

# An intervention to improve the quality of antenatal care in Ermera municipality in Timor-Leste

<b>Submission date</b> 27/05/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/12/2022	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Most maternal and newborn deaths occurred in low- and middle-income countries, and most of these were preventable with appropriate antenatal care, deliveries with skilled birth attendants and postnatal care. These three components are usually referred to as Continuum of Care (CoC), and the effective CoC would reduce preventable child and maternal deaths. However, the increase of CoC is challenging in Timor-Leste, and the inadequate use of health services for pregnant women are the key determinants of maternal deaths. This study aims to assess the effectiveness of the intervention on the quality of care of antenatal care to increase CoC in Ermera municipality in Timor-Leste. Ermera has been selected as the research field due to the poorer coverage of maternal and newborn health services and the higher maternal, fetal and neonatal deaths cases than the other municipalities.

### Who can participate?

The eligible participants are women who have delivered between 1 January 2020 and 31 December 2020 for the baseline period and between 1 June 2022 and 31 October 2022 for the follow-up period.

### What does the study involve?

This study has two interventions. One is the ultrasound scan at least once during the pregnancy. The other is a health promotion card called the CoC card used from pregnancy to postpartum care and the ultrasound in the Guisarudu area. Researchers and the experts developed both interventions before the implementation as part of the project of the Non-profit Organization 'Chikyu-no-Stage (English: Frontline)'. Health units will be allocated to carry out the intervention or to serve as a control (standard practice). The intervention will be used in health units from three municipalities Hatolia, Guisarudu, and Gleno. Health units from the rest of the area: Letefoho, Atsabe, Railaco, and Ermera will serve as controls.

### What are the possible benefits and risks of participating?

Participants may benefit from this study due to the high quality of care. No risks are anticipated.

Where is the study run from?

Department of Community and Global Health, The University of Tokyo (Japan)

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

From April 2020 to November 2022

Who is funding the study?

Investigator-initiated and funded

Who is the main contact?

Kayono Nakajima, kayono714@gmail.com

## Contact information

### Type(s)

Principal Investigator

### Contact name

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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

# Effectiveness of Quality Maternal and Newborn Health Care for Improving Continuum of Care and Maternal Satisfaction in Timor-Leste: A Type 2 Implementation-effectiveness Hybrid Quasi-experimental Trial

## Study objectives

1. The quality of antenatal care in Ermera municipality is likely to influence the uptake of three key maternal and newborn health services
2. The planned intervention (ultrasound and Continuum of Care card) increases the Quality of Care of antenatal care
3. The improved Quality of Care through the intervention affects the uptake of continuity of maternal and newborn health services and maternal satisfaction

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 16/09/2020, Graduate School of Medicine and Faculty of Medicine The University of Tokyo Ethics Committee (7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan; +81-03-5841-0818; ethics@m.u-tokyo.ac.jp), ref: 2020184NI
2. Approved 10/5/2021, the Institute National of Health-Research Ethics & Technical Committee (Rua de Comoro, Dili, Timor-Leste; +671-3331-0099; no email address available), ref: 351/MS-INS/GDE/V/2021

## Study design

Type 2 implementation-effectiveness hybrid quasi-experimental non-randomized trial

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Prevention

## Participant information sheet

See addition file for information sheets in English and Tetun

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

Pregnancy

## Interventions

This study has two interventions. One is the ultrasound implementation during antenatal care, and the other is a health promotion card called the Continuum of Care card. This study developed ultrasound training for health workers and will implement ultrasound scans at least once during the pregnancy for all pregnant women in the intervention area. We also developed the Continuum of Care card with the expert who implemented the Continuum of Care card in

Ghana. It will be used from pregnancy to postpartum care in addition to the ultrasound in the one Community Health Centre covered area. Pregnant women in the control area receive only essential antenatal care.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Continuum of Care completion level from pregnancy to delivery measured using surveys at baseline and at endline

### **Secondary outcome measures**

1. Continuum of Care completion level from pregnancy to postnatal period measured using surveys at baseline and at endline
2. Completion of recommended four antenatal care measured using surveys at baseline and at endline
3. Coverage of institutional delivery measured using surveys at baseline and at endline
4. Quality of Care level (total of 16 points for the essential antenatal care received, a total of 7 points for the health education received, and a total of 18 points for the experience of care) measured using surveys at baseline and at endline
5. Maternal satisfaction level (total 13 points) measured using surveys at baseline and at endline
6. Selected Quality of Care health outcome (perinatal mortality rate, stillbirth rate, maternal mortality rate) measured using surveys at baseline and at endline

### **Overall study start date**

01/04/2020

### **Completion date**

15/11/2022

## **Eligibility**

### **Key inclusion criteria**

1. Pregnant women between 12 and 28 weeks of gestation in April 2022 (delivery between 1 May 2022 and 26 October 2022) for the follow-up data collection and women who delivered between 1 January 2020 and 31 December 2020 for the baseline data collection
2. Aged between 15 and 49 years
3. Living in the Ermera municipality
4. Receiving care at a participating health facility

### **Participant type(s)**

Patient

### **Age group**

Other

### **Sex**

Female

### **Target number of participants**

1,222

**Total final enrolment**

1286

**Key exclusion criteria**

Women who did not receive antenatal care at a health facility

**Date of first enrolment**

01/07/2021

**Date of final enrolment**

10/11/2022

## **Locations**

**Countries of recruitment**

Timor-Leste

**Study participating centre**

**Guisarudu Community Health Centre**

Fatobolo, Hatolia B

Ermera

Timor-Leste

-

**Study participating centre**

**Hatolia Community Health Centre**

Hatolia villa, Hatolia A

Ermera

Timor-Leste

-

**Study participating centre**

**Gleno Community Health Centre**

Gleno, Ermera

Ermera

Timor-Leste

-

## **Sponsor information**

**Organisation**

University of Tokyo

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.ich.m.u-tokyo.ac.jp/en/map.html>

**ROR**

<https://ror.org/057zh3y96>

**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**

01/04/2023

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication.

**IPD sharing plan summary**

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	English language		30/05/2022	No	Yes
<a href="#">Participant information sheet</a>	Tetun language		30/05/2022	No	Yes
<a href="#">Protocol file</a>	version 7	20/04/2022	30/05/2022	No	No
<a href="#">Basic results</a>			19/12/2022	No	No