

# The efficacy of mother's involvement to comfort infants during immunization

<b>Submission date</b> 17/08/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/03/2020	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims

A diphtheria pertussis tetanus (DPT) immunization often causes trauma in infants because it's done by intramuscular injection.

The aim of this study is to determine the effect of facilitated tucking by mothers combined with sitting up position on the level of pain when infants received DPT immunization

Who can participate?

Infants aged 2-12 months that underwent DPT immunization in Bangetayu Health Center Semarang and their mothers

What does the study involve?

Participants will be randomly allocated to one of three groups: (A) facilitated tucking (making flexion on the infant arm) by mothers (B) facilitated tucking by a health worker (C) sitting up position

What are the possible benefits and risks of participating?

Benefit: alleviate the pain level in infants, make the infants more comfort

Risk: there is no risk in this study

Where is the study run from?

Bangetayu Health Center, Indonesia

When is the study starting and how long is it expected to run for?

August 2018 for one month

Who is funding the study?

Sultan Agung Islamic University

Who is the main contact?

Nopi Nur Khasanah

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# Contact information

## Type(s)

Public

## Contact name

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## Contact details

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

207/A.1/FIK-SA/VII/2018

# Study information

## Scientific Title

Facilitated tucking by mothers compared to facilitated tucking by health worker, facilitated tucking by mothers compared to sitting up position by mothers, facilitated tucking by health worker compared to sitting up position by mothers in the comfort of infants during the intramuscular immunization procedure

## Study objectives

Facilitated tucking is more effective done by mothers then by health worker

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 13/07/2018 Ethics Committee of the Faculty of Nursing, Unissula (Komite Etik Fakultas Ilmu Keperawatan Unissula, Jl. Raya Kaligawe Km. 4 Semarang 50112, Po Box 1054, Indonesia; +62 24 6583584), ref: 207/A.1/FIK-SA/VII/2018

## Study design

Interventional randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**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**

Infant distress during immunization procedure

**Interventions**

Participants are divided into three groups randomly by picking up one of three folded paper (A/B/C, A means that the participants included in group 1; B means that participants included in group 2; C means participants included in the control group).

After random allocation, all participants fill out the questionnaire and for the mothers and the health worker wearing the same clothes as the mother.

Group 1: infants sitting up on the mother's lap and mothers make infant's arm flex then the midwife will give an intramuscular immunization

Group 2: infants sitting up on the health worker lap and health worker make infant's arm flex then the midwife will give an intramuscular immunization

Control group: infants sitting up on the mother's lap then the midwife will give an intramuscular immunization.

Video recorded on each participant roughly 5 minutes and send to a pediatric nurse specialist to observe and rate pain according to the FLACC scale.

Data were analyzed by Kruskal-Wallis test and post hoc Mann-Whitney test.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

Pain level in infants measured using FLACC (face, legs, activity, cry, consolability) scale at the time of immunisation

**Secondary outcome measures**

Infants age

**Overall study start date**

13/07/2018

**Completion date**

19/09/2018

## **Eligibility**

**Key inclusion criteria**

Infants aged 2-12 months that underwent DPT immunization in Bangetayu Health Center Semarang

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

48

**Total final enrolment**

48

**Key exclusion criteria**

Infants with chronic condition

**Date of first enrolment**

08/08/2018

**Date of final enrolment**

29/08/2018

## **Locations**

**Countries of recruitment**

Indonesia

**Study participating centre**

**Bangetayu Health Center**

JL. Bangetayu

Genuk

Semarang

Indonesia

50115

# Sponsor information

## Organisation

Sultan Agung Islamic University

## Sponsor details

Jl Raya Kaligawe km.4

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## Sponsor type

University/education

## Website

<http://www.unissula.ac.id>

## ROR

<https://ror.org/015hejj83>

# Funder(s)

## Funder type

University/education

## Funder Name

Universitas Islam Sultan Agung

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

The datasets generated during and/or analysed during the current study are/will be available upon request from <https://drive.google.com/drive/folders/1QhTTRvVMhkhVXdCzofiPPuWrpyMCc5uE?usp=sharing> (Name: Nopi Nur Khasanah, Email: nopi.khasanah@unissula.ac.id, type of data: video recorded, The data will become available on August 2019 for 2 years, data will be shared by google drive, types of analyses by observational, and the mechanism by FLACC scale, consent from participants was obtained, data was anonymous, no legal restrictions)

## Intention to publish date

18/09/2019

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2019	11/03/2020	Yes	No