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# The EPICS Trial: Enabling Parents to Increase Child Survival

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 13/05/2009 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 09/06/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/05/2016 | Other | |

**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**
1000

## Study information

**Scientific Title**
The EPICS Trial: Enabling Parents to Increase Child Survival - a cluster randomised controlled trial

**Acronym**
EPICS

## Study objectives
The aim of the trial is to assess whether an intervention package that includes community health promotion campaign and education through health clubs, intensive training and mentoring of village health workers to diagnose and provide first-line treatment for children's diseases within the community, and improved outreach services can generate a rapid and cost-effective reduction in under-five child mortality in rural regions of Guinea-Bissau.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Ministry of Health, Bissau, Guinea-Bissau, 13/06/2007, ref: 021/2007
2. London School of Hygiene and Tropical Medicine, UK, 03/10/2007, ref: 5173

## Study design
Cluster randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Prevention

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

## Interventions
This is a cluster randomised controlled trial involving 146 clusters. The trial will run for 2.5 years.

Intervention group: community health clubs, trained village health workers, community provision of medicines, and mobile clinics
Control group: standard care

Intervention personnel will assist anyone in Emergencies. Controls will benefit from the training of health staff at clinics.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
The proportion of children that die during the study period. Outcomes assessed until 1st October 2010.

## Key secondary outcome(s))
1. Neonatal, infant and maternal mortality rates
2. Age at and cause of child deaths
3. Treatment practices for sick children
4. Mother's or primary carer's health knowledge

5. Deliveries conducted at institutions or with a trained assistant
6. Indicators of safe birthing practices

Outcomes assessed until 01/10/2010.

### Completion date
01/10/2010

## Eligibility

### Key inclusion criteria
146 clusters were chosen in Quinara and Tombali.

Inclusion criteria for mothers:
Women enumerated during a baseline survey aged between 12 and 49 years

Inclusion criteria for children:
1. Both males and females, five years of age or younger
2. Children born after randomisation, or born after the baseline survey
3. Alive at the time of randomisation

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Sex
All

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
01/09/2007

### Date of final enrolment
01/10/2010

## Locations

### Countries of recruitment
United Kingdom

England

Guinea-Bissau

**Study participating centre**
**London School of Economics**
London
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# Sponsor information

**Organisation**
Effective Intervention (UK)

**ROR**
https://ror.org/00a1wp308

# Funder(s)

**Funder type**
Charity

**Funder Name**
Effective Intervention (UK)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 02/09/2011 | | Yes | No |
| Results article | results | 01/05/2016 | | Yes | No |
| Protocol article | protocol | 03/08/2009 | | Yes | No |