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Improving care for people with diabetes, high blood pressure, lung condition such as asthma in flood-prone areas of India through community and health systems flood preparedness by improving medicine and health information availability.

Submission date
05/08/2025

Recruitment status
Recruiting

Registration date
12/08/2025

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with non-communicable diseases (NCDs) such as high blood pressure, diabetes, and breathing difficulties often face serious health risks during floods, especially when access to essential medications and healthcare services is disrupted. This study aims to co-develop and test a community and health system intervention to better prepare and support patients with NCDs during floods in Bihar, India. It will assess whether this approach improves medication adherence and promotes effective practices for the safe storage of medicine and handover information.

Who can participate?
Adults aged 18 years and older who live in flood-prone areas in three districts of Bihar and have been diagnosed with diabetes, hypertension, or chronic breathing difficulties (such as asthma or COPD) at least 6 months before May 2025.

What does the study involve?
Selected areas will be randomly chosen to either receive a new support programme or continue with usual care. The intervention comprises multiple components to strengthen the health services at health facility and at community level to reduce the impact of flood emergencies on NCD patient and improve services to them. The details of the intervention are yet to be finalised after a series of TOC workshops with stakeholders including communities: They are likely to include the provision of low-cost, flood-proof kits for secure medication storage at patient homes and health facilities; distribution of patient handover cards; training for healthcare workers to improve flood camp NCD services and preparedness activities; access to mental health support; and dissemination of tools and behaviour change activities to enhance

community-level preparedness. Trained researchers will collect information from patients at four points in time: before the intervention (immediately after floods), 6 months later, after the intervention (immediately after floods) and 6 months later. At each point, participants will answer questions and have simple health checks, such as blood pressure measurements. The project comprises a significant level of community engagement and involvement activities throughout the lifecycle of the project with stakeholders and communities and including the government of Bihar.

What are the possible benefits and risks of participating?
Participants may benefit from enhanced flood preparedness in relation to management of NCD, improved access to related medicines, and increased support from health workers. There are minimal risks involved, limited to the time taken to answer questions or minor discomfort from blood pressure checks.

Where is the study run from?
The study is coordinated from Homibhabha Cancer Research Centre, Muzaffarpur district in Bihar, India, with support from Indian and UK-based research partners.

When is the study starting and how long is it expected to run for?
January 2024 to December 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Semira Manaseki-Holland, s.manasekiholland@bham.ac.uk

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
Nil known

Study information

Scientific Title
Improving primary health care for patients with non-communicable diseases during severe flooding in India

Acronym
FUSION

Study objectives
To co-design, implement, and evaluate a complex intervention via a hybrid cluster RCT to improve existing non-communicable disease (NCD) service delivery during flood by strengthening local health system preparedness by involving healthcare providers, communities, and stakeholders.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 05/12/2024, Science, Technology, Engineering and Mathematics (STEM) ethics committee of University of Birmingham (Edgbaston, Birmingham, B15 2TT, United Kingdom; +44 (0)121 414 3344; ethics-queries@contacts.bham.ac.uk), ref: ERN_2178-Dec2024

2. approved 11/01/2024, Institutional Ethics Committee, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivendrum (Jai Nagar W Rd Chalakkuzhi, Thiruvananthapuram, Kerala, 695011, India; +91 (0)471 244 3152; sct@sctimst.ac.in), ref: SCT/IEC/2142/DECEMBER/2023

Study design
Parallel 1:1 hybrid implementation effectiveness cluster randomized controlled trial, guided by the RE-AIM-QUEST framework with clinical and implementation outcomes that include process evaluation, quantitative and qualitative methodologies

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Non-communicable diseases (e.g., hypertension, type 2 diabetes mellitus, chronic respiratory diseases [asthma and chronic obstructive pulmonary disease]) in flood-prone, low-resource settings

Interventions
The intervention will leverage existing health system structures to deliver integrated NCD care during flood events, led by primary care teams and Accredited Social Health Activists (ASHAs). The focus will be on flood preparedness and continuity of care for patients with hypertension, diabetes, and chronic respiratory conditions. ASHAs will work with patients and families for flood preparation by preparing kits with essential NCD medications and a handover document. ASHAs will lead local education sessions using tailored IEC materials. Mental health support will be facilitated by ASHAs or trained community health workers and referred to primary health centres. At the primary care health care providers will receive structured training on flood-responsive NCD management. Providers will follow adapted clinical protocols based on WHO PEN and Indian guidelines. Health systems will be strengthened for flood-proof storage of NCD medications and diagnostics. The UNDRR Public Health Scorecard will be used in both intervention and control clusters to identify and monitor disaster-resilient actions.

This study is a hybrid type II, parallel-group, cluster-randomised controlled trial evaluating the implementation and effectiveness of a multi-component intervention to strengthen non-communicable disease (NCD) management during floods in 26 flood-prone clusters in Bihar, India. The intervention will be co-developed with community members and health system stakeholders and implemented over one flood season across 13 clusters. Final components will be finalised by mid-Autumn 2025 and detailed using the TIDieR framework.

Method of cluster randomisation:
The unit of randomisation is the Community Development Block (CDB), with 26 clusters selected from 34 eligible CDBs across three districts in Bihar: Muzaffarpur, Darbhanga, and East Champaran. Cluster allocation is conducted using a computer-based restricted randomisation algorithm, implemented by an independent statistician to ensure balance in key covariates, specifically population size and geographic proximity to prescribing facilities. Randomisation follows a 1:1 allocation ratio. Allocation concealment is maintained until the randomisation process is complete, which is carried out in consultation with local stakeholders to ensure contextual appropriateness and transparency.

Total duration of intervention and follow-up:
Baseline data collection (S1): Begins in October 2025 immediately post-flood
Intervention Period: July 2026- October 2027

Post-intervention data collection:
Immediate post-flood survey (S3): ~October 2027
6-month follow-up survey (S4): ~May-June 2028

Total duration: Intervention (15 months) and follow-up period

Intervention Type
Behavioural

Primary outcome(s)
1. Medication adherence measured using the Adherence to Refills and Medications Scale (ARMS-12), a validated 12-item questionnaire. Responses are dichotomised based on a threshold score of 12. Timepoints: S1 (baseline), S3 (post-intervention)
2. Flood-proof kit status measured through direct observation and participant self-report regarding the presence of the kit, possession of the NCD handover card, and documentation of prescribed medications. Timepoints: S1 (baseline), S3 (post-intervention

Key secondary outcome(s))
Patient-related:
1. Inpatient admission (any cause and NCD-related), measured by self-report using a patient questionnaire at S1 (baseline), 6 months post baseline (S2), S3 (post-intervention), 6 months post-endline (S4)
2. Outpatient consultation for NCD exacerbations: Self-report of flare-ups or inpatient admissions using a questionnaire at S1, S2, S3, S4
3. Mental health (depression) measured using Patient Health Questionnaire-8 (PHQ-8); anxiety using Generalized Anxiety Disorder (GAD) at S1, S3
4. Blood pressure measured using the WHO STEP protocol (average of 2nd and 3rd readings) at S1, S2, S3, S4
5. Respiratory symptoms (chronic respiratory distress patients) measured using the modified Medical Research Council (mMRC) scale and the Chronic Airways Assessment Test (CAAT) at S1, S2, S3, S4

Healthcare related:
1. Training coverage (HF/ASHA workers) measured via training registers during training
2. Post-training knowledge measured using written MCQ tests (pre- and post-training) during training
3. Availability of HF flood-proof kit and NCD drugs measured using observation checklist pre-flood (July–September)

Patient-reported implementation:
1. Carrying a flood-proof kit to camp measured using patient questionnaire at S1, S3
2. Carrying handover card to camp measured using patient questionnaire at S1, S3
3. Knowledge/use of camp NCD services self-reported via questionnaire at S1, S3
4. Mental health intervention use self-reported at S1, S2, S3, S4
5. Medication availability during flood measured using patient questionnaire (binary or categorical scale) at S1, S3
6. Receiving preparedness advice self-reported at S1, S3

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Adults aged 18 years and above
2. Residing in the flood-prone study cluster since May of the same year (covering the recent flood period and 2 months prior for pre-flood preparations)
3. Have a self-reported diagnosis of one or more study conditions hypertension, diabetes, or chronic respiratory diseases (asthma and COPD) diagnosed before the previous May and currently receiving medication

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient unable to converse in Hindi or English or not cognitively coherent so that they cannot consent
2. Likely to move away from the current house in the next 18 months (until May 2027)

Date of first enrolment
11/08/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
India

Study participating centre
Homi Bhabha Cancer Hospital & Research Center
Uma Nagar, Rasulpur Saidpur Bazid, Bihar
Muzaffarpur

India
842004

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

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
Data will be shared after the publication of study findings, in accordance with institutional policies and ethical approvals. Data will be shared in a de-identified format to ensure participant confidentiality. Anonymised transcripts and relevant datasets may be made available upon reasonable request to the Principal Investigator or the joint Principal Investigator (Dr Jeemon Panniyammakal). Each request will be reviewed by the study's publication committee to assess its scientific merit, ethical compliance, and alignment with the study's data sharing policy. These considerations will be managed on a case-by-case basis to ensure ethical and responsible sharing

of data. Legal guidance may be sought from both the University of Birmingham and SCTIMST to determine whether such agreements are necessary.

IPD sharing plan summary

Available on request

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