq$ 30 years). This enables us to estimate a participation rate of 50% with a margin of error of 9% for a 95% confidence interval [29].

Process evaluation

The feasibility and acceptability of the PLA intervention, its processes, and its outcomes will be assessed through the process evaluation. PE will be an iterative approach that will utilise the Medical Research Council framework to identify effective or ineffective elements that contribute towards the implementation of the intervention, contextual influences, and mechanism of impact [30], assessed through a mixed-method approach.

The implementation of the intervention will be evaluated by assessing the fidelity, reach, and dose delivered for the intervention. Contextual influences refer to the external factors such as contextual, cultural, or socioeconomic factors that act as an enabler or barrier to the delivery and uptake of the PLA intervention components and its outcomes by the population. Perception, engagement, and participant view about the intervention acceptability and trial procedures will be evaluated in terms of responsiveness to the mechanism of impact.

Economic data

Data on intervention costs will be estimated by capturing information on resources utilised in the development, delivery, training, administrative, and monitoring costs. Wider healthcare resource use data by study participants will also be collected. The feasibility of calculating cost-effectiveness analysis will inform a future economic evaluation embedded within a definitive large-scale cRCT.

Statistical analysis

The results for this cRCT will be analysed and reported following the CONSORT extension for pilot and feasibility trials [31].

The primary study outcomes are focused on evaluating the feasibility outcomes of the PLA-based intervention. The key indicators will include the recruitment rate for assessments, retention rate within meetings, adherence, and fidelity to intervention. These will be reported descriptively. Additionally, the secondary outcome measures i.e, data collected through the CRF will be summarised descriptively.

The continuous data will be reported as mean, standard deviation, median, and 25th and 75th percentiles. The categorical data will be reported as frequencies and percentages. Additionally, a 95% confidence interval will be estimated. Data collection completion rates of all the outcome measures will be reported by respective study arms to assess data collection thoroughness

Given the small number of clusters per arm, we acknowledge that any intracluster correlation coefficient (ICC) estimates will be highly imprecise. Nevertheless, we will calculate ICCs for key quantitative outcomes using a one-way random effects model and report the point estimate along with a 95% confidence interval. These ICC estimates are intended to provide preliminary information for planning a future definitive trial, rather than for formal hypothesis testing.

Data management

The Data Management Plan of the EMPOWER-D trial adheres to both the United Kingdom Data Protection Act 2018 [32] and the Pakistan Data Protection Act 2020 [33]. It also abides by the FAIR (Findable, Accessible, Interoperable, and Reusable) Data Principles, endorsed by the National Institute of Health Research (NIHR) Open Research [34].

The CRF will be uploaded to a secure online platform REDCap, and the trial team including CMs and data collectors will be trained to collect data digitally using tablets after obtaining consent. An online data tracker will enable real-time monitoring to ensure timely and accurate data capture. All data gathered will be securely transferred to the institutional database for analysis using the statistical software package STATA version 14 (or later), with regular backups to an online server. Additionally, qualitative data, such as audio recordings from key informant interviews (where applicable), will be securely stored on a password-protected computer belonging to the local qualitative researcher.

Once the verbal transcripts are completed, the recordings will be deleted from the recording device. Any hard copies, including consent forms, supervisor's checklist, attendance records, and reports of meetings, will be securely stored in locked cabinets at host institutions.

All documents and audio recordings will be retained for at least 10 years before being destroyed. Blood samples will be preserved at the laboratory for 1 year following the completion of endline data collection.

Data quality standards

The data collectors, phlebotomists, CMs, and supervisors will be trained in the standard operating procedures for data collection to ensure high data-quality outputs. Blood samples collected in the field will be transferred to the institutional laboratory and processed as per the laboratory protocol. Data quality will be maintained through comprehensive training and continuous supervision. To ensure accuracy, data entry will be regularly validated by double-checking a random sample of field data by the site data coordinator. The quality of qualitative data will be maintained by ensuring that effective questioning techniques are practised by training the researchers led by an experienced qualitative expert. Approximately 10% of the data will be cross-checked by charting into matrices to maintain the accuracy of the reported findings. Overall, the quality of the data will be monitored and maintained by the trial's data management team.

