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School and community driven dengue vector control and monitoring in Myanmar

Submission date 30/05/2022	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/05/2022	**Overall study status** Stopped	
Last Edited 02/02/2023	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Dengue is the most common and widespread mosquito-borne arboviral disease globally estimated to cause >390 million infections and >20,000 deaths annually. There are no effective vaccines or preventive drugs. Control of dengue transmission relies primarily on mosquito vector control. Although most vector control methods currently used by national dengue control programs may temporarily reduce mosquito populations, there is little evidence that they affect transmission. There is an urgent need for innovative, participatory, effective, and locally adapted approaches for sustainable vector control and monitoring in which students can be particularly relevant contributors and demonstrate a clear link between vector reduction and dengue transmission reduction, using tools that are inexpensive and easy to use by local communities in a sustainable manner.

The overall objective of this trial is to assess the impact of student-driven interventions on dengue incidence, mosquito indices, and dengue knowledge, attitudes, and prevention practices in schools and communities. The specific project objectives are to:
1. Reduce dengue incidence in schools and communities
2. Reduce entomological indices in schools and communities
3. Improve knowledge of dengue, entomology, and vector control in students and their parents
4. Engage students, teachers and relevant stakeholders in community vector control and monitoring
5. Facilitate improved teaching capabilities by training of teachers and enhancing the dengue school curriculum
6. Determine implementation fidelity and adaptation of interventions through process evaluation

The trial involves middle school students that positions them to become actors in dengue knowledge transfer to their communities and take a leadership role in the delivery of vector control interventions and monitoring methods. Following this rationale, we believe that students can become change agents of decentralized vector surveillance and agents of sustainable disease control in line with recent new paradigms in integrated and participatory vector surveillance and control. This provides an opportunity to operationalize transdisciplinary research towards sustainable health development.

Who can participate?
6th Grade students in 46 school catchment areas in two townships in Yangon, Myanmar.

What does the study involve?
Of the 46 schools involved in the study, 23 schools will be allocated at random (like tossing a coin) for students to receive vector control and educational/knowledge transfer intervention. Students at the other 23 schools will serve as a control and will not receive these interventions. The study will collect data on dengue cases confirmed by rapid diagnostic tests in the townships, dengue incidence in schools, density of mosquito populations in the community, dengue knowledge, attitudes, and practice, and engagement in the trial.

What are the possible benefits and risks of participating?
Benefits. One advantage of participating in this study is that participants who have a fever will receive a dengue RDT free of charge. This means participants will know quickly whether they have dengue or not, and can seek medical advice quickly. In addition, participants will contribute to a research project that attempts to find better ways to control mosquitoes and reduce dengue. This will be good for the community and for the country. It is expected that the combination of school and village activities will have a wider community impact in reducing mosquitoes and contributing to disease reduction.

Risks. There are no risks associated with participating in this project. If any project participant gets a fever during the study, blood will be taken by pricking the fingertip with a needle. This may hurt a little, but is otherwise not dangerous. Questionnaires, household observations and mosquito collections will take some of participants' time. The proposed interventions have been tested widely and no adverse consequences have been reported. Students will be engaged in collecting mosquito larvae and adults that do not represent any risk of dengue transmission. Handling mosquito-eating fish represents no risks.

Where is the study run from?
Norwegian University of Life Sciences (Norway)

When is the study starting and how long is it expected to run for?
From January 2018 to May 2025

Who is funding the study?
Research Council of Norway (Norway)

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
School and community driven dengue vector control and monitoring in Myanmar (MY-SCHOOL): Study protocol for a cluster randomized controlled trial

Acronym
MY-SCHOOL

Study objectives
The main hypothesis of the study is that the dengue incidence rate will be lower in the intervention arm compared to the control arm. Other hypotheses are that mosquito indices will be lower; and that there will be improvements in the knowledge, attitudes and practices (KAP) regarding dengue risk reduction and community engagement in vector control activities in the intervention arm compared to the control arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/06/2019, Regional Committee for Medical & Health Research Ethics, South East Norway, Section C (Postbox 1130 Blindern, NO-0318 Oslo, Norway; + 47 22 84 55 13; anders.strand@medisin.uio.no), ref: 2019/814/REK sør-øst C
2. Approved 12/06/2020, The Government of the Republic of Myanmar, Ministry of Health and Sports, Institutional Review Board -1 (Office No (4), NayPyiTaw, Union of Myanmar; +95 9 500 9434; khinmchair@gmail.com)
, ref: IRB 1/ 2019-7

Study design
Single-center unblinded cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
The interventions consist of integrated sets of vector control and educational/knowledge transfer interventions will be implemented simultaneously. The vector control intervention has four components: (1) Adult mosquito mass trapping using commercial oviposition traps (Gravid Aedes Trap (BG-GAT) and locally produced traps (plastic bottles) constructed by students will be placed in both schools and students' households. (2) Larval control using larvivorous guppy fish (Poecilia reticulata). (3) Prevention of mosquito breeding using tightly fitting lids or covers for water storage containers . (4) Source reduction by weekly solid waste management and cleanup campaigns by students around their schools and households. The education and knowledge transfer intervention has two components: (1) Dengue curriculum enhancement and capacity building for teachers, consisting of a participatory approach to transformative education. (2) Communication for behavioral change and transfer of knowledge.

