

The EPICS Trial: Enabling Parents to Increase Child Survival

Submission date 13/05/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 09/06/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/05/2016	Condition category Other	☐ 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
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
United Kingdom
W2 1SP

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