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Engagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of type II Diabetes and its Risk factors (EMPOWER-D) - A Protocol for a Cluster Randomised Controlled Trial

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Abstract

Background In Pakistan, every third adult is suffering from diabetes. Community-based approaches have the potential to be effective in preventing diabetes. We aim to evaluate the effectiveness of a Participatory Learning and Action (PLA) intervention in the prevention and control of diabetes.

Methods We will conduct a two-arm cluster randomised controlled-trial in two rural tehsils of district Swabi and district Peshawar in Pakistan.

We will recruit 72 randomly selected clusters (the smallest official administrative unit in a tehsil) from two districts of the Khyber Pakhtunkhwa Province of Pakistan. From each cluster, 177 participants will be randomly selected for baseline and follow-up assessments, constituting a total sample size of 12,744. Following the baseline survey, the 72 clusters will be randomly allocated (1:1) to the intervention and control arms. The intervention arm will receive an 18-month long PLA intervention, including monthly community meetings where group members will identify, prioritise, and address problems associated with diabetes and the related risk factors.

The primary outcomes of the trial are the prevalence of Type II Diabetes Mellitus (TIIDM), prevalence of Intermediate Hyperglycaemia (IHG), and 2-year cumulative incidence of TIIDM. Secondary outcomes include prevalence of hypertension, body mass index, abdominal obesity, prevalence of overweight & obesity, body fat composition, fruit and vegetable intake, physical activity, quality of life, psychological distress, knowledge of TIIDM

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risk factors, symptoms, & complications and self-awareness of diabetic status. Embedded economic and process evaluations will also be conducted.

Ethics and dissemination The trial has received ethics approval from the National Bioethics Committee of Pakistan, and the ethics committees of The Aga Khan University, and Khyber Medical University. We will use a variety of channels, conferences, social media, dissemination events, and scientific publications to share the study findings with all the relevant stakeholders.

Trial registration The trial is registered with clinicaltrials.gov—NCT06561126**.** Date of registration: 23rd August 2024.

Keywords Diabetes, Participatory Learning and Action, Intermediate Hyperglycaemia, Non communicable diseases, Cluster RCT, Rural, Pakistan

Background

Type II Diabetes Mellitus (TIIDM) is rapidly transforming into a health emergency, affecting 537 million adults worldwide in 2021. [1] Global projections for the year 2045 suggest a 12.2% rise in the prevalence of TIIDM, and a 23.6% in the prevalence of Intermediate Hyperglycaemia (IHG). [1] An estimated 80% of the people with TIIDM reside in low-and middle-income countries (LMICs), putting extra strain on health systems that are already overburdened with both infectious and Non-communicable Diseases (NCDs). [2]

According to the International Diabetes Federation (IDF), in 2022, 26.7% (33 Million) of adults in Pakistan were affected by diabetes, with 99% having TIIDM. [1] The enormous burden of TIIDM prevalence in Pakistan can be attributed to behavioural changes over time, limited access to healthcare, and socioeconomic and cultural factors. [3]

Diabetes not only affects the physical health of individuals but puts an additional emotional, social, and economic burden on the patients. The global health expenditure due to diabetes has grown from US $232 billion in 2007 to US $966 billion in 2021 for adults aged 20–79 years–a 316% increase over 15 years. [1] TIIDM resulted in 75·3 million (95% UI 63·5–90·2) global Disability Adjusted Life Years (DALYs) in 2021 and was responsible for 2·6% (2·3–2·9) of total global DALYs. [4] A systematic review of the economic costs of diabetes reported that diabetes management in LMICs is costly, the outpatient visits annual costs in Bangladesh, Iran, and Nigeria were 24 million USD, 26.8 million USD, and 85 million USD, respectively [5]. The annual medicine costs were 195 million USD, 225 million USD, and 522 million USD in Bangladesh, Iran, and Nigeria respectively. [6–8]

Managing diabetes is costly, lifelong, and requires specialised care that is often out of reach for individuals in LMICs. Therefore, it is crucial to focus on population level prevention strategies that are accessible to communities as opposed to costly solutions like insulin and medicines that are more individual focussed. Behavioural therapies, such as behaviour change and counselling, healthy diet, moderate physical activity, smoking cessation, and psychosocial support, have been used to prevent TIIDM in vulnerable populations successfully. [9–11] These interventions, when tailored to the local contexts, have a great potential to decrease both the incidence of TIIDM through addressing its risk factors, as well as its prevalence through better management. [11, 12] Context-sensitive community-based prevention approaches are therefore essential for the prevention and control of TIIDM by providing accessible, cost-effective, and culturally appropriate strategies. [13]

Participatory Learning Action (PLA) is a community-based method that addresses health problems and inequalities by empowering communities to identify needs, plan solutions, and evaluate outcomes. This approach enhances healthcare quality and fosters partnerships among stakeholders. [14] PLA uses various techniques, such as visualisation and group work, and follows a systematic group-based cycle, with the community coming together to identify problems, plan strategies, and then implement them to address them. [15] It has improved maternal and neonatal outcomes in low-resource settings like Nepal, India, Malawi, and Bangladesh, and has recently addressed TIIDM. [14, 15] In Nepal, PLA activities led to a significant reduction in neonatal and maternal mortality. [16] In Jharkhand, India, a trial showed that PLA interventions by women's groups significantly reduced neonatal deaths and were cost-effective. [17]

Following the PLA approach, DMagic (Diabetes Mellitus Action through Groups or Information for better Control), a Cluster Randomised Controlled Trial (CRCT) in Bangladesh, revealed a significant improvement in community awareness and knowledge of TIIDM. The trial involving the PLA intervention was delivered for 18 months with 74% participation and over 90% repeat attendance in monthly group meetings. The end-of-study analysis showed the likelihood of TIIDM and IHG was 64% lower in intervention villages compared to control villages (adjusted odds ratio (95% confidence interval) 0.36 (0.27, 0.48)). In the intervention group, 28.5%

(n = 1,071) of the population had TIIDM or IHG. In contrast, the prevalence was higher in the control group, affecting 48.7% (n = 1,861). [12, 14]

Pakistan, like Bangladesh, is a South Asian LMIC with a very high prevalence of TIIDM. [1, 13] The healthcare system in Pakistan, also similar to Bangladesh, faces challenges like resource constraints. However, what differs between the two are the cultural contexts. Given that community-based approaches have to be context specific and sensitive to cultural dynamics, it is imperative to assess whether an approach that has been successful in one LMIC setting is also successful in another with a different cultural setting and context. The utility of participatory approaches in prevention of disease or improving health outcomes can only be ascertained once they have been tested in varying contexts, as has been the case in improving maternal and child health outcomes in LMICs through PLA. [15, 17] The evidence on preventing TIIDM through PLA is only limited to the DMagic trial in Bangladesh, implying a need for this approach to be tested in other LMIC contexts to establish its utility. We aim to conduct a scientifically robust trial based on a PLA approach to assess the effectiveness of PLA in preventing TIIDM.

The objectives of the Engagement of coMmunity through Participatory learning and action for cOntrol and preVEntion of type II Diabetes and its Risk factors (EMPOWER-D) trial are to adapt, implement, and evaluate PLA-based intervention for the prevention and control of IHG and TIIDM in rural settings of Pakistan.

Methods

Trial design

We will conduct a two-arm cluster randomised control trial (cRCT) of PLA-based intervention with embedded process and economic evaluations. Given that the intervention is community-based and will be implemented at a group level, cRCT is the most appropriate trial design.

Study settings

The EMPOWER-D trial will be conducted in rural settings of two districts of the Khyber Pakhtunkhwa province of Pakistan, namely Swabi and Peshawar (Fig. 1). The Khyber Pakhtunkhwa province lies in the North-Western frontier region of the country, bordering Afghanistan. The two study sites are inhabited mainly by Pashto-speaking ethnic Pashtuns. The two districts have a combined population of 4.3 million. The prevalence of TIIDM in these districts is comparable to national figures. The districts are predominantly rural, however, the infrastructure, including healthcare facilities and security, is adequate to run a large PLA trial.

Study clusters

We will recruit 72 clusters from the two sites (Peshawar and Swabi), i.e. 36 from each site. The two districts are administratively further divided into tehsils. There are seven and four tehsils in Peshawar and Swabi, respectively. We have selected one tehsil purposely from each district. The smallest official administrative unit in the tehsil is called a block. There are 239 and 197 blocks in the tehsils of Peshawar and Swabi, respectively. The average population size of the block is around 1500. This block is our clustering unit for the trial (Fig. 2).

The eligibility criteria is as follows.

Inclusion criteria

- We will recruit clusters that have a population of 1500 or more

Exclusion criteria

- If two clusters with a population of 1500 or more share a geographical border, then the one with a population closer to 1500 will be selected, and the other will be excluded.
- Clusters not willing to participate will be excluded.

Identifying and recruiting eligible clusters

We will get the list of clusters (blocks) from the Pakistan Bureau of Statistics (PBS) for both study sites. That list will be screened for identifying eligible clusters. A random sample of 72 clusters i.e., 36 clusters for each district, will then be drawn from the list of eligible clusters. The local elders or community representatives from each cluster will be approached and provided verbal information about the study. The clusters that do not agree to participate after receiving the trial information will not be enrolled in the trial. Their reasons for declining to participate will be recorded.

Withdrawal of clusters (blocks)

Once recruited, we will endeavour to keep all clusters on board and retain them in the study. If for any reason, a cluster withdraws before baseline assessments we will replace the cluster. However, if the withdrawal takes place after baseline assessments and randomisation, we will not replace such a block and include the data collected to date in our analyses.

Study participants and households

In the first step the eligible households fulfilling the following criteria will be identified.

i. The household must fall within the boundaries of the selected clusters.

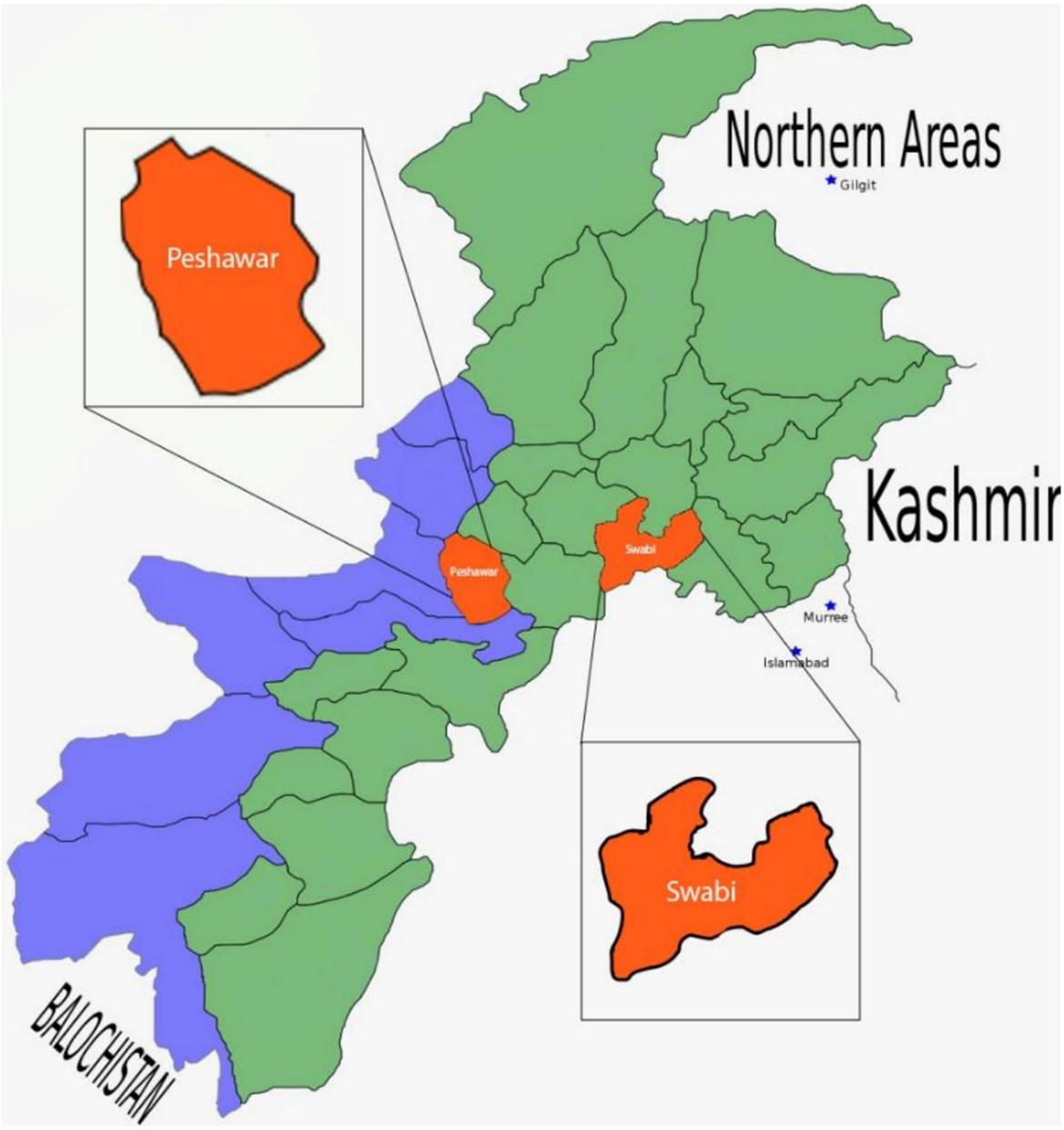

Fig. 1 Map of Khyber Pakhtunkhwa province showing districts

ii. The household must have at least one eligible participant.
iii. The household head consents to the participation of his/her family in assessments.

In the next step participant from the selected household will be identified as per below details.

Participants for baseline and endline assessments

We will assess 12,744 male and female participants aged 30 years and above, from the 72 randomly selected clusters in baseline and the endline assessments.

Inclusion and exclusion criteria for study participants

i. All males and non-pregnant females living at their current address for at least one year.
ii. Aged more than 30 years
iii. Have the ability to provide informed consent and undergo anthropometry and phlebotomy procedures.

Identifying eligible participants

Before starting the assessment community mobilisation activity will be conducted to ensure maximum participation by the community. Following this community

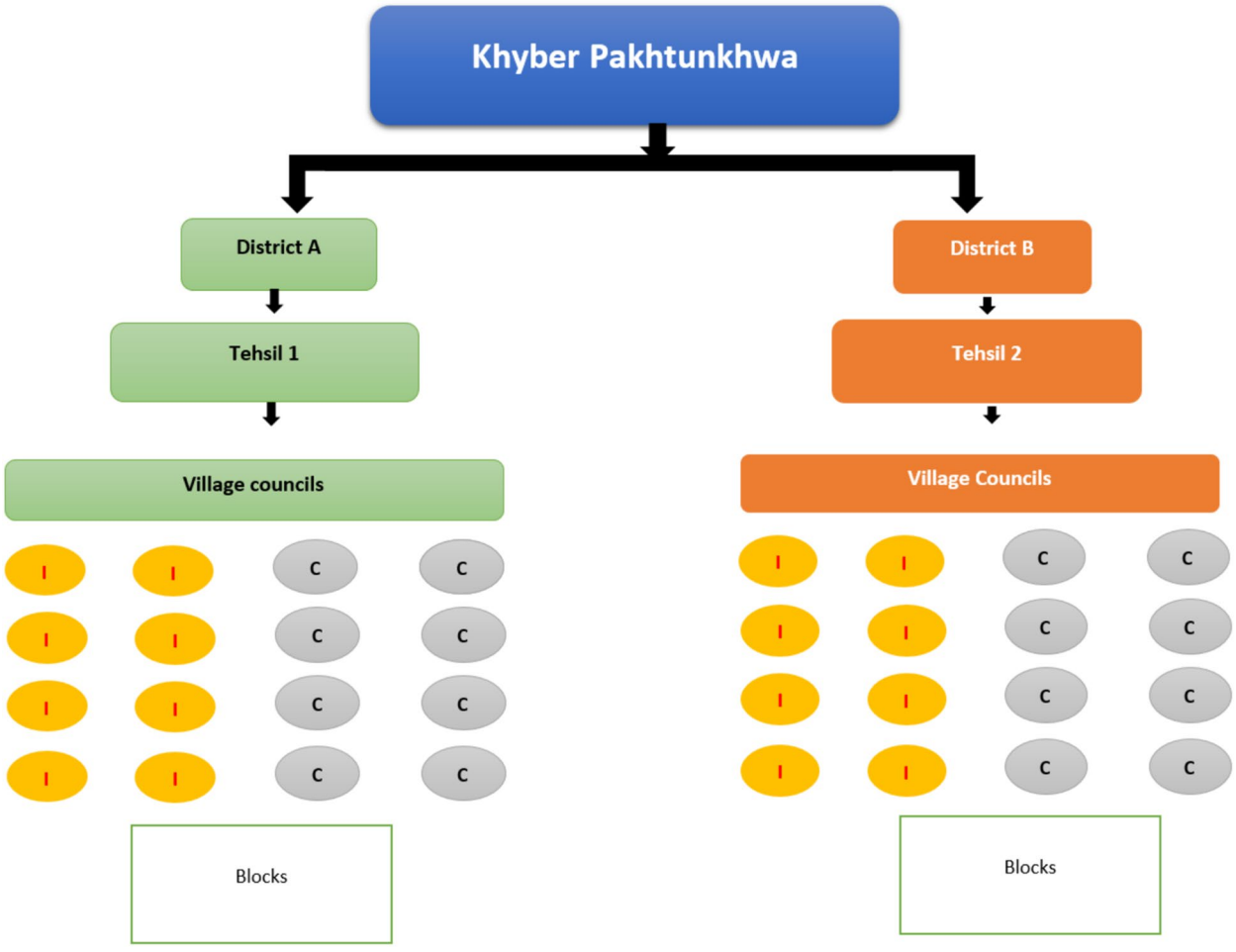

Fig. 2 Flow chart, full trial (Rural - Peshawar and Swabi, Pakistan) (I for intervention, C for control)

mobilisation activity, a line listing of the selected cluster will be performed to list the eligible households and eligible participants. After that, systematic random sampling will be used to select 177 households from the eligible ones in each cluster. Among the selected households, one eligible participant will be selected for the baseline assessments via simple random sampling.

