STUDY PROTOCOL

Effectiveness of Combination Integrated Dengue Education and Learning Module (iDEAL) and Aedestech Mosquito Home System (AMHS) in Dengue Prevention Among School Children in Selangor and Kuala Lumpur: Study Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Dengue is a viral disease that is transmitted by mosquitoes and highly prevalent in Malaysia. The disease is caused by fourdistinct subtypes of dengue virus (DENV) that are closely related. In Malaysia, a total of 123,133 dengue cases were reported in 2023, com-pared to 7,103 cases reported in 2000. Selangor and Kuala Lumpur recorded the highest number and incidence rate of dengue cases and re-lated mortality. **Methods:** This article presents a protocol to explore the efficacy of a combined intervention, integrated dengue education andlearning module (iDEAL) and Aedestech Mosquito Home System (AMHS), in improving schoolchildren's knowledge, attitude, practice (KAP),including environmental cleanliness index and dengue index in Selangor and Kuala Lumpur. Primary (n = 10) and secondary schools (n = 10)in the study locations will be recruited for the cluster randomised controlled trial (RCT) for a 2-year period. The intervention group will be sub-jected to a combined theory-based intervention, IDEAL and AMHS, while the control group will receive conventional education. The efficacyof the intervention module will be evaluated at four time points. Data will be analysed using the Generalised Linear Mixed Model (GLMM) forthe main and interaction effectsat each follow-up point. P-values of 0.05 and 95% confidence interval will be considered for hypothesis testing. **Discussion:** The findings from this study will assist in identifying effective educational strategies for enhancing KAP among this vulnera-ble young population in Selangor and Kuala Lumpur, and possibly other states in Malaysia. **Trial Registration:** This trial has received ap-proval from the Ethics Committee for Research Involving Human Subjects of Universiti Putra Malaysia (JKEUPM-2023-635) and the NationalMedical Research Registration of Malaysia (NMRR) (NMRR ID-23-02822-CPZ). Additionally, the RCT has been registered with the Thai Clini-cal Trial Registry (TCTR) (Reference number: TCTR20230513002).
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Keywords: Dengue, Combination iDEAL and AMHS, Intervention, Knowledge, Attitude, Practice, Environmental Cleanliness index, Dengue index

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INTRODUCTION

Dengue is a viral disease that is transmitted by mosquitoes through bites and caused by four distinct subtypes of dengue virus (DENV) that are closely related [1]. Dengue constitutes an important public health problem in several tropical and subtropical countries worldwide [2]. According to the World Health Organisation (WHO), the number of dengue cases increased from 505,430 in 2000 to 5,2 million in 2019; reflecting a significant rise in two decades [1]. In Malaysia, a

total of 123,133 dengue cases were reported in 2023, representing a more than 17-time increase compared to 7,103 cases reported in 2000 [3]. Selangor and Kuala Lumpur recorded the highest number and incidence rate of dengue cases and related mortality [4,5]. The incidence of dengue in Malaysia is expected to surge again in the coming years due to its cyclical pattern with peaks occurring every four to five years [4].

Dengue may occur clinically either as mild illness or severe complications, with a higher risk of severe disease in those contracting opportunistic and secondary infections caused by distinct DENV serotypes [6]. The primary symptoms of dengue are similar to those of other febrile diseases, usually culminating into misdiagnosis and underestimation of its severity and prevalence [7,8].

The economic and social burden associated with dengue, particularly in endemic areas, is often substantial [9]. Global estimates reported a decade ago revealed approximately 58.40 million symptomatic infections of dengue, including 13,586 fatal cases, with the yearly global cost of the disease amounting to $8.9 billion [10]. Likewise, dengue constitutes a substantial economic burden in Malaysia, reported at 102.25 million USD per year, or roughly USD3.72 per capita as at 2013 [10]. This economic burden is expected to increase further as a result of the costs associated with preventing and controlling the disease, surveillance, and consequences in the long term [11].

Several researchers have highlighted the importance of knowledge, attitude, and practice (KAP) studies as an effective approach in the management of dengue infection [12-15]. Hence, it is pertinent to develop an integrated programme for the prevention of this disease, especially among schoolchildren. Furthermore, a combined school-based health integrated dengue education and learning (iDEAL) and Aedestech Mosquito Home System (AMHS) is a potential candidate for enhancing KAP among school children, as well as their environmental cleanliness index and aedes index.

