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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 - an external pilot trial

Submission date 11/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/08/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/10/2026	**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 common in Bangladesh and Pakistan and can increase the risk of serious health problems such as heart disease, stroke and kidney disease. Many people living in low-income urban areas have high blood pressure that has not been diagnosed or is not well controlled. Community pharmacies are often easy to access and are regularly used for medicines and health advice, meaning they may provide an opportunity to offer additional support for managing high blood pressure.

The COPE-BP programme has worked with people with hypertension, pharmacists, doctors, community members and policymakers to develop a community pharmacy-based service for hypertension management. Before undertaking a large trial to test whether the service is effective, this external pilot study will examine whether the intervention and trial procedures are feasible and acceptable. The findings will be used to refine the intervention and determine whether and how to proceed to a larger definitive trial.

Who can participate?

Adults aged 30 years or older who live in one of the predefined low-resource urban study areas and have uncontrolled high blood pressure may be eligible. Participants must have lived in the locality for at least six months, expect to remain available for the four-month follow-up period, and be able to provide informed consent.

People who are pregnant, have certain advanced medical conditions, have severely elevated blood pressure requiring urgent clinical assessment, or have acute symptoms suggesting cardiovascular or neurological instability will not be enrolled at that time.

What does the study involve?

Ten groups (clusters) of community pharmacies in Dhaka and Narsingdi in Bangladesh and Peshawar and Abbottabad in Pakistan will take part. We aim to recruit approximately 400 participants.

The pharmacy clusters will be randomly allocated to one of two groups. Participants attending

pharmacies in the intervention group will receive the COPE-BP service for four months. Trained pharmacists will provide structured blood pressure monitoring, support with taking medicines, advice on healthy lifestyles, regular follow-up and referral to a linked physician when clinical review is required. Pharmacists will not prescribe or change blood pressure medicines themselves.
Participants in the control group will receive the usual care available from their community pharmacy and will continue to use their normal healthcare services.
Participants in both groups will attend a baseline assessment and a follow-up assessment approximately four months later at a centralised neutral assessment location separate from the participating pharmacies. These assessments will include blood pressure and other physical measurements, questionnaires and, for participants who agree, blood and urine tests. Outcome assessors conducting these assessments will be blinded to the participant's trial allocation.

What are the possible benefits and risks of participating?
Participants may benefit from having their blood pressure and other health measures assessed and from identification of health concerns requiring referral. Participants in the intervention group may also benefit from structured pharmacy-based support for hypertension management. However, individual benefit cannot be guaranteed. The study will help researchers determine whether the COPE-BP service and trial procedures are suitable for evaluation in a larger trial. The intervention does not introduce new medicines, and pharmacists will not independently prescribe or change antihypertensive treatment. Participants requiring clinical assessment will be referred to an appropriate physician or healthcare service. Approved travel reimbursement for central assessment visits will be offered equally to participants in both trial groups.

Where is the study run from?
The study will be conducted through community pharmacies in Dhaka and Narsingdi in Bangladesh and Peshawar and Abbottabad in Pakistan.

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR), United Kingdom (Grant ID: NIHR206976), using UK International Development funding from the UK Government to support global health research. The study is sponsored by the University of York, United Kingdom.

When is the study starting and how long is it expected to run for?
Recruitment is planned for November 2026–January 2027, beginning from 2 November 2026. Each participant will be followed for approximately four months. Participant follow-up is expected to continue until May 2027, with study analysis and reporting continuing until July 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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University of York, UK

Contact information

Type(s)
Public, Scientific, Principal investigator

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National Institute for Health and Care Research (NIHR)
206976

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 external pilot trial

Acronym
COPE-BP

Study objectives
Current study objectives as of 13/10/2026:

This external pilot cluster randomised controlled trial aims to determine whether the COPE-BP community pharmacy-based intervention for hypertension management and the associated trial procedures are feasible and acceptable in Bangladesh and Pakistan, and to inform progression to a future definitive multicountry cluster randomised controlled trial. The study will assess recruitment and retention; randomisation, allocation and potential contamination between trial arms; acceptability and fidelity of intervention delivery; and feasibility and completeness of data-collection procedures. It will also estimate key parameters, including the pooled standard deviation of systolic blood pressure and intraclass correlation coefficients, to inform the design and sample size of the future definitive trial. An embedded mixed-methods process evaluation and economic data-collection pilot will also be undertaken.

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Previous 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. Submitted 09/10/2026, Health Sciences' Research Governance Committee, University of York (Heslington East, York, YO10 5DD, United Kingdom; +44 7803414852; stephen.holland@york.ac.uk), ref: Reference not provided

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

Primary study design
Interventional

Study design
Multicentre interventional two-arm cluster randomised controlled external pilot trial

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
Current interventions as of 13/10/2026:

Ten clusters of community pharmacies across Bangladesh and Pakistan will be randomised to one of two trial arms using minimisation, stratified by city. Six clusters will be allocated to the intervention arm and four to the control arm. The unit of randomisation is the cluster, defined as an aggregation of registered community pharmacies within a defined geographical area. Randomisation will be undertaken by an independent statistician at the York Trials Unit before participant recruitment.
1. Intervention arm:
Participants will receive the multicomponent COPE-BP intervention through trained community pharmacists over a period of four months, in addition to continuing their usual healthcare. The intervention includes structured blood pressure monitoring and follow-up; clinical record keeping; assessment of and support for medication adherence; lifestyle and health education covering diet, salt intake, physical activity, tobacco use and weight management; and structured pharmacist–physician referral and care coordination. Each intervention pharmacy will be linked with local physician(s) to support referral and clinical review. Pharmacists will not independently prescribe or modify antihypertensive medication. Intervention pharmacy follow-up visits will generally take place every 4–6 weeks, with additional visits or referrals where clinically indicated.
2. Control arm:
Participants in control clusters will receive usual care from their community pharmacy. This typically involves medication dispensing and informal advice but does not include the structured blood pressure monitoring, lifestyle education, adherence assessment and support, or pharmacist–physician care coordination provided as part of the COPE-BP intervention.
Participants in both arms will remain free to access physicians and other routine healthcare services as they normally would.
Participants will be followed for four months. Baseline and Month 4 outcome assessments will be undertaken by blinded outcome assessors at a centralised neutral location separate from the participating pharmacies.

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Previous interventions as of 06/03/2026:

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 4 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 do not typically include a structured, pharmacist-led support programme like the COPE-BP intervention.

The study will begin on 1 October 2026 and end on 31 July 2027 for both the intervention and control arms. Recruitment will take place during the first two months in both arms, followed by a four-month 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.

Previous 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)
Current primary outcome(s) as of 13/10/2026:

1. Recruitment: Recruitment rates for community pharmacies and participants, assessed using trial management logs as the numbers approached, screened, eligible, consenting and recruited out of those eligible, together with the time taken to achieve recruitment targets, throughout the recruitment period
2. Retention: Proportion of recruited community pharmacies and participants retained at Month 4, including reasons for withdrawal or loss to follow-up where known, assessed using trial management records
3. Data completeness: Completeness of planned clinical, participant-reported and process outcome measures at baseline and Month 4, assessed from study data-collection records
4. Intervention acceptability and appropriateness: Assessed through the embedded mixed-methods process evaluation, including semi-structured interviews and focus group discussions with intervention participants, community pharmacists/pharmacy staff and physicians during and /or at the end of the four-month intervention period. The process evaluation will explore experiences of the intervention and trial procedures and barriers and facilitators to intervention

delivery and participation
5. Intervention fidelity: Extent to which key components of the COPE-BP intervention are delivered as intended, assessed using an observational fidelity checklist for approximately 10% of intervention sessions and a short questionnaire administered to intervention participants at the Month 4 outcome assessment. Measures will include pharmacy attendance and delivery of key intervention components and physician referral/attendance
6. Intervention contamination: Assessed using a quantitative exit survey among a feasible sample of general clients attending control-arm pharmacies at approximately Month 1 and Month 3 of the four-month implementation period, together with qualitative interviews/focus group discussions with control-arm pharmacy staff to explore potential contamination and its source
7. Parameters for the definitive trial: Estimation of the pooled standard deviation of systolic blood pressure and intraclass correlation coefficients to inform the sample size and design of the future definitive trial

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Previous primary outcomes as of 06/03/2026:

1. Feasibility of the COPE-BP intervention, assessed by recruitment rate (% of eligible participants enrolled) and retention rate (% completing 4-month follow-up), measured from study screening logs and participant records at baseline and 4 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 4-month implementation period .
3. Data completeness measured by the proportion of participants with complete outcome data at 4 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 4 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.