Consenting and enrolling eligible participants

Participants will be informed about the project's purpose, and their specific role, and notified (via a participant information sheet) that their anonymized data may be published in journals and conferences. Written informed consent) will be obtained from all participants either through signatures or thumb impressions. This will include consenting for anthropometric measurements, blood sampling, survey forms, participation in PLA sessions, and subsequent interview recordings during the process evaluation phase, and the storage and use of anonymized data. Participants who provide consent will be given a date, time, and venue for the baseline assessments.

Ineligible and non-consenting participants

Adults who do not meet the eligibility criteria or those who meet the criteria but do not agree to participate after receiving the trial information, will not be enrolled. Their reasons for not meeting the eligibility criteria or declining to participate will be recorded. This information will be kept anonymous.

Withdrawal of participants

Any participant, if wants to, can withdraw from the trial even after enrolment. This will apply to both the participants of the assessments and the intervention.

Cluster randomisation and allocation

Once the baseline assessments are carried out, the selected clusters will be randomly allocated to the two trial arms i.e. intervention and control groups in a ratio of 1:1. This will be done by trial statistician.

As per the sample size calculations, 72 clusters i.e. 36 intervention and 36 control will be selected, half in each district. To avoid allocation bias, we will ensure that all baseline data are collected before treatment allocation.

Minimising contamination

Every effort will be made using available information, maps, and population data to purposefully select clusters (blocks) to be non-contiguous to minimise contamination between intervention and control clusters.

The PLA intervention

The intervention clusters will receive a PLA based community intervention spanning over a period of 18 months, while the control group will continue as usual. The details of the trial timelines have been given in Fig. 3.

Participatory learning approach (PLA) groups

The intervention will involve the formation and facilitation of separate participatory groups for adult males and females (approximately 20 members each), following local cultural norms, to ensure female participation. To be part of the PLA group, any community member of the intervention arm clusters having age more than 20 years will be eligible. At least one male and one female group will be formed in each cluster and efforts will be made to ensure equal numbers of male and female groups. Separate male and female PLA groups are a necessity, due to the conservative culture and local social norms.

A population coverage of 1 group per 500–600 population (250–300 eligible participants i.e. age more than 20 years) will be ensured. Each group will proceed through a series of 15 monthly meetings and three wider community-level meetings, following the four phases of the PLA cycle.

PLA phases:

The four phases of the intervention (Fig. 4) will be carried out as per the community mobiliser's manual, that will be adapted in the earlier stage of the trial. In phase 1 of the PLA cycle, focus will be made to educate the participants of the PLA groups on TIIDM and its risk factors. Discussion will be made on their existing knowledge of TIIDM and identifying problems and prioritising factors that affect their health, specifically addressing threats that increase the risk of developing or failing to manage TIIDM. Phase 2 will involve the collective design of strategies that participants and their communities can implement to address the problems and threats identified in Phase 1. In phase 3, the communities and the participants

	Enrolment	Allocation	Post allocation				
TIMEPOINT	**Sep/Oct 2024**	**Nov 2024**	***Dec 2024***	***Dec 2025***	***May 2026***	***Aug/sep 2026***	***Close out***
ENROLMENT:							
Identification of suitable clusters	X						
Community mobilization and Informed consent	X						
Allocation		X					
INTERVENTIONS:							
PLA intervention (36 clusters)			←	—	—	→	
			X		X		
Control arm		X					
ASSESSMENTS:							
Baseline assessments*	X						
Process evaluation			X	X	X	X	
End line assessments*						X	
Analysis, reporting and dissemination			X	X	X	X	X

Fig. 3 Study time frame (SPIRIT figure) – EMPOWER-D* Sociodemographic information, Anthropometry, fasting plasma glucose, Hba1c, complete blood count, co-morbidities and medications, health related behaviours, diabetes related knowledge, physical activity, dietary profile, tobacco use, anxiety and depression, health related quality of life

Fig. 4 Four phases of PLA

will implement these strategies. In phase 4, the participants will reflect on and evaluate the success of the strategies they have implemented.

Every meeting will feature a variety of activities such as picture card games, discussions, role-playing, and storytelling to enhance awareness and support, and to improve preventive and treatment behaviours for the general population and specifically for those with TIIDM and their families. Attendees will be encouraged to share their insights and key messages with community members who couldn't attend.

The purpose of these meetings is to increase the awareness and acceptance of the PLA intervention among the general population and to engage them in the planning and prioritising of strategies.

Intervention schedule:

Meetings of each PLA group will be held at a central place that will be convenient and freely accessible to all community members such as a *hujra* (communal gathering place), community member's home, community centres, or any other convenient location. The time and day of the meeting will be based on the availability of the majority of the participants, communicated and mutually agreed upon in advance. Each PLA group will have one meeting every month, which will last for an hour or so, and maximum participation will be ensured. They will also participate in the three wider community meetings.

Adherence to intervention protocol

In order to ensure adherence to the protocol, the intervention delivery team, consisting of group facilitators, will be trained with the help of an operational and community mobiliser's manual. The operational manual will cover operational aspects of the intervention including logistics and administrative details. The community mobilisers manual will enlist details of each PLA group meeting as per the four phases of PLA cycle.

Checklists for each PLA group meeting will be designed which will be filled by the PLA group facilitator, to ensure adherence to the protocol. Apart from this, a supervisory team consisting of the research assistants, will use a supervisory checklist for monitoring the adherence to the intervention delivery as per protocol.

Control arm

The control arm will be equally entitled to have all the services available to the interventional arm except the PLA intervention. These include the provision of information about the trial and proper guidance on who to contact in case someone is found to be having IHG or TIIDM at the time of study assessments. Moreover, disease burden in the area may point out any alarming findings such as high incidence or prevalence of TIIDM and these areas can be focused on for any future strategies. Secondly, the findings of the control arm will be included in the advocacy and dissemination of evidence at provincial, national, and international levels.

Outcome assessments

Baseline and endline survey/assessments will be done to measure the intended outcomes (as mentioned below). The baseline assessments will be done prior to randomisation. While, the follow up assessments will take place after the end of 18 months intervention. The end line assessments sample will be independent of the baseline except for the cohort who had IHG at baseline.