Allocation of interventions will be done after baseline collections (described below). Of the 46 eligible schools, 23 will be allocated to the intervention arm and 23 to the control arm. This will be accomplished by an open public lottery event. At this event, representatives from each school will attend, including regional and township health and educational representatives, teachers, parents and students. Information about dengue and the goals of the project will be given. The reasons for randomization, its procedures and the concepts of intervention and control will be explained. Attendees will also have a chance to ask questions about dengue, vector control, health seeking behaviors, personal experiences of dengue and specific details about the project. The lottery will be carried out as follows. Small pieces of paper, indistinguishable from one another, numbered from 1 to 46, will be folded and placed in non-transparent envelopes and mixed in a bowl. Each number represents a cluster (school) and a list of the schools with their respective number will be consulted during the process. A large screen with the numbered list of school names will be shown above the bowl, visible to everyone. A person not involved in the study, and accepted by all participants, will be selected to make the draw. Two flip boards with large sheets of paper will be placed on either side of the bowl with the heading 'Intervention' and 'Control' (in Burmese). The first number drawn (representing a specific school) will be assigned to the Intervention arm, the next number/school drawn will be assigned to the Control arm, and so on. Following the draw, the implications of being in either of the two arms will be discussed and the roles of participants, health volunteers, and sub-district hospital staff will be reviewed. By following this lottery scheme, the interventions are allocated at the same time as the sequence is generated, obviating the need for allocation concealment. At this meeting we will take care not to provide any information about planned dengue control interventions that will be used in the trial to participants from the control arm to minimize contamination between the groups.

Intervention Type
Mixed

Primary outcome(s)

Dengue incidence rate in communities measured continuously during the intervention period by passive case detection using dengue rapid diagnosis tests (RDT) in public hospitals and health centers. Rate is given as the confirmed number of dengue cases (numerator) and the estimated population in each school catchment area (denominator).

Key secondary outcome(s))

1. Dengue incidence rates in schools measured by seroconversion rates in school children between baseline, and after 4 months and 8 months
2. Mosquito adult index in schools and households given as the mean number of adult female Ae. aegypti and Ae. albopictus mosquitoes per school/household measure by indoor and outdoor mosquito collections using a battery-driven mechanical aspirator at baseline, and after 4, 8, and 12 months
3. Breteau index in schools and households given by the number of Aedes positive containers per 100 schools/households at baseline, and after 4, 8, and 12 months
4. Knowledge, attitudes, and practice scores in students and parents given as sum scores on a scale from 1-10, where ten indicates the highest score, determined by KAP questionnaires at baseline, and after 4, 8, and 12 months
5. Behavioral assessment of students and parents on dengue control and prevention given as human decision-making in the uptake of vector control activities assessed by responses to statements on a 5-point Likert scale using questionnaires and structural equation modelling at baseline, and after 4, 8, and 12 months
6. Engagement assessment among students is the degree of engagement in education /knowledge transfer activities among students measured by photographs and qualitative data collected by photovoice methodology and group discussions once at 5 months after the intervention
7. Engagement assessment among parents and teachers is the degree of engagement in education/knowledge transfer activities among parents and teachers measured by qualitative data qualitative methods: in-depth interviews and focus group discussions and code book. Assessments in parents will be done once during parent-teacher meetings at 5 months after the start of the intervention. Assessments in teachers will be done three times at 1, 5, and 9 months after the start of the intervention.

Completion date

01/05/2025

Reason abandoned (if study stopped)

due to Covid-19 and political unrest

Eligibility

Key inclusion criteria

Schools:
1. High and middle schools in selected townships in Yangon
2. Schools that have ≥40 6th grade students
3. Approval by the headmaster of school through signed informed consent and Letter of Agreement
4. Approval by relevant teachers by signed informed teacher consent

Students:
1. Will start 6th grade in June Year 1

2. Signed informed assent
3. Signed informed consent by parents

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Schools:
1. Schools with other ongoing dengue interventions
2. International schools not using the national curriculum and Burmese as language of instruction
3. Boarding schools

Students:
1. Students who are seriously ill and not considered physically fit to participate
2. Students whose parents do not provide consent

Date of first enrolment
01/01/2023

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
Myanmar

Study participating centre
Malaria Consortium
Yangon
Myanmar
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Sponsor information

Organisation

Norwegian University of Life Sciences

ROR
https://ror.org/04a1mvv97

Funder(s)

Funder type
Government

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed in this study will be made available in data repository of the Norwegian Centre for Research Data (NSD) http://nsddata.nsd.uib.no.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/08/2022	02/02/2023	Yes	No
Participant information sheet			31/05/2022	No	Yes