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Reducing the risk of human Nipah virus exposure in Bangladesh through school-based education

Submission date
02/07/2025

Recruitment status
No longer recruiting

Registration date
19/08/2025

Overall study status
Ongoing

Last Edited
19/08/2025

Condition category
Infections and Infestations

[_] 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
Nipah virus (NiV), a highly virulent zoonotic pathogen with a 75% case fatality rate, causes outbreaks of encephalitis and/or severe respiratory disease every year in Bangladesh since 2001. About 42% of the affected cases are <18 years. Humans are primarily affected by the consumption of raw date palm sap contaminated with bat saliva or urine. People in certain regions are more affected due to high-risk practices. Currently, there are no effective vaccines or treatments available for NiV. Raising awareness and promoting changes in these practices could significantly lower exposure to NiV. Peer education is a popular learning tool for health promotion in young people. This study is useful to generate potential estimates of the effect of school-based peer education to improve young people's knowledge and practice about NiV exposures and prevention. By generating scientific evidence on the implementation process, potential benefits and limitations of educating school children to improve community awareness for reducing transmission of a highly-lethal pathogen with epidemic potential, this research has the potential to lead to the reduction of NiV outbreaks in Bangladesh. This study aims to co-develop/adapt, implement and evaluate the feasibility, acceptability and added value of Little Doctors, a school-based, peer education project, in improving knowledge and practices of school students and their family members to reduce NiV exposures in Bangladesh. Additionally, a realist-informed process evaluation will be conducted to explore the feasibility, acceptability, appropriateness, mechanisms of change, how the intervention works in different contexts and test and revise the Little Doctors logic model.

Who can participate?
School students within years IV-VIII, adult household/family members of students and teachers from each of the two primary and one secondary schools nearest to the bat roost within the unions of the selected subdistricts.

What does the study involve?
This pilot study will use a mixed-methods approach combining a pilot cluster-randomised controlled trial with an embedded process evaluation. Collecting data via school-based and household surveys, difference-in-difference analysis using multivariate linear regressions,

controlling for school and individual attributes, will be employed to assess the potential effectiveness of Little Doctors in improving knowledge and practices of school students and their family members. Three key messages (3D) will be communicated to students for them to share with their friends and families. These messages include: Don't drink raw date palm sap, Don't eat partially bat/birds/animal-eaten fruits and Don't allow livestock to graze under bat roosts. Direct observations, key-informant interviews (KIIs) and focus group discussions (FGDs) will be used for process evaluation.

The key outcome measures/variables are whether knowledge of students and their families is improved and risk behaviours reduced. The research may lead to the development of a new approach to enhancing community engagement and community awareness for preventing infectious disease outbreaks in Bangladesh and other low-income settings.

What are the possible benefits and risks of participating?
This proposed school-based intervention will improve knowledge of Nipah virus transmission and prevention among students compared to those who do not receive the intervention.

There is no risk for school students in participating in this study. The study will take the child's time to answer the required questions about Nipah virus transmission and its control.

Where is the study run from?
icddr,b, Bangledesh

When is the study starting and how long is it expected to run for?
June 2025 to March 2026

Who is funding the study?
UK Public Health Rapid Support Team (UK-PHRST), UK

Who is the main contact?
Dr Sukanta Chowdhury, sukanta@icddrb.org

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
31782

Study information

Scientific Title
Little Doctors for reducing the risk of human Nipah virus (NiV) exposure in Bangladesh: A pilot evaluation

Acronym
Little Doctors

Study objectives
This proposed school-based intervention will improve knowledge of Nipah virus transmission and prevention among students compared to those who do not receive the intervention.