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Previous primary outcomes:

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)

Current key secondary outcome(s) as of 13/10/2026:

1. Systolic and diastolic blood pressure, measured using standardised digital blood pressure monitors at baseline and Month 4
2. Anthropometric measurements, including height, weight, body mass index (BMI) and waist circumference, assessed at baseline and Month 4
3. Glycaemia, assessed using HbA1c from venous blood samples at baseline and Month 4 among participants consenting to blood sampling
4. Lipid profile, assessed from venous blood samples at baseline and Month 4 among participants consenting to blood sampling
5. Kidney function, including serum creatinine with calculated estimated glomerular filtration rate (eGFR), assessed at baseline and Month 4 among participants consenting to blood sampling
6. Urinary markers, including urinary sodium and urine albumin-to-creatinine ratio (UACR), assessed from spot urine samples at baseline and Month 4 among participants consenting to urine sampling
7. Medication adherence, assessed using the Hill-Bone Compliance to High Blood Pressure Therapy Scale (HB-HBP) at baseline and Month 4
8. Health-related quality of life, assessed using the EQ-5D-5L at baseline and Month 4
9. Physical activity, assessed using the International Physical Activity Questionnaire – Short Form (IPAQ-SF) at baseline and Month 4
10. Smoking and dietary behaviours, assessed using relevant WHO STEPwise Approach to Noncommunicable Disease Risk Factor Surveillance (STEPS) items and other specified smoking measures at baseline and Month 4
11. Healthcare resource use, including physician visits, medication purchases and costs, and other clinical-event-related healthcare use, assessed using a bespoke healthcare resource use questionnaire at baseline and Month 4
12. Adverse events, recorded throughout the trial from enrolment to Month 4, including active safety follow-up with participants at Month 2

Previous key secondary outcomes as of 06/03/2026:

1. Systolic Blood Pressure measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 4).
2. Diastolic Blood Pressure measured using standardised digital blood pressure monitors at baseline (month 0) and follow-up (month 4).
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 4).
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 4).
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 4).
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 4).
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 4).
8. Dietary Salt Intake measured using a urine sodium excretion test from a spot urine sample at baseline (month 0) and follow-up (month 4).
9. Lipid Profile measured using a fasting blood sample at baseline (month 0) and follow-up (month 4).
10. Diabetes measured using HbA1c levels from a blood sample at baseline (month 0) and follow-up (month 4).
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 4).
12. Health-Related Quality of Life measured using the EQ-5D-5L questionnaire at baseline (month 0) and follow-up (month 4).

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Previous key secondary outcomes:

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
31/07/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 13/10/2026:

1. Aged 30 years or older
2. Resides within a pre-defined low-resource urban locality, neighbourhood or mapped sub-area in a participating study city
3. Has uncontrolled hypertension, defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg, based on the average of the second and third readings from three blood pressure measurements using the study-standardised procedure. For individuals without a previous diagnosis of hypertension, elevated blood pressure at the initial screening visit will be confirmed by repeat measurement on a separate day before enrolment, with the findings reviewed by a designated study physician to confirm hypertension for eligibility purposes
4. Has lived in the locality for at least six months
5. Expects to remain available within the study area for the four-month follow-up period
6. Willing and able to provide informed consent

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Previous key inclusion criteria as of 06/03/2026:

1. Aged 30 years or older.
2. Having uncontrolled hypertension, defined as having a systolic BP ≥140 mm Hg or a diastolic BP ≥90 mm Hg. This includes both newly diagnosed patients and those with a previous diagnosis of hypertension.
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.

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Previous 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
Mixed

Lower age limit
30 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 13/10/2026:

1. Pregnancy. Women within four months postpartum following pregnancy-associated hypertension will also be excluded
2. Advanced medical disease, for example dialysis, liver cirrhosis or active cancer
3. Severely elevated blood pressure at screening, defined as systolic BP ≥180 mmHg and/or diastolic BP ≥110 mmHg. Such individuals will be referred promptly for clinical assessment and may be re-screened if they subsequently become stable
4. Acute red-flag symptoms suggestive of cardiovascular or neurological instability, including chest pain, shortness of breath at rest, severe headache, visual disturbance, syncope or focal neurological deficits

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Previous 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
02/11/2026

Date of final enrolment
15/01/2027

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
University of York

ROR
https://ror.org/04m01e293

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