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EcoHealth approach for dengue control

Submission date 25/09/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2018	**Overall study status** Ongoing	
Last Edited 07/02/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Dengue is a viral infection spread by mosquitoes that is increasing in its global presence, with an estimated 4 billion people at risk of infection in at least 128 countries. Environmentally friendly approaches to mosquito control are needed to permanently reduce mosquito populations. The aim of this study is to find out whether an EcoHealth intervention based upon community mobilization reduces the risk of dengue virus infection among 3 to 9 years olds compared to usual dengue control practice in Fortaleza, Brazil. In 2025, the study location was updated to Dhaka, Bangladesh, where children 2 to 12 years old will be recruited.

Who can participate?
Households with children aged 2 to 12 years

What does the study involve?
Participating areas are randomly allocated to one of two groups. Household visits occur at baseline and after 2 years of follow-up to administer questionnaires and collect dried blood spot (DBS) samples. Clusters will be allocated to intervention or control immediately after the baseline collection. In the intervention clusters, community mobilization activities begin and locally customized activities are implemented. Customized community activities are developed during community meetings, lead by community members. Volunteers from the communities serve as organizers and educators trained by facilitators from the research team. Inter-community visits are organized to share experiences between communities and to strengthen the group dynamics and collective preventive action. The control group receive standard vector control, according to the study site. Rates of dengue infection and the number of adult Aedes mosquitos are measured at baseline and endline over a 2-year period.

What are the possible benefits and risks of participating?
The results will help develop evidence-based mosquito control programs in countries struggling with mosquito-transmitted diseases. Importantly, this study will also provide estimates of dengue burden based upon a representative population sample, which is currently lacking in Brazil/Bangladesh as they rely on passive surveillance. There is the potential risk of residents who fail to participate in community vector control activities being stigmatized, although based on previous studies this risk is minimal. The researchers will monitor this risk throughout the study through community meetings and a reporting mechanism.

Where is the study run from?
Universidade Estadual do Ceara (Site 1: Fortaleza, Brazil)

BRAC University (Site 2: Dhaka, Bangladesh)

When is the study starting and how long is it expected to run for?
October 2018 to March 2027

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Dr Kate Zinszer

Contact information

Type(s)
Scientific

Contact name
Dr Kate Zinszer

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Additional identifiers

Protocol serial number
201803PJT-400444-RC2-CFCA-120159

Study information

Scientific Title
Improving Aedes control through community mobilization to reduce dengue incidence in Brazil: a cluster randomized controlled trial

Study objectives
The principal research question is: does community mobilization reduce the risk of dengue virus infection compared to usual dengue control practice in Fortaleza, Brazil.

Added 07/02/2025:
Note that the study site has been modified to Dhaka, Bangladesh.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 17/12/2024, Health Research Ethics Committee at the University of Montreal (CERSES, Bureau de la conduite responsable en recherche, Université de Montréal) (Université de Montréal 3333, chemin Queen-Mary, Montréal , H3V 1A2, Canada; +1 (0)514 343-6111 #2604; cerses@umontreal.ca), ref: # 2024-6439
2. Approved 16/11/2024, Research Review Committee (RRC), International Centre for Diarrhoeal Disease Research, Bangladesh (68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka, 1212, Bangladesh; +880 (0)1713039813; sasarker@icddrb.org), ref: PR-24128
3. Approved 10/10/2024, Institutional Review Board of the BRAC James P Grant School of Public Health, BRAC University (6th Floor, Medona Tower, 28 Mohakhali Commercial Area, Bir Uttom A K Khandakar Road, Dhaka, 1213, Bangladesh; +880 (0)2-48812213-18; irb-jpgsph@bracu.ac.bd), ref: IRB-2024-IS-25

Site 1:
1. Approved 30/01/2019, Health Research Ethics Committee at the University of Montreal (Bureau de la conduite responsable en recherche, Université de Montréal, C.P. 6128, succursale Centre-ville, Montréal, Québec, Canada H3C 3J7; Tel: +1 (0)514 343 6111 x27395; Email: camille.assemat@umontreal.ca), ref: 18-141
2. Approved 14/12/2018, Comité de Ética em Pesquisa da Universidade Estadual do Ceará (State University of Ceará, Av. Silas Munguba 1700, Itaperia, 60.714-903, Fortaleza – CE, Brazil; Tel: +55 (0)85 3101 9890; Email: cep@uece.br), ref: 3.083.892

Site 2:
Approved by the committees listed above

Study design
Two-arm cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dengue infection

Interventions
The present study will follow a pragmatic cluster RCT design with randomization at the census tract level with equal allocation to the two arms. There will be 34 clusters in each arm of 86 children aged between 2 to 12 years old for a total of 5,848 children enrolled in the study.

Household visits will occur every six months for a total of six visits over a 3-year period to cover both dry and rainy seasons. At allocation, community mobilization activities will begin and locally customized activities will be implemented. Customized community activities will be developed during community meetings, lead by community members. There will be volunteers from the communities, who will serve as organizers and educators trained by facilitators from the

research team. Inter-community visits will be organized to share experiences between communities and to strengthen the group dynamics and the collective preventive action.

The control group will receive standard vector control in Fortaleza as determined by the Municipal Health Department of Fortaleza, which includes the application of temephos, an organophosphate larvicide, in all water storage containers during outbreaks as well as insecticide spraying inside households and of the surrounding environment.

Baseline and follow-up findings will be presented individually during households visits and by cluster during community meetings to further engage households and community members. The duration of data collection is two years.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 07/02/2025:
Measured twice over a 2-year period:
1. Rates of anti-dengue Immunoglobin G (IgG) seroconversion (from negative to positive at follow-up) to evaluate the incidence of primary infections, measured using enzyme-linked immunoabsorbent assays (ELISA)
2. Adult female mosquitoes per person (number found per 100 households examined) to evaluate the mosquitoes' density/presence, measured by visual inspection

Previous primary outcome measures:
Measured every 6 months over a 3-year period:
1. Rates of anti-dengue Immunoglobin G (IgG) seroconversion (from negative to positive at follow-up) to evaluate the incidence of primary infections, measured using enzyme-linked immunoabsorbent assays (ELISA)
2. Level of IgG to N-term-34kDa salivary peptide in blood (salivary biomarkers of Aedes exposure), measured using ELISA
3. Pupae per person (number of pupae found per 100 households examined) to evaluate the mosquitoes' density/presence, measured by visual inspection

Key secondary outcome(s))
Current secondary outcome measures as of 07/02/2025:
Measured twice over a 2-year period:
1. Anti-dengue IgG antibodies waning rates (from positive at baseline to negative at follow-up), measured using ELISA
2. Additional entomological indexes, based upon visual inspection
3. Self-reported health status and previous fever events, measured using a standardized questionnaire
4. Knowledge, attitudes and practices (KAP) changes, measured from questionnaires
5. Household social capital, measured from questionnaires
6. Social acceptability of activities, measured from focus groups and in-depth interviews
7. Implementation and adaptability processes, measured from focus groups and in-depth interviews
8. Potential for sustainability (intervention), measured from focus groups, in-depth interviews, and document analysis
9. Empowerment of individual and communities, measured from focus groups and in-depth interviews

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9. Empowerment of individual and communities, measured from focus groups and in-depth interviews

Completion date
31/03/2027

Eligibility

Key inclusion criteria
Site 1 (Fortaleza, Brazil):
Eligibility will be evaluated on three levels: clusters, households, and individual. The inclusion criteria are:
1. Any of the 3,020 census tracts from the 2010 Census
2. Households permanently inhabited
3. Children aged 3 to 9 years

Added 07/02/2025:
Site 2 (Dhaka, Bangladesh):
Eligibility will be evaluated on three levels: clusters, households, and individual. The cluster inclusion criteria are: for areas of Dhaka city will be selected for inclusion in the study based on recent data on dengue prevalence. Any households within the selected clusters will be eligible to participate in the study if they
1. Have at least one child between the ages of 2 and 12 years old, who has lived in the household for at least 6 months, and
2. There is a parent/guardian or other adult caregiver that can provide informed consent.

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Child

Lower age limit

2 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
Site 1 (Fortaleza, Brazil):
1. Census tracts where interventions outside of vector control standard practices occurred within the last 5 years
2. Census tracts deemed to insecure for study personnel (determined based upon the opinion of the research team and stakeholders)
3. Clusters with less than 120 households
4. Abandoned or non-permanent households or households with the intention to move outside of the household during the study period
6. Children with chronic disease or other health condition that preclude participation in the study
7. Parents or guardians who are unable to give informed consent

Added 07/02/2025:
Site 2 (Dhaka, Bangladesh):
Clusters will be excluded from the study if:
1. They experienced interventions outside of standard vector control practices within the last two years
2. They contain less than 62 households as our formative study suggested that 62-70 households are required to obtain the needed sample size.

Households will be excluded from participating in the study if:
1. They intend to move outside of the cluster during the period of the study (2024-2027)
2. They do not have any children between the ages of 2 and 12 years old
3. The child has a chronic disease or other health condition that precludes participation in the study
4. There is not a parent/guardian or other adult caregiver that can provide informed consent.

Additionally, households will be excluded from participating in the entomology assessment if there is no electricity in their home (electricity is required for the mosquito traps). There are no exclusion criteria for the qualitative components of the study.

Date of first enrolment
15/10/2019

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Bangladesh

Brazil

Study participating centre
Universidade Estadual do Ceara
Av. Dr. Silas Munguba, 1700 Campus do Itaperi
Fortaleza
Brazil
60.714.903

Study participating centre
BRAC James P Grant School of Public Health, BRAC University
6th Floor, Medona Tower, Bir Uttam AK Khandakar Rd
Dhaka
Bangladesh
1213

Study participating centre
International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)
68, Shaheed Tajuddin Ahmed Sarani Mohakhali
Dhaka
Bangladesh
1212

Sponsor information

Organisation
Université de Montréal

ROR
https://ror.org/0161xgx34

Organisation
Universidade Estadual do Ceara

Organisation
Institut de Recherche pour le Développement

ROR
https://ror.org/00bnthp71

Organisation
Secretaria Municipal de Saúde de Fortaleza

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The trialists' intention is to have participant level data stored in a repository although the details of this have not yet been confirmed.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2023	09/04/2024	Yes	No
Protocol article	protocol	14/02/2020	17/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes