

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

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

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

Female

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

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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?
Basic results			19/12/2022	No	No
Participant information sheet	English language		30/05/2022	No	Yes
Participant information sheet	Tetun language		30/05/2022	No	Yes
Protocol file	version 7	20/04/2022	30/05/2022	No	No