

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

INTERVENTION TO IMPROVE HYGIENE PRACTICE AMONG PRIMARY CAREGIVERS OF ORANG ASLI (INDIGENOUS) CHILDREN UNDER THREE YEARS OLD IN KUALA LANGAT DISTRICT, SELANGOR

Protocol summary

Study aim

To develop, implement and evaluate the effectiveness of IMB-based intervention on hygiene practice among the primary caregivers of Orang Asli children under three years old in Kuala Langat District.

Design

Single blinded cluster randomized controlled trial (RCT) with pre and post (1 and 3 months) intervention evaluations

Settings and conduct

The study were held at 4 health clinics in Kuala Langat District mainly attended by the Orang Asli (indigenous) population. Only the researcher knew the group allocation (intervention or control). Individuals who were involved in assessing the outcomes (research enumerator) and administration staffs or local healthcare providers were unaware of the group assignment or allocation. Respondents in the intervention group were only aware during the first day of the intervention program.

Participants/Inclusion and exclusion criteria

Inclusion criteria a. Primary caregivers with at least one Orang Asli children aged between 6 months to 3 years old b. Primary caregivers age is more than 18 years old c. Able to understand Malay Language Exclusion criteria Primary caregivers with children who have been diagnosed with any chronic diseases.

Intervention groups

The intervention group received a one day course of Information Motivation Behavioural Skills (IMB) Model based hygiene intervention module which consists of 3 main components: a) Information - health talk related to routes of disease transmission, benefits of good hygiene practice and hygiene practices to prevent diseases; b) Motivation - support group discussion regarding beliefs, barriers and myth related to hygiene behavior; and c) Behavioural skills-practical session focusing on proper

hand washing technique and good hygiene practice in preparing food

Main outcome variables

Improvement of hygiene practice among primary caregivers of Orang Asli children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043296N1**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

liyanatul najwa zakaria

Name of organization / entity

University Putra Malaysia

Country

Malaysia

Phone

+60 3-8705 3873

Email address

liyanatul.zakaria@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-30, 1397/01/10

Expected recruitment end date

2018-10-30, 1397/08/08
Actual recruitment start date
 2018-03-30, 1397/01/10
Actual recruitment end date
 2018-10-30, 1397/08/08
Trial completion date
 2018-10-30, 1397/08/08

Scientific title
 INTERVENTION TO IMPROVE HYGIENE PRACTICE AMONG
 PRIMARY CAREGIVERS OF ORANG ASLI (INDIGENOUS)
 CHILDREN UNDER THREE YEARS OLD IN KUALA LANGAT
 DISTRICT, SELANGOR

Public title
 HYGIENE PRACTICE AMONG PRIMARY CAREGIVERS OF
 INDIGENOUS GROUP

Purpose
 Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Primary caregivers with at least one Orang Asli children
 aged between 6 months to 3 years old Primary
 caregivers age is more than 18 years old Able to
 understand Malay Language
Exclusion criteria:
 Primary caregivers with children who have been
 diagnosed with any chronic diseases.

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **186**
 Actual sample size reached: **166**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Randomization at individual level was not conducted, but
 instead at the cluster level (4 health clinics) by randomly
 allocate the clusters equally into intervention and control
 groups (1:1). All respondents who met the inclusion
 criteria were included in the study. All respondents listed
 from both health clinics and head of village lists were
 contacted and invited to participate in the study during
 their follow up mobile clinic. Four (4) clusters were
 sequentially numbered (number 1 to 4) on a piece of
 paper and kept in a concealed envelope. An independent
 person, the head of staff nurses (Matron) from the
 District Health Office who was not involved in this study
 was asked to carry out the randomization procedure.
 Four numbers were generated using the random
 sequence number generator where each cluster had an
 equal chance to either be in the intervention or control
 group (<http://www.randomiser.org>).

Blinding (investigator's opinion)
 Single blinded

Blinding description
 This is a single blinded study whereby only the
 investigators not the respondents know the which cluster
 receive the intervention or being the control group.

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Research & Ethics Committee (MREC)

Street address

Institut Pengurusan Kesihatan, Jalan Rumah Sakit

City

Kuala Lumpur

Postal code

59000

Approval date

2017-08-03, 1396/05/12

Ethics committee reference number

NMRR-17-1241-26510 (IIR)

Health conditions studied

1

Description of health condition studied

The study is a preventive medicine study to improve
 hygiene practice among primary caregivers of Orang Asli
 (indigenous) children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hygiene practice

Timepoint

1 and 3 months post intervention

Method of measurement

a validated and pre-tested questionnaire by face-to-face
 interviews

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

District Health Office Kuala Langat, Selangor

Full name of responsible person

Dr Wan Ahmad Razmanbin Wan Abdul Salim

Street address

Pejabat Kesihatan Daerah Kuala Langat, Jalan Morib,

City

Kuala Langat

Postal code

42700

Phone

+60 3-3187 2355

Email

pkdkualalangat@moh.gov.my

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University Putra Malaysia

Full name of responsible person

Ass Prof Dr. Azmawani Abd Rahman

Street address

PEJABAT TIMBALAN NAIB CANSELOR (PENYELIDIKAN DAN INOVASI), Jalan Sungai Besi

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Email

tndpi@upm.edu.my

Grant name

GP-IPS

Grant code / Reference number

GP-IPS/2018/9639900

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University Putra Malaysia

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of Putra Malaysia

Full name of responsible person

Liyanatul Najwa Zakaria

Position

Medical Officer

Latest degree

Master

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Putra Malaysia

Full name of responsible person

Ass Prof Halimatus Sakdiah Minhat

Position

Senior Lecturer

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Person responsible for updating data

Contact

Name of organization / entity

University of Putra Malaysia

Full name of responsible person

Liyanatul Najwa Zakaria

Position

Medical Officer

Latest degree

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Other areas of specialty/work

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Effectiveness of IMB based intervention on hygiene practice among primary caregivers of Orang Asli children in Kuala Langat District

When the data will become available and for how long

After the data has been published

To whom data/document is available

people working in public health area

Under which criteria data/document could be used

Data on change of hygiene practice within and between trial groups post intervention will be shared. The request will be reviewed by the correspondence through email.

From where data/document is obtainable

The data can be requested through email to the correspondence Ass Prof Halimatus Sakdiah Minhat via email at halimatus@upm.edu.my

What processes are involved for a request to access data/document

The data can be requested through email to the correspondence of the study which will be replied accordingly.

Comments