Reporting of adverse events (AEs)

When a participant reports an AE, research assistants will promptly complete an AE form, including a medical diagnosis if available. Although minimal to no AEs are expected due to the non-invasive, non-pharmacological nature of the intervention, any AE will be reported to the trial manager on the same day. The possible AEs could include bruising at the needle puncture site, hematoma, dizziness, or fainting due to any reason. The trial manager will classify the event and report it to the Principal Investigator (PI) within 3 days. Minor discomfort, such as pain or anxiety during blood sampling, may occur, and the team will be trained to manage these situations.

AE data will be compiled and submitted to trial sponsors and the National Bioethics Committee every 6 months and shared with the study Steering Committee, and Data Safety & Management Board (DSMB). Serious adverse events (SAEs) must be reported to the PI within 24 h and to the sponsors, National Bioethics Committee, and DSMB within three working days. The PI is responsible for ensuring compliance with all reporting protocols.

Patients and public involvement

The EMPOWER-D feasibility trial is a community-based and community-driven participatory project that considers community members as equal stakeholders. The public involvement will thus encompass the entire duration of the project and even after trial, with community

members owning the intervention for sustainability and its future potential effectiveness. This will enable us to strengthen and support the trial and will add relevance to the intervention.

Regular community mobilisation activities will be conducted before assessments and intervention meetings for community engagement and involvement. This will include individual and group meetings with the local community representatives of the area, briefings to the local Union Councils or *Muhalla Nazims* about the project, mobilization through social media messages and campaigns, and dissemination of project information through local influencers or Masjid Imams (local religious leaders).

A community advisory panel will also be formed that will be involved at every step of the trial including planning, implementation, assessments, interpretation of findings, and dissemination. Owing to the vision of NIHR, this will help us undertake the trial with the community that is affected by T2DM [35].

Protocol amendment, violations, and deviations

The research team will receive comprehensive training to prevent any protocol deviations. However, deviations will only be permitted when necessary for participant safety and must be approved by the PI, the ethics committee, and the program steering committee. Any changes in research activities will first be reviewed with the PI before submission to the ethics committee for formal approval. The program steering committee will guide whether the deviation or amendment is classified as major or minor. All deviations will be recorded in a protocol deviation log. Minor amendments can be implemented upon notification, while major amendments require ethics committee approval before implementation.

Discussion

To the best of our knowledge, this EMPOWER-D feasibility trial is one of the first to implement a culturally tailored PLA intervention for the prevention and control of T2DM in the urban context. By conducting a cluster randomised controlled feasibility trial, we aim to add evidence and insights into the acceptability, fidelity, and implementation of culturally tailored PLA intervention for the prevention and control of T2DM in these relatively underexplored urban settings.

Addressing NCDs specifically T2DM is a key priority area and aligns with the agenda Sustainable Development Goals for 2030 [36]. Given the burden of T2DM in urban environments of LMICs [37], it is both important and pertinent to explore community health participatory research as an emerging implementation science approach to empower communities to explore local determinants and risk factors contributing to the burden of NCDs; and develop their health and wellbeing targets with cultural relevance. The planned mixed method approach will also estimate the impact of community mobilization through community-level strategies, implementation, and process evaluation to inform CHPR approach feasibility and a definitive future trial.

Dissemination

The findings of this trial will be published in peer-reviewed journals and will be disseminated to all stakeholders through conferences, social media, dissemination events, and scientific publications. Additionally, in case of proven feasibility of the trial, we will leverage our resources to evaluate this intervention with a definitive trial for full-scale implementation in urban settings across other cities, provinces, and nationwide.

Abbreviations

T2DM	Type 2 diabetes mellitus
LMICs	Low- and middle-income countries
DALYs	Disability adjusted life years
CHPR	Community Health Participatory Research
PLA	Participatory learning and action
EBI	Evidence-based intervention
NCDs	Non-communicable diseases
D-Magic	Diabetes Mellitus: Action through Community Groups or mHealth Information for better Control EMPOWER-DEngagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of type II Diabetes and its Risk factors
cRCT	Cluster randomised control trial
UCs	Union Councils
CMs	Community mobilisers
IHG	Intermediate hyperglycemia
REDCap	Research Electronic Data Capture
CRF	Case Report Form
NIHR	National Institute of Health Research
AEs	Adverse events
PI	Principal investigator
DSMB	Data Safety & Management Board
SAEs	Serious adverse events

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-025-01762-x.

Additional file 1: SPIRIT 2013 Checklist.

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Nohail Khan, Saud Abbassi, Haroon Rasheed.

Authors' contributions

Sara Imtiaz (SI) conceptualised and designed the trial, drafted the manuscript, tables, and figures, designed the study data management systems, was responsible for the final version of the manuscript, and overlooked the intervention delivery. Rubia Zafar (RZ) conceptualised and designed the trial, drafted the manuscript, tables, and figures, was responsible for the final version of the manuscript, and will lead the trial. Amber Tahir (AT) conceptualised and designed the trial, drafted, reviewed, and edited the manuscript, and will lead the process of assessments and process evaluation. Mariam Abdeali

(MA) prepared the manuscript and will support the intervention delivery, trial assessments, and process evaluation. Farrukh Ahmed (FA) prepared the manuscript and led all field work relevant to intervention delivery and the assessments. Amna Mansoor (AM) prepared the manuscript and will support the intervention delivery and assessment teams. Asima Khan (AK) conceptualised and designed the trial, reviewed and edited the manuscript. Asher Fawwad (AF) conceptualised and designed the trial, reviewed and edited the manuscript. Abdul Basit (AB) conceptualised and designed the trial, reviewed and edited the manuscript, and is the co-principal investigator of the trial. Simon Walker (SW) conceptualised and designed the trial and will lead the economic analysis of the data. Saima Afaq (SA) conceptualised and designed the trial, reviewed the manuscript, and will lead the adaptation of the intervention. Khalid Rehman (KR) conceptualised and designed the trial, prepared and reviewed the manuscript, leading the trial for rural Pakistan. Zohaib Khan (ZK) conceptualised and designed the trial, prepared and reviewed the manuscript, leading the assessments for rural Pakistan. Mona Kanan (MK) conceptualised and designed the trial, provided expertise on sampling, and will lead the statistical analysis. Hannah Maria Jennings (HMJ) conceptualised and designed the study, reviewed the manuscript, will oversee adaptation, intervention delivery, and process evaluation. Abdul Rahman Shahab (ARS) conceptualised and designed the study and reviewed the manuscript, leading the trial in Afghanistan. Kamran Siddiqi (KS) conceptualised and designed the study, reviewed the manuscript, and will oversee the trial. Zia ul Haq (ZH) conceptualised and designed the study, reviewed the manuscript, and was co-principal investigator for the trial.

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Data availability
Data sharing is not applicable to this article, as no datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The EMPOWER-D protocol has been granted ethical approval by the National Bioethics Committee of Pakistan (NBC-R-1070). Additionally, ethics approvals from the Ethics Review Committee of The Aga Khan University (2024-9340-28927), Khyber Medical University (KMU/IPHSS/Ethics/2023/EO/0136) and Baqai Institute of Diabetes and Endocrinology (BIDE/IRB/ABDULBA-SIT/05/15/24/025) have also been obtained.
The study will adhere to the MRC Good Clinical Practice guidelines [38] and the National Health Service (NHS) Research Governance Framework [39]. The trial will uphold participants' human rights and dignity as outlined in the 1996 Declaration of Helsinki [40]. Informed written consent will be taken from all participants included in the assessments and the intervention after informing them about the study's purpose, procedures, potential risks, and benefits. Participants will not receive financial incentives for their involvement.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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