

Neonatal survival, cultural safety and traditional midwifery in indigenous communities of Guerrero State, Mexico

Submission date 28/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 24/07/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/07/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Neonatal survival, cultural safety and traditional midwifery in indigenous communities of Guerrero State, Mexico: a cluster-randomised controlled trial

Acronym

BMx

Study objectives

1. Recovery and strengthening of traditional Amuzgo culture is important for the physical and mental health of Amuzgo people in the Mexican State of Guerrero
2. Recovery and strengthening of the traditional role of the midwife is a necessary condition for the safety of the Amuzgo 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
4. Birth attendant training conducted by biomedical practitioners, however respectful and sensitive, is inherently culturally unsafe
5. 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
6. Once their role and authority is stabilised, traditional midwives are more likely to adapt biomedical perspectives and technologies that they see, on the basis of evidence, to be helpful to the fulfilment of their roles

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Comisario Ejidal (representing the Amuzgo communities of Xochistlahuaca) approved on 5 March 2009
2. Ethics Committee of the CIET Tropical Disease Research Centre, University of Guerrero with indigenous participation, approved on 2 March 2009
3. CIETcanada Research Ethics Board approved on 7 December 2008

Study design

Single-centre cluster-randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

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

Maternal, perinatal and neonatal health

Interventions

The following interventions to be carried out immediately in three randomly selected geographic areas of the municipality and, after the two-year trial period, in the remaining three areas:

1. Material support for each of the identified midwives in intervention areas to create or maintain a "school" of disciples or apprentices whom they will assist to pursue a vocation to midwifery
2. Support from indigenous health promoters in intervention areas to midwives, pregnant women and newborns consisting of:
 - 2.1. Surveillance of pregnancies
 - 2.2. Organisation of pregnant mothers' groups
 - 2.3. Liaison with nearest health centre
 - 2.4. Facilitation of contacts between pregnant women, midwives and health centres
 - 2.5. Organisation of transport in obstetric and neonatal emergencies
 - 2.6. Early postnatal visits to weigh newborns and check on their health status
3. Pregnant women's groups for mutual support in intervention areas
4. Organisation of existing public transport for response during obstetric and neonatal emergencies based on reimbursement for fuel costs through voucher provided by indigenous health promoter

The following interventions will be carried out immediately in the entire municipality and in the nearby regional hospital:

1. Updated training of hospital and health centre staff in obstetrics and neonatal care
2. Intercultural training of hospital and health centre staff
3. Training of translators at hospitals and health centres
4. Provision of residential space for family members who accompany indigenous mothers to regional hospital in Ometepec
5. Revision of norms and guidelines for responding to obstetric and neonatal emergencies among the indigenous population

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The 2011 follow-up survey will measure the following indicators from the 2008 baseline survey among women who gave birth during the previous three years:

1. Neonatal deaths
2. Number of times women seen by midwife during pregnancy
3. Proportion of births at home attended by midwives
4. Frequency of recourse to midwife in case of pregnancy complications
5. Frequency of recourse to midwife in case of complications with newborns

6. Proportion of women intending to have future births at home
7. 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

Secondary outcome measures

1. From survey of women who gave birth in previous three years:
 - 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
3. From survey of health workers:
 - 3.1. Consistency of criteria for classifying levels of pregnancy risk and referral of high risk pregnancies, complicated births and neonatal emergencies
 - 3.2. Willingness to allow midwives to participate in institutional births and to charge for it
 - 3.3. Proportion of workers who have received any intercultural training

All secondary outcomes will be followed-up for three years.

Overall study start date

01/04/2009

Completion date

01/04/2011

Eligibility

Key inclusion criteria

The following have been randomised into three geographic areas for immediate intervention and three for delayed intervention:

1. Twenty midwives identified by the baseline survey as having assisted at three or more births in the previous 3 years
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. Community health managers (gestores) certified by the Red de Promotores de Salud Indigenas Amuzgos, A.C. (Indigenous Amuzgo Health Promoters Network)
6. Medical personnel and support staff of health centres and hospitals serving the municipality of Xochistlahuaca

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

20 midwives; 30 - 40 mothers; 1,500 community members

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2009

Date of final enrolment

01/04/2011

Locations

Countries of recruitment

Mexico

Study participating centre

CIET Tropical Disease Research Centre

Acapulco

Mexico

80001

Sponsor information

Organisation

CIET Tropical Disease Research Centre (Mexico)

Sponsor details

Calle Pino

Acapulco

Mexico

80001

Sponsor type

Research organisation

Website

<http://www.ciet.org>

ROR

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

Funder(s)**Funder type**

Other

Funder Name

Anonymous foundation (Switzerland)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration