

# Safe motherhood in cultural safety: the impact of supporting traditional midwifery and intercultural dialogue in indigenous peoples in Guerrero State, Mexico

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| <b>Submission date</b><br>16/11/2016   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>06/12/2016 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>27/10/2022       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Indigenous people in the Sierra Madre in Guerrero State (south of Mexico) suffer higher rates of maternal deaths and diseases than the general population. Although these communities have authentic traditional midwives (ATMs) who are actively involved in the birthing culture of women in these communities, evidence about their role is scarce and weak. Western obstetric service in these territories is low quality, mainly because of underinvestment, and in part because it does not take into account the traditional culture of the communities. The aim of this study is to measure the impact on maternal health of strengthening authentic traditional midwifery and promoting intercultural dialogue between midwives and Western practitioners.

### Who can participate?

This study involves 80 indigenous communities with about 8000 households. Women who give birth or become pregnant during the study period and their adult family members are included. Authentic traditional midwives identified by the community constitute another group of participants. A group of 20 intercultural brokers are also part of the study.

### What does the study involve?

40 of the participating communities are randomly selected to receive the intervention, which consists of basic material support for ATMs, support for one apprentice for each ATM, informing public health staff to improve their understanding and attitudes toward ATMs, and training and supporting a group of intercultural brokers to support the role of ATM, and foster coordination between Western health services and communities. The other 40 communities do not receive any additional action from the study. A follow-up survey is conducted in 2017 in both groups to measure factors such as the attendance of midwives at births and the number of maternal and newborn deaths.

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

Strengthening traditional healthcare practices can lead to better maternal health outcomes for

at least three reasons: it promotes a better use of local resources owned by communities; health actions are tailored to the local features of the communities by taking into account the culture of the people and the environmental characteristics of the territory; and fostering interaction between ATMs and Western health services increases cultural awareness in obstetric care and makes it culturally safe. A previous study suggested that the midwives are as effective as the official Western health service in terms of birth problems. Based on previous observations, no negative side effects are expected as a result of the strategy.

Where is the study run from?

The Tropical Disease Research Centre from the University of Guerrero runs the study in 80 communities representing four indigenous groups in four municipalities (Me pahaa and Náhua in Atlixnac, Na Savi in San Luis Acatlan, Me Pahaa in Acatepec, and Nancue Ñomndaa in Xichistlahuaca). The Department of Family Medicine of McGill University (Canada) and the Centre for Intercultural Medical Studies (Colombia) are also involved.

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

May 2013 to February 2017

Who is funding the study?

The National Council of Science and Technology of Mexico (CONACYT)

Who is the main contact?

Mr Ivan Sarmiento

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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Protocol serial number

BMx2

# Study information

## Scientific Title

Safe motherhood in cultural safety: the impact of supporting traditional midwifery and intercultural dialogue in indigenous peoples in Guerrero State, Mexico. A cluster-randomised controlled trial

## Acronym

BMX2

## Study objectives

1. Recovery and strengthening of health care traditions have a positive impact on indigenous people's health
2. Recovery and strengthening the traditional role of midwives is a necessary condition for the safety of the indigenous birth culture
3. Traditional birth practices have some advantages over common biomedical practices for the physical and mental health of both the mother and the newborn in indigenous settings
4. The transmission of traditional midwifery skills from generation to generation involves knowledge and practices that are sacred to the culture and best conveyed through a process of apprenticeship
5. Once their role and authority are stabilised, traditional midwives can engage in an intercultural dialogue with Western Medicine in order to adapt biomedical perspectives and technologies
6. Culturally safe interventions require taking into account the cultural and environmental needs of communities through intercultural dialogue
7. Intercultural dialogue between traditional medicine and Western medicine can be fostered by training local leaders as brokers in this process

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Ethics Committee of the CIET Tropical Disease Research Centre (University of Guerrero), 22/10/2013, ref: 2013-014
2. The project was approved by community assemblies representing the indigenous peoples involved in the trial between January and February 2015
3. Research Ethics Office of McGill University, 12/06/2017, ref: A06-B28-17B

## Study design

Cluster-randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Other

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

Maternal and neonatal mortality, pregnancy and birth problems

## **Interventions**

The concern is the real-life effect of supporting authentic traditional midwives and fostering intercultural dialogue through a group of intercultural brokers in four indigenous groups of four municipalities in Guerrero State.

