

# Community health and medical provision: impact on neonates

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>07/02/2007   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>20/03/2007 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>06/07/2017       | <b>Condition category</b><br>Neonatal Diseases    | <input type="checkbox"/> Individual participant data                                              |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
Version 1.0, 05/02/07

## Study information

**Scientific Title**

## Community Health And Medical Provision: Impact On Neonates (CHAMPION)

### Acronym

CHAMPION

### Study objectives

Neonatal mortality rates in India are high compared to other low income countries, and there is a wide variation of rates across regions. One area with a particularly high rate is Mahabubnagar District in the state of Andhra Pradesh, where neonatal mortality is estimated to be in the region of 4-9%. The area suffers from a vicious cycle of both poor supply of and small demand for health care services.

Neonatal mortality can be reduced through systemic changes to the provision and promotion of health care.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Institutional Review Board of the L.V. Prasad Eye Institute, Hyderabad, India, ref: LEC07002 - approval pending

### Primary study design

Interventional

### Study design

Unblinded cluster-randomised controlled trial

### Study type(s)

Treatment

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

Neonatal mortality

### Interventions

Unblinded cluster-randomised controlled trial involving 464 villages, with the village as the unit of randomisation

A multi-level program: community health promotion and contracting out primary and secondary health services to non-public providers. The health promotion campaign will include a health education campaign, participatory discussion groups, training of village health workers and midwives, and improved coordination of antenatal services. These services will be provided for free to pregnant women and neonates in the intervention communities. The intervention group will also have subsidised access to primary and secondary pregnancy-related health care services at non-public health centres.

### Intervention Type

Other

### Phase

Not Applicable

**Primary outcome(s)**

Neonatal mortality

**Key secondary outcome(s)**

1. Neonatal death
2. Neonatal morbidity
3. Maternal mortality and morbidity
4. Health service usage
5. Costs and several process
6. Knowledge outcomes

**Completion date**

01/01/2011

**Eligibility****Key inclusion criteria**

The trial site is the Nagarkurnool division of Mahabubnagar district in the Indian state of Andhra Pradesh. The trial will involve only those villages in the division with a population of less than 2,500 people. A woman is eligible for inclusion in the trial if she satisfies the following criteria: she is married, less than 50 years old, and resident in one of the 464 villages at the time of a baseline survey that is to be carried out immediately prior to randomization. Once the baseline survey has been carried out and the eligible women listed, the only permitted addition to the trial will be those women who marry into a trial village. Women will not be added or removed from the list as a result of either temporary or permanent migration from the village in which they are initially registered.

Only those children of eligible women whose estimated date of delivery at enumeration is at least six months after randomization will be included in the trial. As training and establishment of services in intervention villages will require time to be achieved, this lag in measurement is necessary to ensure exposure to the intervention.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

Women and their children will be excluded from the trial if the woman in question is unmarried, if she is aged 50 or over at the time of the baseline survey or if she refuses to participate in the baseline survey.

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

01/01/2011

## **Locations**

**Countries of recruitment**

United Kingdom

England

India

**Study participating centre**

**Effective Intervention**

London

United Kingdom

WC2A 2AE

## **Sponsor information**

**Organisation**

Effective Intervention (UK)

**ROR**

<https://ror.org/00a1wp308>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Effective Intervention in the Centre for Economic Performance at the London School of Economics (UK registered charity no. 1111709) (UK)

**Funder Name**

The Naandi Foundation (India trust registration number 1745/98) (India)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 05/07/2017   |            | Yes            | No              |