During assessments an interviewer administered Case report form (CRF) will be administered, that includes anthropometry, validated questionnaires on mental and physical aspects of health (WHOQOL Bref, PHQ-9, GAD-7, FFQ, IPAQ-U). Case report form Supplementary file 1.

Process evaluation will be conducted to assess the implementation of PLA intervention, its processes, and the contextual factors affecting the intervention and its outcomes. A full economic evaluation, in the form of a cost-effectiveness analysis, will be conducted.

Primary outcome

We intend to measure the prevalence of TIIDM, prevalence of IHG and 2-year cumulative incidence of TIIDM. We will use World Health Organization (WHO) and IDF cutoffs for normoglycemia, IHG and TIIDM. Details are provided in Table 1

Table 1 Study outcomes and their operational definitions

Outcome/Measure	Assessment/Tool	Operational Definition
Primary Outcomes		
Prevalence of TIIDM/Hba1c	Hba1c biochemical test	The proportion of adults ≥ 30 years with ≥ 6.5% [26]
Prevalence of TIIDM/FPG	FPG biochemical test	The proportion of adults ≥ 30 years with ≥ 126 mg/dl [26]
Prevalence of IHG/Hba1c	Hba1c biochemical test	The proportion of adults ≥ 30 years with ≥ 6.0–6.4% [26]
Prevalence of IHG/FPG	FPG biochemical test	The proportion of adults ≥ 30 years with 110-125 mg/dl [26]
2-year cumulative incidence of TIIDM/Hba1c	Hba1c biochemical test	The proportion of adults ≥ 30 years identified with IHG at baseline with ≥ 6.5% at endline [26]
2-year cumulative incidence of TIIDM/FPG	FPG biochemical test	The proportion of adults ≥ 30 years identified with IHG at baseline with ≥ 126 mg/dl endline [26]
Secondary Outcomes		
Prevalence of hypertension/BP Measurement	Digital BP apparatus	The proportion of adults ≥ 30 years with SBP ≥ 140 mmHg or DBP ≥ 90 mmHg or self-reported current treatment with antihypertensive medications
Abdominal obesity/Anthropometry	Measuring Tape	The proportion of adults men and women of age ≥ 20 years with waist-to-hip circumference ratio > 0.9 or > 0.85 respectively
Prevalence of overweight and obesity	Height: Height chart/stadiometer; weight: weighing scale machine	The proportion of adults of age ≥ 20 years with BMI ≥ 23 kg/m^2
Body Fat Composition/Anthropometry	BF Measuring weighing scale	Mean BF%
Quality of life/Mean health-related quality of life	WHOQOL Bref questionnaire [27]	Mean quality of life scores
Psychological distress/Depression, Anxiety	Depression: PHQ-9 [28] Anxiety: GAD-7 [29]	Screening for depression and anxiety
Fruit and vegetable intake	Pakistan validated FFQ [30]	Mean no. of portions of fruit or vegetables consumed per adult age ≥ 30 years per day
Physical Activity	IPAQ-U [31]	The proportion of adults age ≥ 30 years engaged in ≥ 30 min of physical activity per day on at least 5 days per week
Population knowledge of diabetes risk factors, symptoms, and complications/Survey	Questions adapted from DMagic [14] and PDS [32]	The proportion of adults age ≥ 30 years who are (a) able to name at least one cause of diabetes, (b) able to report at least one symptom of diabetes, (c) able to report at least one complication of diabetes, (d) able to recognize complications of diabetes when prompted, (e) able to report at least one way to reduce the risk of getting diabetes and (f) able to report at least one way to control diabetes if diagnosed
Self-awareness of diabetic status/Survey	Questions adapted from DMagic [14] and PDS [32]	The proportion of diabetics who correctly report their diabetic status
Receipt of advice or treatment for diabetes/Survey	Questions adapted from DMagic [14] and PDS [32]	The proportion of diabetics receiving care or advice from a medical professional for their diabetes

Abbreviations: *BF* Body Fat, *BMI* Body Mass Index, *BP* Blood Pressure, *FFQ* Food Frequency Questionnaire, *FPG* Fasting Plasma Glucose, *GAD-7* Generalized Anxiety Disorder Scale, *IAM* Intervention Appropriateness Measure, *IHG* Intermediate Hyperglycaemia, *IPAQ-U* International Physical Activity Questionnaire-Urdu, *PDS* Pakistan Diabetes Survey, *PHQ-9* Patient Health Questionnaire, *PLA* Participatory Learning and Action, *TIIDM* Type II Diabetes Mellitus, *WHOQOL-Bref* World Health Organization Quality of Life Brief

Secondary outcomes

There are a number of secondary outcomes on which data will be collected. They include prevalence of hypertension, abdominal obesity, body mass index, prevalence of overweight & obesity, body fat composition, fruit and vegetables intake, quality of life score, physical activity, psychological distress, knowledge of TIIDM risk factors, symptoms, & complications and self-awareness of diabetic status. Details are provided in Table 1.

Data collection methods

Our team of trained data collectors will visit each selected sampled household and meet the selected individual on the day of data collection. Consent will be taken from each selected individual after providing them with the study information. The data collectors and the study participants will be blinded to the study status of their cluster at the baseline, but may be aware of this status during the end-line assessments due to the nature of the trial. Data will be collected via electronic tools (Android tablets) using a specialised survey software (REDCap). All selected individuals will also undergo anthropometry and blood glucose testing (Fasting Plasma Glucose (FPG) and glycosylated haemoglobin (HbA1c)) at both baseline and the endline. The anthropometry and phlebotomy will be carried out by a trained team at the participant's home or an identified communal setting, as preferred by the communities. Instructions for overnight fasting will

be provided to the participants a day prior to the blood collection.

Statistical considerations

Sample size

Based on Aamir et al.,[18] the expected prevalence of TIIDM and IHG is 16.9% and 10.9%, respectively. For simplicity, it is assumed that the combined prevalence is 28%. Fottrell et al. [14] found an absolute reduction in the combined prevalence of TIIDM and IHG of 20.7% (95% CI 14·6–26·7). For sample size calculations, it is assumed that the combined prevalence in the intervention arm is 80% of that of the control arm, which is a reduction of 20%; this in turn results in a Risk Ratio (RR) of 0.80 comparing the intervention arm to the control arm. This expected reduction will result in a combined prevalence of 22.4% in the intervention arm.

Assuming 150 participants are recruited per block and an intra-cluster correlation (ICC) of 0.03 for Hba1c, [19, 20] 35 blocks per arm will be required. It is worth mentioning that a power of 0.8 is assumed, with a significance level of 0.05, and a coefficient of variation for the block size of 0.096 (based on recent census data from districts. [21]

Due to pragmatic reasons, block sizes of 1500 or more (556 blocks out of 2330 blocks) and blocks that do not share borders will be recruited. This will ensure that enough households in a block can recruit one eligible participant per household; based on the 2017 census the average household size is 8 individuals across the two districts.

Allowing for a dropout of one block per arm, 36 blocks per arm will be required. In addition, accounting for a non-response rate of 15% per block, see Aamir et al.,[18] 177 participants per block will have to be recruited. This would result in 6372 participants per arm, a total of 12,744.

Statistical analysis

All the data will be analysed using STATA-16. The trial data will be analysed according to the CONSORT guidelines, CONSORT flow diagram (Fig. 5) and the analysis will be done on the basis of intention to treat principle by considering the stratified and cluster nature of the data. All the analysis will be carried out by using two sided statistical tests at 95% confidence interval and 5% significance level.

For the baseline data, descriptive statistics will be used for preparing the summary of participant characteristics and clusters by study arms. We will present continuous data as mean and standard deviation while categorical data as frequency and percentages.

For the effectiveness of intervention on the prevalence of TIIDM, we will be using logistic regression while incorporating for the baseline covariates with random effects and the model will also include the stratified and cluster nature of the data. Sensitivity analysis of the primary outcome will be done to assess the effect of missing data using multiple imputation and screening effects of individuals which will be included in both the baseline and endline of the study. Post-hoc sensitivity analysis will be used to assess for the sampling error, data collector bias and blood glucose measurement bias. Also the analysis will be restricted to participants who have normal blood glucose level at the baseline.

Analysis of intervention effect on the combined prevalence of TIIDM and IHG will include all the individuals from whom the blood samples will be collected at the endline survey.

For the effectiveness of intervention on the cumulative incidence of TIIDM in the participants with IHG cohort, the analysis population will be individuals who are diagnosed with IHG at the baseline of the study and for whom a blood glucose measurement is taken at the endline of the study.

Economic evaluation

An economic evaluation, in the form of a cost-effectiveness analysis, will be conducted for the trial. [22]

The cost-effectiveness analysis will examine the value for money and the population health impact of the intervention over the trial period in rural Pakistan. Cost-effectiveness will be assessed from a healthcare perspective in the base case, with alternative perspectives reflecting broader economic outcomes considered as scenario analyses. [23] Outcomes will be measured in disability-adjusted life-years (DALYs), a generic measure of health that captures both morbidity and mortality. Intervention development and delivery costs will be captured. Wider healthcare resource use will be captured using a modified client service receipt inventory (CSRI) and costs estimated by applying unit costs to resource use. Costs falling on individuals including out-of-pocket and transport costs will also be captured in the CSRI. Cost-effectiveness will be presented using incremental cost-effectiveness ratios, incremental net health benefits and net monetary benefits based on appropriate cost-effectiveness thresholds. [24]

Process evaluation

Process evaluation (PE) will be conducted to assess the implementation of PLA intervention, its processes, and the contextual factors affecting the intervention and its outcomes. Medical Research Council (MRC) Framework for PE will be utilised[25] to inform the context, implementation, and mechanisms of impact (Fig. 6). Data will be collected on the following aspects of the intervention:

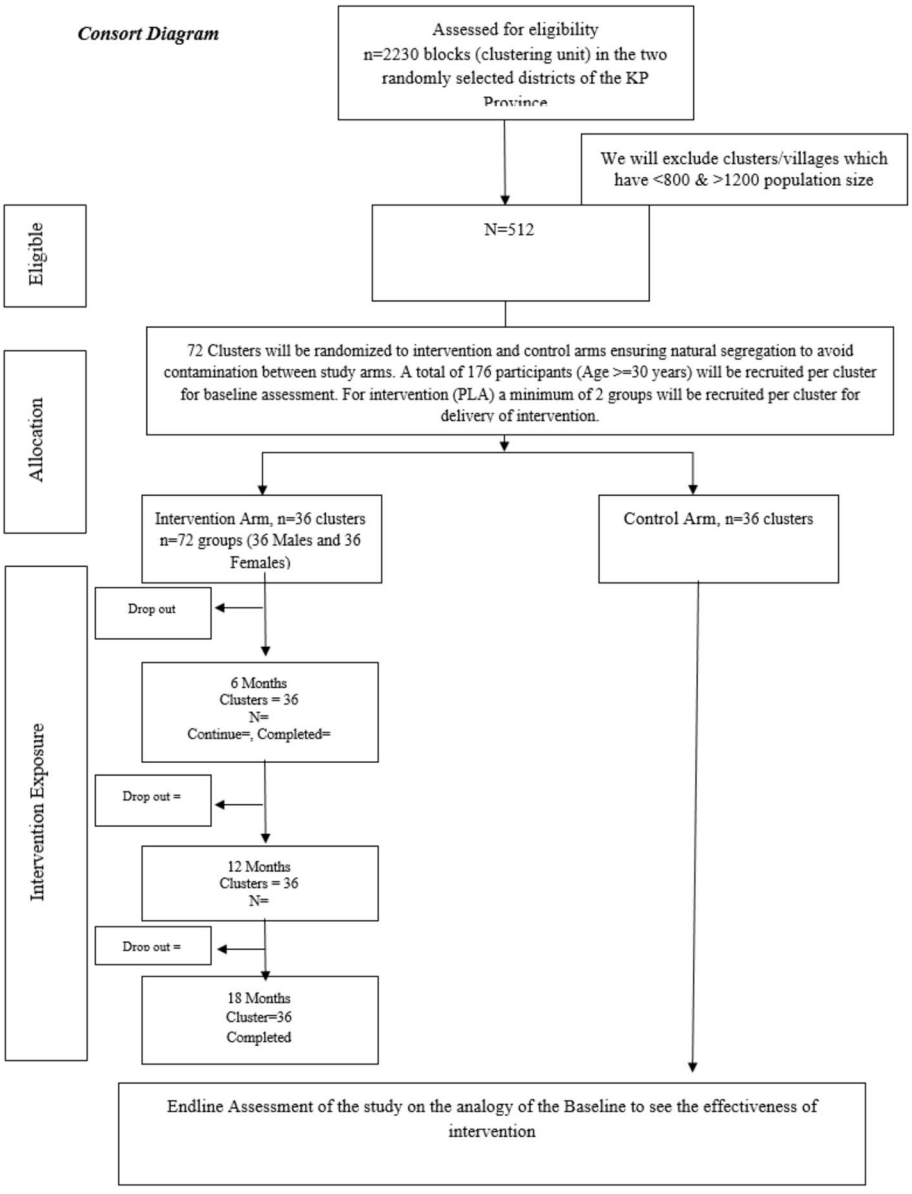

Fig. 5 CONSORT diagram. Consort diagram of the full trial (rural Pakistan- Peshawar and Swabi)

The *fidelity and implementation of the PLA intervention* will be assessed to determine the extent to which the intervention will be delivered as intended. A fidelity checklist will be devised, outlining specific components, activities, and behaviours that should be present during the implementation. Key aspects of the intervention protocol, such as content delivery, participant engagement, and facilitator behaviours, will be included. Participants involved in the fidelity assessment will include trained facilitators who will deliver the PLA sessions, community members who will participate in the sessions, and project team members responsible for monitoring the fidelity of the intervention. Data will be collected using structured fidelity checklists during each session. These checklists will be completed independently by trained project team members or designated observers, who will record the presence or absence of specific components either in real-time or by reviewing recorded sessions. Semi-structured interviews will be conducted with facilitators to explore their experiences and challenges in adhering to the protocol, while participant focus groups will provide insights into the delivery of sessions and participant engagement. Descriptive statistics will be calculated to determine the percentage of sessions in which each fidelity component will be present. Mean adherence scores and attendance rates will be analysed to assess overall fidelity. Thematic analysis will be employed to code transcripts and observation notes, identifying themes related

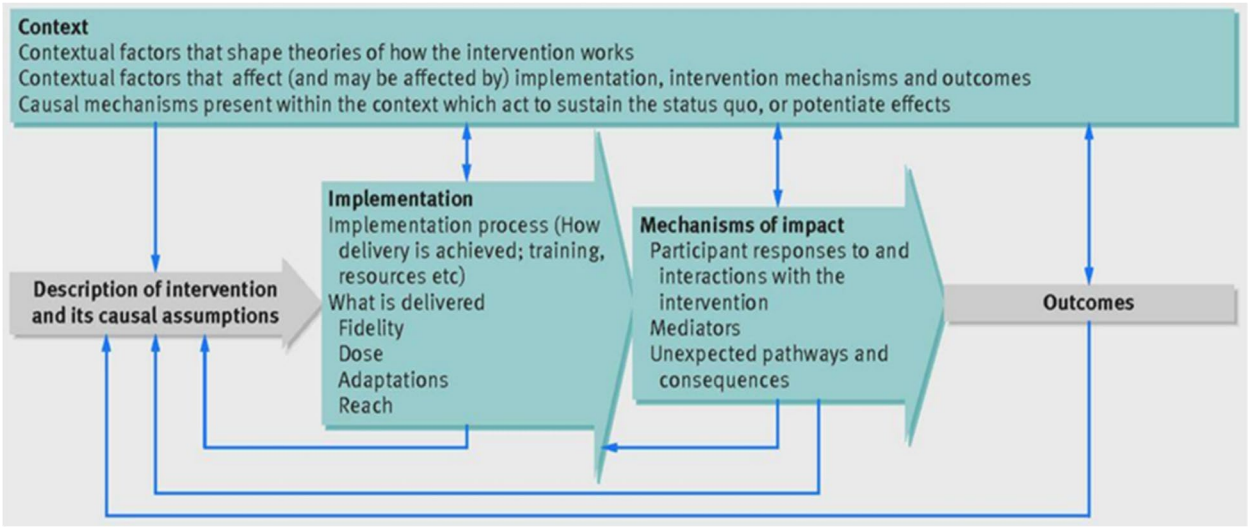

Fig. 6 MRC Framework for Process Evaluation

to fidelity, such as adherence to content, facilitator challenges, and participant engagement.

The *reach of the intervention* will be assessed by evaluating the extent to which it will reach the intended population. Attendance logs will be maintained to record the number of participants and their demographic characteristics. Participation metrics, including total participants, session attendance rates, and frequency of attendance, will be calculated.

The *dose of the intervention* will be evaluated by analysing the nature and number of PLA strategies adopted by community members. Data on the number of sessions held, session duration, and types of activities will be collected. Metrics such as total sessions, average session duration, and attendance rates will be analysed. 4) Mechanisms of action will be explored through interviews and focus groups with participants to assess their engagement, perceptions of the intervention's usefulness, and any challenges encountered. Thematic analysis will be used to identify themes related to participant engagement and the qualitative impact of the intervention, providing insights into individual and community-level changes in behaviours and norms resulting from the intervention.

Data management

The survey questionnaire will be uploaded on an online secure platform (REDCap). The field data collectors will be trained to collect survey data digitally i.e., with tablets. An online data tracker will help in monitoring timely data capture. All data will be transferred to a secure database at Khyber Medical University. The data will be analysed using the statistical software package STATA.

Additionally, qualitative data i.e. audio recordings from key informants'interviews (where possible) will be collected and transferred to the password-protected computer of the local qualitative researcher.

Data quality standards

The blood samples collected in the field will be transferred to the Public Health Reference Laboratory (PHRL) and will be processed the same day. Overall data quality will be ensured through training and supervision. Data entry validation will occur by double-checking a random sample of the data in the field. Moreover, quantitative data once entered will also be checked by the statistician.

The quality of the qualitative data will be ensured by training the researchers by an experienced qualitative expert, to ensure good questioning techniques. In all steps of the data analysis, rigorous procedures to ensure 'trustworthiness' of the findings will be undertaken—the framework matrices (for each participant group) will be produced as a team, a 10% subsample of data charting into the matrices will be checked.

Data security and confidentiality of potentially disclosure information

The Data Management Plan is in accordance with the Data Protection Act 2018 in the United Kingdom (UK) and Pakistan Data Protection Act 2020 and will involve procedures for data quality, confidentiality (labelling, access, storage) and security. This will be reviewed and updated throughout the study, National Institute of Health Research (NIHR) Open Research endorses the FAIR Data Principles as a framework to promote the broadest reuse of research data. FAIR stands for Findable, Accessible, Interoperable, and Reusable (The FAIR Guiding Principles for scientific data management and stewardship).

Each participant will be asked to understand and sign an approved consent form before they take part in the EMPOWER-D trial. Data collected using questionnaires and interviews/FGDs will be pseudo-anonymised to remove information, which could identify the participant. Consent forms, digital recorders and transcripts will be kept inside a locked cabinet in the relevant office. Electronic data will be collected on password-protected devices. Data will be transferred securely to the database, which will be installed on a secure server (password-protected). Digital audio recordings will only be listened to by members of the research team. All documents and audio recordings will be retained for a minimum of 5 years and then destroyed, according to the Khyber Medical University and University of York's policy. Blood samples will be preserved in the PHRL for 1 year after endline data collection.

Adverse events (AEs)s procedures

We are expecting a minimal number of AEs and no serious adverse events (SAEs) during the study. PLA is a community based intervention and has been very well received in previous studies.

[14] Without leading to any directly related AEs. However, there might be some cases of pain or anxiety during blood sampling. The team will be trained to deal with such cases. There will be a vigilant surveillance system in place for AEs occurring during the course of the trial with particular emphasis on identifying, recording, reporting and managing any SAEs.

Detecting, recording and reporting of AEs and SAEs

In the event of any AE reported by the participant, the research assistants will complete an AE form, which will include a medical diagnosis, if relevant and available.

The research assistant will also call the trial manager on the same day providing a verbal report of the event. The trial manager will ensure that the event is classified appropriately after receiving the verbal report.

All AEs will be reported to the principal investigators within three days of detection. AE data will be collated and reported to the trial sponsor and National Bioethics Committee at 6 monthly intervals, and also be reported to the study steering committee, and the Data Safety & Management Board (DSMB) at their regular meeting. All SAEs must be reported to the principal investigator within 24 h of detection and should also be reported to the trial sponsor and National Bioethics Committee within three working days. All serious events must also be reported to all study investigators and the chair of the DSMB within three working days. The Principal Investigator will have the overall responsibility to ensure that all AEs are reported according to the above protocol.

Patient and public involvement

Since this is a community based trial, no patients will be involved. Community engagement activities will be conducted to ensure maximum participation of the target communities.

Study organisational structures

Our trial management relies on (a) a trial coordination team (KMU, HPF & York) consisting of a trial manager, statistician, quantitative & qualitative researchers and an economist. A Program Steering Committee (PSC) has been formed consisting of global health research experts and colleagues from the trial team. They will provide trial oversight and specialist advice on research, capacity building and information dissemination plans. The board's independent oversight will maintain the trial's credibility and scientific validity..

An independent Data Safety and Monitoring Board (DSMB) will be formed. It will periodically review and evaluate the study data for participant safety, study conduct and progress and when appropriate, efficacy.

Protocol amendment

Any changes in research activity will be first discussed and reviewed by the PI and then submitted to the ethics committee for formal approval. A judgement will be made on the nature of the amendment, i.e. major or minor, applying guidance from the program steering committee. All minor amendments are implemented once notified, while all major amendments are implemented once approved by the ethics committee.

The study will be conducted in accordance with current Medical Research Council (MRC) Good Clinical Practice guidelines and the NHS Research Governance Framework. Administrative approval will be sought from the provincial government.

The trial will be conducted to protect the human rights and dignity of the participants as reflected in the 1996 version of the Declaration of Helsinki. Participants will not receive any financial inducement to participate in the trial. In order to protect the trial participants, the following provisions will be made/upheld: the trial has been designed to minimise the burden of participants and any foreseeable risk in relation to the intervention involved; the explicit wishes of the participant will be respected, including the right to withdraw from the trial at any time; the interest of the participant will prevail over those of science and society and provision will be made for indemnity by the investigator and sponsor.

Ethical approvals have been received from Khyber Medical University, Aga Khan University and National bioethics committee of Pakistan.

Discussion

This protocol describes the EMPOWER-D trial which, through implementation science methods, mix methods process evaluation and economic evaluation using a two arm cluster randomised controlled design, will inform us about the effectiveness of PLA in control and prevention of TIIDM. Study findings will provide evidence on how population level strategies of community mobilisation can be implemented to prevent and control TIIDM and NCDs. It will also increase our understanding of TIIDM and other NCDs and its risk factors in rural Pakistan.

Dissemination

NCDs are one of the top priorities of the provincial government. If the PLA intervention is found to be effective we will use advocacy and our existing linkages to maximise the impact of our results in the province and country. The main findings of research will be shared with all stakeholders through conferences, social media, dissemination events, and scientific publications.

Abbreviations

cRCT	Cluster randomized control trial
DALYS	Disability-adjusted life-year
DSMB	Data Safety and Monitoring Board
NCDs	Non communicable diseases
PLA	Participatory learning approach
PSC	Program Steering Committee
NIHR	National Institute for Health and Care Research
REDCap	Research Electronic Data Capture
TIIDM	Type 2 diabetes mellitus

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-025-24371-y.

Supplementary Material 1.

Supplementary Material 2.

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Trial sponsor

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Study sponsor has provided oversight to the process of study design.

Authors' contribution

ZH, KS, ZK, SA, led the application for funding. All authors (KR, AT, SI, ZK, SA, AK, IS, MK, NS, NK, MA, SW, FA, HJ, SA, SF, AR, MI, RZ, AB, KS, ZH) contributed to study conception and participated in critically appraising and revising the intellectual content of the manuscript. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The EMPOWER-D protocol has been approved by the National Bioethics Committee of Pakistan (NBC-R-1070). We also got ethics approvals from Ethics Review Committee of The Aga Khan University (2024-9340-28927), Khyber Medical University (KMU/IPHSS/Ethics/2023/EO/0136), and. The trial has been registered at Clinicaltrial.gov (NCT06561126).
Written informed consent will be taken from all participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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