Among a sample of 80 clusters representative for the four municipalities, the intervention is assigned to 40 randomly selected clusters (10 clusters by each municipality), the remaining 40 clusters received usual care. Indigenous peoples and municipalities included are: Me pahaa and Náhua in Atlixac, Na Savi in San Luis Acatlan, Me Pahaa in Acatepec, and Nancue Ñomndaa in Xichistlahuaca.

The intervention, based on discussions with traditional midwives, includes:

1. Supply basic material support for ATM in order to strength their practice and foster the relay of their profession (one ATM for each community)
2. Support for an apprentice for each midwife
3. Inform public health staff to improve understanding and attitudes toward midwives
4. Training and support a group of intercultural brokers to support the role of the midwives, and foster coordination between Western health services and communities

The training of intercultural brokers was concluded on June 2016, and support for traditional midwives started on 01/07/2015. The intervention will remain active until the end of the project. In February 2017 a final follow-up survey will be conducted.

## **Intervention Type**

Other

## **Primary outcome(s)**

The 2017 follow-up survey will measure the following indicators from the 2015 baseline survey among women who gave birth during the past year:

1. Maternal deaths
2. Neonatal deaths
3. Number of times women seen by midwife during pregnancy
4. Proportion of births at home attended by midwives
5. Frequency of recourse to midwife in case of pregnancy complications
6. Frequency of recourse to midwife in case of complications with newborns
7. Proportion of women intending to have future births at home
8. Infection postpartum
9. Cost of birthing
10. Among women who gave birth in health institutions, questions about their treatment including birth position, availability of translators, presence of family members at birth, presence of midwife at birth, bathing in cold water, treatment of the placenta, retention of amulets and how respectful they considered their treatment to have been

## **Key secondary outcome(s)**

Secondary outcomes will also be measured in the 2017 follow-up survey:

1. From a survey of women who gave birth in previous year:
  - 1.1. Prevalence of violent acts toward pregnant women
  - 1.2. Proportion of births without external assistance
2. From survey of husbands, mothers and mothers-in-law:
  - 2.1. Opinion as to whom the woman should consult first when she learns she is pregnant
  - 2.2. Opinion as to who should attend the woman first if she has complications during pregnancy

2.3. Opinion as to who should decide whether to take the woman to the hospital if there are complications during childbirth  
2.4. Perception of neighbours' preferences as to who should provide antenatal care  
2.5. Perception of neighbours' preferences as to home vs institutional birth  
A mid-course evaluation using the technique of Most Significant Change with local stakeholders will inform about additional secondary outcomes regarding maternal health and cultural safety.

**Completion date**

31/05/2017

## Eligibility

**Key inclusion criteria**

1. Authentic traditional midwives identified by the community
2. All women in the baseline sample clusters who give birth or become pregnant during the trial period
3. All adult family members of the above
4. All families of the baseline sample communities where pregnancies or births occur during the trial period
5. Twenty intercultural brokers certified by the University of Guerrero

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

872

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/02/2015

**Date of final enrolment**

31/01/2016

## Locations

**Countries of recruitment**

Canada

Colombia

Mexico

**Study participating centre**

**University of Guerrero**

CIET Tropical Disease Research Centre

Calle Pino s/n

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**Study participating centre**

**McGill University**

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**Study participating centre**

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## **Sponsor information**

**Organisation**

University of Guerrero

**ROR**

<https://ror.org/054tbkd46>

## **Funder(s)**

**Funder type**

Government

### Funder Name

Consejo Nacional de Ciencia y Tecnología

### Alternative Name(s)

Consejo Nacional de Humanidades, Ciencias y Tecnologías, Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

Mexico

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during or analysed during the current study will be available upon request from CIET at the Universidad Autonoma de Guerrero. Before the information can be shared, the requester will need to present a plan for data analysis. Also, the requester will need to complete the procedure for ethical approval of the secondary analysis in accordance with the procedures defined by the Ethics Board of the University Autonoma de Guerrero and the agreements with communities to ensure the protection of the participants.

### 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>               |                               | 17/01/2022   | 27/10/2022 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol                      | 04/07/2018   | 27/11/2020 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |