# Improving measles immunization through community involvement among the marginalized population in Sabah

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
02/11/2023		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/11/2023	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
14/04/2025	Infections and Infestations			

## Plain English summary of protocol

Background and study aims

The COVID-19 pandemic has significantly impacted health services, particularly immunization services, leading to a reduction in measles immunization coverage from the targeted 95%. This has resulted in global post-pandemic measles outbreaks, and those at risk in Sabah were the marginalized population due to the barriers they faced in getting measles immunization. Thus, this study aimed to implement the intervention and evaluate its effectiveness in completing the three doses of measles immunization.

#### Who can participate?

All the children (aged up to 12 years) in all the settlements in Kota Kinabalu, Sabah, Malaysia, born from October 2021 to March 2022.

#### What does the study involve?

Ten (10) marginalized settlements in Kota Kinabalu, Sabah, were randomly divided into the intervention and control groups. All the children in all the settlements, born from October 2021 to March 2022, were recruited. In Sabah, there are three doses of measles immunization provided for children at the ages of 6 months, 9 months, and 12 months. Hence, children who were at the age of 6 months and had not taken their measles immunization were included in this study.

Community volunteers assisted the community in this study's intervention by using the reminder and recall method to complete the measles immunization. An additional five settlements within the control group were provided with regular immunization health services.

What are the possible benefits and risks of participating?

The possible benefits include community empowerment and community engagement in assisting the parents living in the same settlements to get measles vaccines for their children. There were no risks in participating in this study, as all the participants involved continued to have access to the routine immunization health care services provided by the health department.

Where is the study run from? Kota Kinabalu District Health Office (Malaysia)

When is the study starting and how long is it expected to run for? March 2021 to April 2023

Who is funding the study? Investigator initiated and funded

Who is the main contact?
Dr Hazeqa Salleh, zeqa89@yahoo.com
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## 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

Nil known

# Study information

#### Scientific Title

A community-based intervention to improve measles immunization status among the marginalized population in Kota Kinabalu, Sabah

## **Study objectives**

The odds of having a complete measles immunization increased for those who received the community-based intervention compared to those who received only routine health care services.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

1. Approved 09/03/2022, Medical Research and Ethics Committee, Ministry of Health Malaysia (Kompleks Institut Kesihatan Negara (NIH) No.1, Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam, Selangor, 40170, Malaysia; +60 3-33628888/ 33628205; nmrr@moh.gov.my), ref: 22-00051-88T(2)

2. Approved 16/03/2022, Medical Research Ethics Committee, Faculty of Medicine and Health Sciences, University Malaysia Sabah (Jalan UMS, Kota Kinabalu, 88400, Malaysia; +60 88-320 000 ext. 611001 /611010; pejfpsk@ums.edu.my), ref: UMS/FPSKG.9/100-6/1/95

#### Study design

Cluster randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Cluster randomised trial

#### Study setting(s)

Community

## Study type(s)

Prevention

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Prevention of measles disease among children through measles immunization

#### **Interventions**

A cluster randomized control trial was conducted in this study. Ten (10) marginalized community settlements in Sabah were randomized to either the intervention or control group. The intervention was implemented in five urban slums for six months by community volunteers who provided solutions to address the barriers faced by the community in obtaining and completing the measles immunization through the reminder and recall method. Another five (5) settlements in the control group received only the routine immunization health services. All the children from both groups were followed up until they were supposed to complete their three doses of measles immunization by the age of 12 months.

The community-based intervention includes four measures, which are: (i) education and encouragement; (ii) reminder activities, (iii) home visits, (iv) assistance, and solutions. The intervention employed community volunteers to mainly remind parents of their children's immunization appointments, do home visits, and provide service if needed for parents who had difficulties going to the clinic to get their children immunized. The community volunteers were those who lived within the same village and were chosen by the community themselves and trained by the researcher to work as a team. Cooperation from the head of villages and the village committee were needed throughout the study period. This community-based intervention was implemented at an individual level for each child that was recruited into the study. Hence, continuous communication between the Healthcare workers and community volunteers was important. The healthcare workers will provide a list of children with their details within each village whose parents consented to the study to the community volunteers The

details of their measles immunization appointments will also be included. The community volunteers will then do the intervention for each of the children during the scheduled appointment times with their own village healthcare workers.

#### Intervention Type

Other

#### Primary outcome measure

- 1. Measles Immunization Status is an individual binary outcome where yes, the immunization is complete, and no, the vaccination is not complete.
- 2. Full measles immunization means the children took the three vaccinations at six, nine, and 12 months old. While incomplete measles immunization implies that the children missed either one of the measles vaccinations or did not take any vaccination,

These data were collected by extracting the information from the Maternal Child Health Booklets kept at the clinic and by the mothers. After a child was immunized, a record of the date of vaccination was written by the nurses inside the book. Measles immunization was considered complete when there were three recorded vaccinations in the booklet.

#### Secondary outcome measures

1. The community's perception regarding their satisfaction with the services they received and the acceptability of the intervention program. Satisfaction and acceptability were assessed at the end of the program. For the satisfaction assessment, all the sample's caretakers were asked to complete the Client Satisfaction Questionnaire (CSQ-8). Assessments were conducted towards the conclusion of the research, and the parents or caregivers were contacted to complete the questionnaire either at their homes or during their visit to the health clinic.

2. The community's acceptance of the Intervention was measured using the AIM questionnaire conducted towards the conclusion of the research, and the parents or caregivers were contacted to complete the questionnaire either at their homes or during their visit to the health clinic.

## Overall study start date

01/03/2021

## Completion date

01/04/2023

# Eligibility

## Key inclusion criteria

- 1. Children born from October 2021 to March 2022
- 2. Parents consented to join the study
- 3. Parents living long term at the marginalized settlements of 6 months or more

#### Participant type(s)

Resident

#### Age group

Mixed

#### Lower age limit

0 Days

#### Upper age limit

12 Months

#### Sex

Both

## Target number of participants

470

#### Total final enrolment

470

#### Key exclusion criteria

- 1. Contraindicated towards measles vaccination
- 2. Parents are community volunteers in the village.

#### Date of first enrolment

09/03/2022

#### Date of final enrolment

08/03/2023

## Locations

#### Countries of recruitment

Malaysia

## Study participating centre

#### Kota Kinabalu District Health Office

Aras 4, Blok A, Kompleks Pentadbiran Kerajaan Persekutuan Sabah Jalan UMS Kota Kinabalu Malaysia 88300

# Sponsor information

#### Organisation

Universiti of Malaysia Sabah

#### Sponsor details

Faculty of Medicine and Health Sciences University Malaysia Sabah Jalan UMS Kota Kinabalu Malaysia 88400 +60 88-320 000 phm@ums.edu.my

## Sponsor type

University/education

#### Website

https://www.ums.edu.my/fpsk/

#### ROR

https://ror.org/040v70252

# Funder(s)

## Funder type

Other

#### **Funder Name**

Investigator initiated and funded

# **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

09/03/2025

## Individual participant data (IPD) sharing plan

The datasets generated during and/ or analyzed during the current study will be available upon request from Dr Hazeqa Salleh, zeqa89@yahoo.com

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol file</u>	version 1.0	01/12/2021	16/11/2023	No	No
Results article		12/04/2025	14/04/2025	Yes	No