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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

Registration date
31/05/2022

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 antental 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

Primary study design
Interventional

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

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