This article presents a protocol to explore the efficacy of a combined intervention, integrated dengue education and learning module (iDEAL) and Aedestech Mosquito Home System (AMHS), in improving schoolchildren's knowledge, attitude, practice (KAP), as well as environmental cleanliness index and dengue index in Selangor and Kuala Lumpur.

METHODS

Study design

A randomised control and parallel trial will be conducted, involving 2 arms and single blinding. School children will be randomly allocated into an intervention and a control group based on clusters to prevent contamination. A school that fulfils the inclusion and exclusion criteria and comparable to other schools is considered a cluster. The intervention, comprising iDEAL and AMHS will be administered to the intervention while a standard/ conventional education module will be provided to the control group.

Study duration

This study will be carried out for approximately 24 months, specifically from September 2024 to August 2026. Data collection will commence in the first week of November 2024. The various stages of the trial entail research design, development of the intervention, implementation of the intervention, and evaluating the efficacy of the intervention. Figure 1 depicts the proposed flow and sequence of events in the RCT, comprising the intervention development, ethical approval, recruitment of participants, measurement of outcome measures, and the assessment period.

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		
TIMEPOINT	- T_0	T_0	T_1	T_2	T_3
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
[Intervention]			X	X	X
[Control]			X	X	X
ASSESSMENTS:					
[sociodemographic, socioeconomic and history of dengue infection]		X			
[Knowledge, attitude and practice]		X	X	X	X
[Environmental cleanliness index and dengue index]		X	X	X	X

Figure 1: Schedule of enrolment, interventions, measuremnet and assessment.

Study location

The two main locations of this study are Selangor and Kuala Lumpur, which are officially established as the hotspots for dengue in Malaysia [16]. Selangor State (latitudes 235′ –360′ N and longitudes 10045′ –102.00 E) is among the most advanced and highly populated state in Peninsular Malaysia [17,18]. Although Kuala Lumpur is a separate federal territory, its location within Selangor has a significant effect on the state's economic and social development. Besides, there are interconnections within these territories in terms of ecological patterns, fluxes, and processes. Thus, we decided to include Kuala Lumpur in the present analysis.

Kuala Lumpur is located on the west coast of the Malaysian Peninsula (coordinates 38′ 28.3″ N 10141′ 11.5″ E) covering a land area of about 243 km2 [17]. The most recent geographical data indicates that Selangor's population is around 6.9 million people with a population density of 880/km2. Moreover, minors account for almost 30% of the population. Kuala Lumpur was projected to have 8,622,000 inhabitants in 2020 with the country's maximum population density at 8,157 inhabitants per square kilometre [17].

Study population
This trial will be carried out in primary and secondary schools registered and managed by Malaysia's Ministry of Education (MOE). Specifically, schoolchildren in standard 4 and form 4 in the aforementioned schools located in Selangor and Kuala Lumpur will be recruited into the study. There are 661 and 279 primary and secondary schools respectively in Selangor, whereas those in Kuala Lumpur are relatively lower at 218 and 175, respectively. These schools include technical, national, religious, and scientific boarding institutions [19]. The sampling frame will comprise a list of standard 4 and form 4 classrooms in both study locations.

Inclusion and exclusion criteria
The eligibility criteria in this trial entails the following:
- Malaysian citizen
- Standard 4 or Form 4 from primary and secondary school respectively
- Consented to participate in the study by parents or caregivers
- Consented by the school

Meanwhile, the exclusion criteria are as follows;
- not able to read Bahasa Malaysia or English
- physically or mentally impaired with disability card holder
- temporary student as defined as less than six months during the study period

Sample size estimation
The required sample size for this study was estimated based on the main study outcomes, KAP on the prevention and control of dengue. Upon employing the formula for evaluating the difference in the proportion between two groups [20] and adjusting for an attrition rate of 70%, the minimum sample size was estimated as 400 for each group, Therefore, a total of 800 participants will be recruited in this study.

Sampling method and subject recruitment
A multistage sampling strategy will be employed in this trial. First, proportional sampling will be used to select 10 primary schools and 10 secondary schools based on the districts in Kuala Lumpur and Selangor. Thereafter, a classroom will be selected from each school. Thus, the second stage will involve a random selection of 10 classrooms each from Standard 4 and Form 4 from a selected primary and secondary school, respectively. All student in a specific classroom will be invited to take part in the trial.

Randomisation
In order to ascertain administrative efficiency and limit the risk of experimental contamination and enhance compliance among school children, the school clusters will be randomised. Overall, 10 classrooms from Standard 4 and Form 4 in the selected schools will be randomly allocated to the control and intervention groups. A ratio of 1:1 will be employed for the randomisation process.

Sequence generation
A random allocation sequence will be generated following the recruitment of schools fulfilling the eligibility criteria, thereby facilitating the assignment into either the control or intervention group. A software obtained from a web page "Create a block randomization list" (Sealed Envelope Ltd, 2019) will be used in generating the randomisation sequence. The principal investigator will perform the sequence generation and allocation concealment process. Meanwhile, trained researchers will conduct the implementation process which entails participant enrolment, opening the envelop and administering the intervention. These processes will be executed as recommended by the CONSORT statement [21]. In this trial, schools will be allocated into the various groups by using the permuted block randomisation. This technique is employed to ensure that schools are allocated to each trial arm in a close and balanced manner. The researcher will be blinded from predicting the school's allocation process by using a variable block size, comprising block size of 4,6 and 8. The same software used for the random allocation sequence will be employed for the permuted block randomisation.

Allocation concealment
Sequentially numbered, opaque, sealed enveloped methods will be used for as the allocation concealment method. Specifically, a randomisation list will be obtained from the software on the web page "Create a block randomization list" (Sealed Envelope Ltd, 2019). The list also comprises unique allocation codes synthesised by the software, consisting two letters and at least 1 digit (e.g.: BW2, AM4, AB1 and etc). These unique codes represent either the control or intervention group, thereby reflecting that only the sequence generator will be aware of the meaning of the code. This method will facilitate effective allocation concealment. Subsequently, the "sequentially numbered, opaque, sealed enveloped methods" will be applied while recruiting the participants.

The unique code will be printed, cut and sealed in opaque envelops. As the researcher recruits the schools fulfilling the eligibility criteria, the liaison officer in each school will open the opaque envelope containing various codes. The randomisation code will only be released following the recruitment of the school into the RCT, which coincides with the completion of the baseline measurement. As a result, the various parties involved in the randomisation process will be blind from the group that the school is assigned to before revealing the unique code.

Blinding
A single blinding technique will be applied in this study, whereby the schoolchildren will be unaware of

the group they are assigned to. This blinding method is designed to minimise performance bias, which is also referred to as the Hawthorne effect in which subjects may alter their responses or behaviours if they are aware of the group they are allocated to. Nevertheless, the field researcher in this trial cannot be blinded since they are responsible in delivering the intervention to the recruited participants.

Intervention Group

Each school undergoing the intervention will be administered a combined theory-based iDEAL and AMHS. The intervention will be standardised by making use of trained researchers to administer the intervention in each school. Further optimisation will be performed by using pre-recorded videos, briefing the participants and serial supervision by the principal investigator. The efficacy of the intervention at pre and post-intervention periods will be gleaned from responses to the questionnaire administered at four time points (T_0, T_1, T_2, T_3). The instruments will be self-administered questionnaires to gather data on the primary outcomes while the secondary outcome will be assessed in an observational checklist tool.

Integrated Dengue Education and Learning Module (iDEAL)

This RCT aims to develop a comprehensive and robust educational intervention known as iDEAL to enhance dengue prevention and control-related KAP. Three Phases Intervention Module Development (3P-IMD) procedure will be used in designing the intervention, which will entail the input of experts from various educational research areas and stakeholders. This collaborative approach and all-inclusive process will ensure that the iDEAL encompasses the current and evidence-based data, particularly in relation to the recent progress and advances in dengue prevention and control measures.

In order to ensure the efficacy of the intervention, the iDEAL will pass through a rigorous assessment of its content, medium, and evaluation methods. Series of discussion will be held to examine the main elements and in-depth refinement. As a result, valuable insights and diverse views will be provided regarding the content and ensuring the suitability of the contents for the targeted audience. A dynamic and engaging learning environment remains the main focus of the intervention. Effective knowledge transfer will be facilitated by employing various educational techniques, such as visual aids, interactive modules, practical demonstrations, and case studies. These procedures are expected to also strengthen the adoption of preventive behaviours.

By employing innovative instructional strategies, the iDEAL is designed to improve comprehension, empower individuals, and support long-term shifts in behaviours and attitudes regarding dengue prevention and control. Notably, rather than being a static resource, iDEAL will be a dynamic document that is open to innovation in response to concurrent feedback and evaluation. The efficacy and impacts of the educational module will be enhanced via pilot testing and exhaustive evaluations, as well as employing robust evaluation framework that incorporates context, input, process, and product (CIPP). Therefore, continuous development and refinement will be facilitated, and ensuring that the educational module stands out in dengue education and prevention initiatives. Individuals, school children in this case, will be equipped with the important knowledge and skills necessary to prevent and control dengue effectively, thereby contributing in creating an environment that is healthy and safe for everyone.

Aedestech Mosquito Home System (AMHS)

The AMHS is an effective solution to mosquitoes' control and prevention. The system is effective in attracting disease-transmitting mosquitoes via an attractant. Accumulated evidence depicts that the AMHS has the ability to arrest the development of 99% of eggs laid into healthy larva irrespective if they hatch or nots, as well as retarding the growth of mosquitoes by cutting food supply. In addition, the AMHS has an Insect Growth Regulator (IGR) that completely prevents the transition of pupae into the adult stage, while killing female aedes mosquito will be killed within 24 hours after making contact with the formulation when eggs are laid. Another mechanism used by the AMHS is an auto dissemination principle whereby female mosquitoes play the role of vehicles in transferring the insecticides to other breeding sites. Furthermore, the approach is not laborious as the intelligent design and sustainable system provide long-lasting support for the products and refilling is only required after four to six weeks. The solution used is environmentally friendly as recommended rate to prevent development of aedes and approved for use in drinking water. Lastly, the device is not complex and easy to set up for community and school use.

Questionnaire

The primary outcomes in this RCT are the KAP scores, which will be measured by employing validated and self-administered surveys at four different time points; baseline (T_0), Immediately after the intervention (T_1), and at one month (T_2), and three months (T_3) post-intervention. The questionnaire will be a newly developed instrument in two language versions; Malay and English. Validation of the questionnaire will be based on combining various questionnaires on the similar topic. There are four broad aspects in the questionnaire (1) Respondent information, which comprises items to gather respondents' sociodemographic characteristics, socioeconomic data and history of dengue infection, (2) Knowledge of dengue control and prevention, (3) Attitude towards dengue control and prevention, and (4)

Practices of dengue control and prevention.

For the secondary outcomes, environmental cleanliness and aedes indices will be measured using an observational checklist tool by trained researchers at the aforementioned follow-up points (T0 to T4).

Validity and reliability

The validity of the questionnaire will be evaluated by diverse group of experts, including public health medicine specialist, health educators, family medicine physicians, school teachers and health promoters from various agencies. the acceptability of the instrument will be determined by calculating the content validation ratio (CVR). Additionally, the experts' comments and feedback will be considered for further refinement of the questionnaire. The assigned experts will also calculate the Content Validity Index (CVI) to evaluate the relevance of the questionnaire, before proceeding to the item CVI (I-CVI) and scale average CVI (S-CVI/Ave) estimates. These parameters will be used in modifying the instrument in alignment with the experts' agreement levels.

In terms of reliability, the questionnaire will be subjected to reliability analysis by computing the internal consistency in IBM SPSS (Version 28). A web-based sample size calculator will be used to determine the required sample size for the reliability of the instrument. Thereafter, the respondents will be recruited to attain the required sample size. All the participants in the pilot test and reliability analysis will not be recruited in the final study. The internal consistency and reliability of each item and overall domain will be assessed based on the Cronbach's alpha coefficient (for Likert scale items) or Kuder-Richardson coefficient (dichotomous responses).

Data collection

Consent from the schoolchildren's parents will be obtained by the liaison officer. Thereafter, the baseline data will be collected at T_0 from participants providing consent to participate in the RCT. Those allocated to the intervention group will be scheduled for intervention delivery within one month after recruitment. The intervention session will last for about 30 minutes over the course of three meetings. The schoolchildren will be instructed to complete a post-intervention evaluation to assess the primary and secondary research outcomes at T_1, T_2, and T_3. Likewise, the control group will be subjected to the same assessment as the intervention group. The flowchart of the RCT design is presented in Figure 2 according to the CONSORT 2010 statement [21].

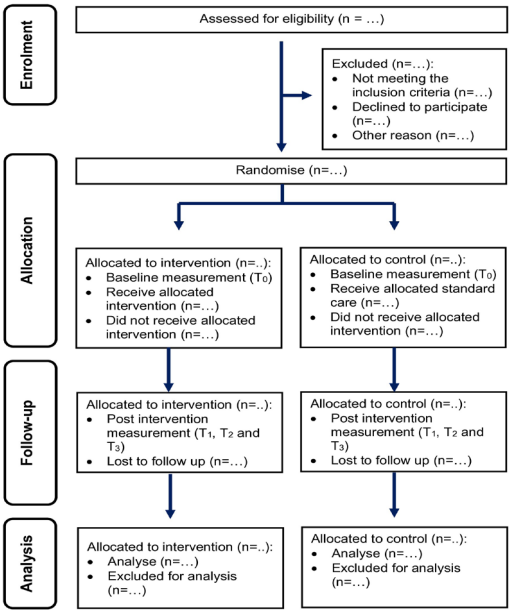

Figure 2: Flow digram of study conduct based on CONSORT statement.

Data analysis

The gathered data will be descriptively and inferentially analysed using IBM Statistical Package for the Social Sciences (SPSS) version 28. All data will be screened for data entry errors, missing data, and outliers. Subsequently, data distribution will be assessed using statistical tests such as the levels of skewness and kurtosis, and Kolmogorov-Smirnov. Graphical methods will be used to assess data normality based on the normality curve, histogram, stem and leaf box plot. Additionally, upon determining the data normality and distribution, the normally-distributed data will be presented as mean and standard deviation, whereas non-normally distributed data will be summarised using the median and first and third quartiles (Q1, Q3). Categorical data will be presented using frequencies and percentages.

A significance level of p-value of 0.05 and a 95% CI will be employed in testing the research hypotheses. For the continuous and normally distributed data, mean differences between the two arms will be compared using the independent sample t-test. One-way repeated measures ANOVA will be employed for the differences in the outcome measures over time, as well as the effects of the intervention. On the other hand, non-normally distributed data will be compared using the Mann-Whitney U test while categorical outcomes between the groups will be analysed using the Chi-square or Fischer's exact test depending on the expected count in each cell in the 2 by 2 table. Cochran's Q test will be used for categorical data analyses within groups.

Main and interaction effects at T0, T1, T2, and T3 will be analysed using the Generalised Linear Mixed Model (GLMM). Intention to treat analysis will be performed to enable the analysis of all the randomised subjects based on the groups they were originally assigned, irrespective of whether they were exposed to the intervention or not.

Ethics approval, trial registration, and consent to participate

This trial has received approval from the Ethics Committee for Research Involving Human Subjects of Universiti Putra Malaysia (JKEUPM-2023-635) and the National Medical Research Registration of Malaysia (NMRR) (NMRR ID-23-02822-CPZ). Additionally, the RCT has been registered with the Thai Clinical Trial Registry (TCTR) (Reference number: TCTR20230513002) on 13/05/2023. All the schoolchildren will be informed that their recruitment into the trial does not in any way affect the relationship with their school or teachers. The researcher will obtain signed consent from each participant parents' or caregiver' upon agreeing to take part in the trial before completing the baseline questionnaire. Participants will be informed that participation in the RCT is voluntary and they have the right to decline participating in the study. They can as well withdraw from the RCT at any time without giving any reason.

Consent for publication and dissemination

The consent for participation will be used to obtain participants' consent for publication. The research findings will be presented in conferences and international journals. Nevertheless, personnel or school-related information will not be revealed in the publications or dissertation.

Supervisory committee

The entire process in the trial, ranging from inception to completion and data monitoring will be examined by a supervision committee comprising researchers and key stakeholders. The committee will provide guidance on the research methodology and their appropriateness in achieving the research objectives. While scheduling monthly meetings, the supervisory members will be asked for further input, such as auditing trial conduct, reviewing interim analysis results, and stopping guidelines if necessary.

DISCUSSION

Participants' sociodemographic characteristics are not expected to differ between the intervention and control groups. We posit a significant improvement in the primary and secondary outcomes among the intervention group relative to the control group. In the GLMM analysis, the combination of theory-based iDEAL and AMHS is hypothesised to improve the KAP, environmental index, and dengue index among schoolchildren in Selangor and Kuala Lumpur.

Data sharing plan

Only researchers and research assistants involved in the trial will have access to the research data. All data including identifiable data will be kept strictly confidential. Three methods will be applied in disseminating and applying the research findings. First, the combined intervention module will be expanded in school curricula across the country by increasing the network of national stakeholders. Second, the Parent and Teachers Association (PIBG), school teachers and other co-curriculum instructors will be involved in the implementation of the intervention. Subsequently, train-the-trainer (TTT) programmes will be implemented to further expand the implementation of the intervention across the country. Thirdly, the research findings will be disseminated through conventional academic channels, including peer-reviewed research articles and conferences.

Result/ Trial status

The subject matter experts (SME) for developing the intervention module and potential schools to be recruited for the trial have been identified. The experts' comments and feedback on the refinement of study protocol, which entails a combination of iDEAL and AMHS, is currently being considered.

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