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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

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
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 measure
The proportion of children that die during the study period. Outcomes assessed until 1st October 2010.

Secondary outcome measures
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.

Overall study start date
01/09/2007

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

Age group
Child

Sex
Both

Target number of participants
11,400 children and their mothers

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
England

Guinea-Bissau

United Kingdom

Study participating centre
London School of Economics
London
United Kingdom
W2 1SP

Sponsor information

Organisation
Effective Intervention (UK)

Sponsor details
c/o Dr Peter Boone
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Houghton Street
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Sponsor type
Charity

Website
http://www.effint.org/

ROR

https://ror.org/00a1wp308

Funder(s)

Funder type
Charity

Funder Name
Effective Intervention (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/08/2009		Yes	No
Results article	results	02/09/2011		Yes	No
Results article	results	01/05/2016		Yes	No