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Determinants of delivery service utilisation among women in Ambanja region, Madagascar

Submission date
15/08/2015

Recruitment status
No longer recruiting

Registration date
22/08/2015

Overall study status
Completed

Last Edited
16/02/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Madagascar has a high rate of deaths among women giving birth. It has been shown that giving birth in a health facility, such as a hospital, with a skilled health-care professional can reduce the risk of complications, such as excessive bleeding (haemorrhage) which leads to death of mothers and their newborn babies. In Madagascar, only 44% give birth with a skilled birth attendant, such as a midwife or doctor, present and only 35% of these give birth in a health care facility. mHealth is a system which uses mobile technology, such as mobile phones or personal digital assistants (PDAs) to support healthcare. The PANDA system is part of a mHealth system, which aims to provide complete antenatal care to pregnant women in the Ambanja region of Madagascar, and encourages women to give birth safely with a skilled birth attendant or in a healthcare facility. The aim of this study is to find out whether women who have taken part in the PANDA study have a better knowledge of the dangers of childbirth and if that makes them more likely to give birth in a healthcare facility.

Who can participate?
Women within a year of giving birth, who either have or have not taken part in the PANDA study.

What does the study involve?
Participants are given a questionnaire designed to test their knowledge of the dangers of pregnancy and childbirth, and to find out whether they gave birth in a healthcare facility or with the help of a birth attendant. The questionnaires for women who have taken part in the PANDA study are then compared to the questionnaires for women who have not.

What are the possible benefits and risks of participating?
All women will benefit from a individual educational session about obstetric danger signs for mother and child. There are no notable risks of taking part.

Where is the study run from?
Dispensaries served by the St. Damian Centre (Madagascar)

When is the study starting and how long is it expected to run for?
January 2015 to October 2015

Who is funding the study?
GRSSGO (Switzerland)

Who is the main contact?
Dr Nicole Schmidt

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Determinants of health service utilisation for delivery among women in Ambanja region, Madagascar

Acronym
RENY

Study objectives
Women knowing about obstetric danger signs are more likely to deliver in a health facility.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Commission of the Canton of Geneva, 16/03/2015, ref: 15-023.

Study design
Prospective single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Place of delivery

Interventions
Exploring if women who participated in the PANDA study (study providing antenatal care using a m-Health device) will have an increased knowledge of obstetric danger signs. The PANDA study, approved by the ethical commission of Geneva (CER 14-217), and started in January 2015 at the CMC Saint Damian in the Ambanja region, aims to reach women in remote areas. The Pregnancy And Newborn Diagnostic Assessment (PANDA) is an mHealth system specifically designed for community-Health Workers (CHWs) to reach pregnant women in remote areas, collect information, conduct screening and provide health education. The system, as well as being a promising solution to increase access to antenatal care (ANC), also automatically generates enough data to evaluate its own performance. The main objective is to assess the functionality and acceptance of Panda system for providing ANC in hard to reach areas and to operationalize data monitoring for flagging of high-risk pregnancies." (Extract from the approved protocol CER 14-217). Furthermore, the PANDA includes a short educational part for the women informing them about danger signs during pregnancy as well as for the newborn.
Using a prospective case-control design 136 women of all ages who have given birth in the last 12 months and having been included in the PANDA study will be compared with 136 women with the same criteria but having not participated in the PANDA study. In case of difficulties to recruit 136 women having participated in the PANDA study, it would be also possible to include 100 women as cases and 200 women as controls. Women will be recruited from April to October 2015 and be invited to answer a questionnaire taking approximately 30 minutes.

Intervention Type
Other

Primary outcome measure

Whether women who participated in the PANDA study are more likely to deliver in a health facility measured in the first year postpartum using a questionnaire.

Secondary outcome measures
1. Whether women having participated in the PANDA study have and increased knowledge of danger signs measured in the first year postpartum using a questionnaire.
2. Whether women with an increased knowledge of danger signs are more likely to give birth in a health facility measured in the first year postpartum using a questionnaire.

Overall study start date
01/01/2015

Completion date
31/10/2015

Eligibility

Key inclusion criteria
1. Women within a year of giving birth
2. Women who have participated in the PANDA study (cases)
OR
3. Women who have not participated in the PANDA study (controls)

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
136 women of all ages who have given birth in the last 12 months and having been included in the PANDA study will be compared with 136 women with the same criteria but having not participated in the PANDA study. In case of difficulties to recruit 136 women having participated in the PANDA study, it would be also possible to include 100 women as cases and 200 women as controls.

Key exclusion criteria
N/A

Date of first enrolment
01/04/2015

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
Madagascar

Study participating centre
Dispensaries served by the St. Damian Centre, Ambanja, Madagascar
Centre Medico-Chirurgical St-Damien
Ambanja
Madagascar
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Sponsor information

Organisation
University Hospitals of Geneva, Department of Obstetric and Gynaecology

Sponsor details
Boulevard de la Cluse 30
Geneva
Switzerland
1205

Sponsor type
Hospital/treatment centre

Website
http://www.hug-ge.ch/gynecologie-obstetrique

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Research organisation

Funder Name
GRSSGO (Gynaecology and Obstetric Society of the French Part of Switzerland)

Results and Publications

Publication and dissemination plan
Intention to publish the results (primary and secondary objective) of the study.

Intention to publish date
28/02/2016

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?
Results article	results	05/02/2018		Yes	No