Specific aims
1. Generate initial estimates of the potential effect of Little Doctors in improving school students' knowledge of Nipah virus exposures and reducing risk behaviors/practices (including reduction in drinking of raw date palm sap).
2. Generate initial estimates of the potential effect of Little Doctors in improving knowledge of Nipah virus exposures and reducing risk behaviors (including reduction in drinking of raw date palm sap) among family and community members of students
3. Explore the feasibility and acceptability of the Little Doctors intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/06/2025, icddr,b Ethical Review Committee (68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka, 1212, Bangladesh; +880-2-9827084; shiblee_s@icddrb.org), ref: PR-25019

Study design
Pilot cluster randomized controlled trial and embedded process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, School

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Improving knowledge and practices of school students, their families and community members to reduce Nipah virus exposures

Interventions
The two primary and one secondary schools will receive intervention. The same number of schools will be selected for control. Each selected class and school will be considered as a cluster. The required number of students, according to the sample size in each class, will be selected randomly. Random numbers will be generated for randomization.

The proposed intervention involves 30 minutes of training per week for a total of 8-10 weeks, using leaflets, posters, and/or placards to cover information on Nipah virus exposures, protective behaviors, hand hygiene, respiratory hygiene, communication, and confidence-building. The key messages on protective behaviors will be “don’t drink raw date palm sap”, “don’ t eat partially bat/bird-bitten fruits”, and “don’t allow domestic animals to graze under a bat roost”. Other messages include “wash locally grown fruits before eating”, “don’t play under the bat roost”, and “don’t allow domestic animals to eat partially bat/bird-bitten fruits.” In rural Bangladesh, children are often responsible for feeding and rearing domestic animals. The intervention content, timing, and delivery strategy will be refined with feedback from students, teachers and relevant stakeholders. Each student will be provided with leaflets and/or posters to facilitate knowledge sharing with peers (classmates) and family members, and/or friends.

Intervention Type
Behavioural

Primary outcome measure
1. Knowledge, defined as a 30% improved knowledge among participants of the intervention arm about Nipah compared to the control arm, will be measured from total knowledge scores using a pretested structured questionnaire to collect data at baseline (July-August 2025), during the intervention (September-November 2025) and the post-intervention assessment (February-March 2026)
2. Risk behaviors, defined as a 20% risk exposure reduction among participants of the intervention arm compared to the control arm, will be measured as Relative risk reduction (RRR) and absolute risk reduction (ARR) using a pretested structured questionnaire to collect data during the post-intervention assessment (February-March 2026)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/06/2025

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. The two primary and one secondary schools nearest to the bat roost within the unions of the selected subdistricts that provide school-level informed written consent and agree to deliver the Little Doctors project
2. School students within years IV-VIII from each enrolled school and their households/family members
3. Students who provide written informed assent for participation
4. Students whose parents/legal guardians provide informed written consent for their children's participation
5. Adult household/family members of students who provide informed written consent
6. Teachers who provide informed written consent for participation

Participant type(s)
Learner/student

Age group
Child

Lower age limit
9 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
560

Key exclusion criteria
1. Residential schools
2. The school authority does not provide written consent
3. Parents do not provide informed written consent
4. Students do not provide informed assent
5. Students with special needs

Date of first enrolment
15/06/2025

Date of final enrolment
30/07/2025

Locations

Countries of recruitment
Bangladesh

Study participating centre
Faridpur and Rajbari districts, Bangladesh
Faridpur and Rajbari
Faridpur and Rajbari
Bangladesh
7800

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
UK Public Health Rapid Support Team (UK-PHRST)

Results and Publications

Publication and dissemination plan
1. Research findings will be published in peer-reviewed journals
2. Disseminate findings at the international conference
3. Disseminate findings to the Directorate General of Health Services, Department of Education, Bangladesh and other relevant stakeholders

Intention to publish date
30/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Sukanta Chowdhury, sukanta@icddrb.org.

• The name and email address of the investigator/body who should be contacted for access to the datasets: Sukanta Chowdhury, Principal Investigator, Email: sukanta@icddrb.org
• The type of data that will be shared: All data except the personal data of study participants
• Timing for availability: After publication of the study findings
• Whether consent from participants was required and obtained: Consent will be taken for further sharing of data only for research purposes
• Comments on data anonymization: No personal data of study participants will be shared
• Any ethical or legal restrictions: No
• Any additional comments: No

IPD sharing plan summary
Available on request