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Testing a new approach to manage high blood pressure among low-income urban residents through community pharmacies in Bangladesh and Pakistan - a feasibility trial

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Registration date 26/08/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 22/08/2025	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
High blood pressure is a common and serious health issue in Bangladesh and Pakistan, particularly in low-income urban communities. If not managed well, it can lead to heart disease and strokes. We believe that local community pharmacies, which are easy for people to access, could play a bigger role in helping people manage their blood pressure.
We aim to design a new support programme called COPE-BP that will be delivered by specially trained pharmacists. Before running a large-scale trial to test its effectiveness, we will first carry out this smaller “feasibility” study to check whether our study methods work in practice. We will assess how best to recruit participants, whether pharmacists can deliver the programme as planned, and how acceptable it is to participants and providers. The findings will help refine the design for a future, larger trial.

Who can participate?
To take part, individual participants must be:
- Aged 30 years or older.
- Diagnosed with high blood pressure.
- A long-term resident of one of the low-income urban study communities and available for follow-up visits.
- People who are pregnant or have certain other advanced medical conditions cannot take part.

To take part, community pharmacies must:
- Have a valid registration to operate.
- Employ at least one qualified (degree-holder) pharmacist.
- Have staff who are willing to be trained and to deliver the assigned care (either the COPE-BP intervention or usual care) for the entire study period.
- Pharmacies with unresolved legal or regulatory issues will not be included.

What does the study involve?
The study involves community pharmacies that will be randomly placed into one of two groups. Participants will join the group that their local pharmacy has been assigned to.
If a participant is in the first group, they will receive the new COPE-BP support programme from their pharmacist for 6 months. This involves regular blood pressure checks, advice on medications and healthy lifestyle choices, and a referral to a doctor if their blood pressure is too high.
If a participant is in the second group, they will receive the normal 'usual care' from their pharmacy and doctor, just as they would if they were not in the study.
All participants will be asked to attend two main appointments at their pharmacy: one at the beginning of the study and one after 6 months. During these visits, pharmacists will take measurements like blood pressure and the researchers will ask them to complete questionnaires.

What are the possible benefits and risks of participating?
Participants receiving the new support might benefit from better blood pressure control. The main benefit of taking part is helping researchers understand how to run a future large-scale study, which could improve blood pressure care for many people in Bangladesh and Pakistan.
The risks of taking part are very low. The COPE-BP programme is based on current best practices for managing high blood pressure and does not involve any new medicines. The main inconvenience is the time needed for study appointments, but participants will be reimbursed for their travel costs.

Where is the study run from?
The study is being run in communities within four cities: Dhaka and Narsingdi in Bangladesh, and Peshawar and Abbottabad in Pakistan. The lead research institutions are Khyber Medical University in Pakistan and the ARK Foundation in Bangladesh.

When is the study starting and how long is it expected to run for?
The study is planned to start recruiting participants from 1st March 2026. This feasibility study will last for 12 months in total, with each participant's involvement lasting for approximately 6 months. The study will end on 28th February, 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) in the United Kingdom.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR206976

Study information

Scientific Title
Community-pharmacy based intervention to improve hypertension control among low-income urban residents in Bangladesh and Pakistan (COPE-BP) - A cluster randomised feasibility trial

Acronym
COPE-BP

Study objectives
This feasibility trial aims to determine whether a structured, community pharmacy-based intervention for hypertension management can be delivered and sustained for low-income urban residents in Bangladesh and Pakistan. The study will assess feasibility through recruitment, retention, and intervention fidelity, and evaluate acceptability among participants and pharmacy staff. The level of contamination between intervention and control groups will be assessed. Preliminary effects on blood pressure control will be explored. In addition, the standard deviation for the primary outcome(s) in this population will be estimated to inform the sample size for a future definitive trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/03/2025, Health Sciences' Research Governance Committee, University of York (Heslington East, York, YO10 5DD, United Kingdom; +44 7803414852; stephen.holland@york.ac.uk), ref: HSRGC/2025/677/C

2. approved 04/02/2025, Khyber Medical University-IPHSS Ethics Committee (KMU main campus, near PDA building, Phase 5, Hayatabad, Peshawar, 25000, Pakistan; +92-91-9217268; rec.iph@kmu.edu.pk), ref: KMU/IPHSS/Ethics/2024/CP/248

3. approved 11/02/2025, Khyber Medical University Ethics Board (KMU main campus, near PDA building, Phase 5, Hayatabad, Peshawar, 25000, Pakistan; +92-091-9217258; reb@kmu.edu.pk), ref: DIR/KMU-EB/CP/000999

4. approved 27/05/2025, National Bioethics Committee for Research (NBC-R) (Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, Islamabad, 44000, Pakistan; +92-51-9224325; nbcpakistan@nih.org.pk), ref: NBCR-1227

5. approved 03/07/2025, Bangladesh Medical Research Council (BMRC) (BMRC Bhaban, Mohakhali, Dhaka, Dhaka-1212, Bangladesh; +88-029848396; info@bmrcbd.org), ref: BMRC /NREC/2025-2027/209

6. approved 26/02/2025, Institutional Review Board of the Institute of Health Economics, University of Dhaka (Arts Building (4th Floor) Dhaka-1000, University of Dhaka, Ramna, Dhaka, Dhaka-1000, Bangladesh; +88-09666911463; director.ihe@du.ac.bd), ref: IHE/IRB/DU/07/2025 /Final

Study design
Multicentre interventional two-arm cluster randomized controlled feasibility trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Prevention and management of hypertension to reduce cardiovascular disease risk in low-income urban residents (LIURs) in Bangladesh and Pakistan.

Interventions
Clusters of community pharmacies will be randomly allocated to one of two arms using minimisation:

1. Intervention Arm: Participants in the intervention arm will receive the COPE-BP intervention from trained community pharmacists for a period of 6 months. This multicomponent intervention includes blood pressure monitoring, medication adherence advice, health education, and a referral pathway to a linked primary care physician for participants with poorly controlled blood pressure or at high cardiovascular risk.

2. Control Arm: Participants in the control arm will receive usual care, which consists of the standard healthcare services available in their communities which does not typically include a structured, pharmacist-led support programme like the COPE-BP intervention.

The study will begin on 1 March 2026 and end on 28 February 2027 for both the intervention and control arms. Recruitment will take place during the first three months in both arms, followed by a six-monthly follow-up for each participant from their recruitment date. This is a cluster randomised controlled trial (cRCT). The randomisation process is as follows:
-The unit of randomisation is a "cluster", which is a predefined geographical area (based on our initial geospatial mapping and survey conducted before the trial). Each cluster will contain aggregated registered community pharmacies.

-The randomisation of these clusters to either the intervention or the control arm will be performed through minimisation by a statistician who is independent of the recruitment team to ensure allocation is concealed and free from bias. All eligible participants who provide consent will be enrolled in the study arm (intervention or control) to which the pharmacy cluster they were recruited from has been allocated.

Intervention Type
Behavioural

Primary outcome(s)
1. Feasibility of the COPE-BP intervention, assessed by recruitment rate (% of eligible participants enrolled) and retention rate (% completing 6-month follow-up), measured from study screening logs and participant records at baseline and 6 months.
2. Intervention acceptability measured using validated questionnaires: 'Acceptability of Intervention Measure' (AIM), 'Feasibility of Intervention Measure' (FIM) and Intervention Appropriateness Measure (IAM) at the end of the 6-month implementation period .
3. Data completeness measured by the proportion of participants with complete outcome data at 6 months post-randomisation.
4. Contamination between trial arms measured using a survey of control-arm pharmacies during the trial period.
5. Feasibility of collecting economic data measured using Resource Use questionnaires at baseline and 6 months post-randomisation.
6. Standard Deviation of the mean difference in systolic blood pressure between trial arms will be determined to inform the main trial sample size calculation.

Key secondary outcome(s))
1. Systolic Blood Pressure measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 6).
2. Diastolic Blood Pressure measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 6).
3. Blood Pressure Control (defined as systolic BP <140 mm Hg and diastolic BP <90 mm Hg) measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 6).
4. Very Poorly Controlled Blood Pressure (defined as systolic BP ≥160 mm Hg or diastolic BP ≥100 mm Hg) measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 6).
5. Adherence to Antihypertensive Medications measured using the Hill-Bone Compliance to High Blood Pressure Therapy Scale (HB-HBP) at baseline (month 0, for those already diagnosed) and follow-up (month 6).
6. Body Mass Index (BMI) and Waist Circumference measured using a stadiometer, weight machine, and standard measuring tape at baseline (month 0) and follow-up (month 6).
7. Lifestyle Risk Factors (including physical activity, smoking status, fruit and vegetable intake) measured using the International Physical Activity Questionnaire - Short Form (IPAQ-SF), a smoking status questionnaire, and a Food Frequency Questionnaire (FFQ) at baseline (month 0) and follow-up (month 6).
8. Dietary Salt Intake measured using a urine sodium excretion test from a spot urine sample at baseline (month 0) and follow-up (month 6).
9. Lipid Profile measured using a fasting blood sample at baseline (month 0) and follow-up (month 6).
10. Incident Diabetes measured using fasting plasma glucose levels from a blood sample at baseline (month 0) and follow-up (month 6).

11. Kidney Function (including eGFR and urine albumin excretion) measured using a serum creatinine test and a urine albumin-to-creatinine ratio (UACR) at baseline (month 0) and follow-up (month 6).
12. Health-Related Quality of Life measured using the EQ-5D-5L questionnaire at baseline (month 0) and follow-up (month 6).

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Aged 30 years or older.
2. Diagnosed with hypertension, which is defined as either the current use of antihypertensive medications or having a persistently elevated blood pressure (systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg).
3. A stable resident (living for 6 months or more) of the defined cluster locality and available for follow-up visits.
4. Able to provide informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
120 years

Sex
All

Key exclusion criteria
1. Pregnancy.
2. Individuals with advanced medical diseases, such as those on dialysis, with liver cirrhosis, or with cancer.
3. Individuals with a history of severe allergies or severe adverse reactions to antihypertensive medications.

Date of first enrolment
01/03/2026

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
Bangladesh

Pakistan

Study participating centre
Not yet identified.
Peshawar and Abbottabad
Pakistan
25000

Study participating centre
Not yet identified.
Dhaka and Narsingdi
Bangladesh
1000

Sponsor information

Organisation
National Institute for Health and Care Research

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.
- A fully anonymised individual participant data (IPD) file containing all quantitative variables (questionnaire responses and biochemical measurements) will be shared. Anonymised transcripts from qualitative interviews and focus groups will also be made available where explicit consent has been given for public sharing.
- The data will be deposited and made publicly available after the completion of the feasibility study.
- Informed consent from participants will include permission to share their anonymised data through a public repository for future research. Before deposit, all direct and indirect identifiers will be removed from the dataset to ensure participant confidentiality is protected, in line with the study's data management plan.
- The sharing of data is contingent upon the permissions granted in the informed consent process and must comply with the ethical approvals obtained from the Ethics Committees in Bangladesh and Pakistan, and the University of York, UK.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes