

Emotional stimulation as a cost-effective addition to emergency food intervention for malnutrition in a low income country

Submission date 31/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/11/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

East Africa is suffering from devastating droughts and, in Ethiopia, it is estimated that there are 652,000 malnourished children under the age of five in need of emergency food. Malnutrition prevents a child from developing normally and can often lead to death. It also has a negative effect on the relationship between a parent and child. We know that parental support of a child, such as playing with toys with them, has a positive effect on a child's development. However, in many developing countries only 10-40% of parents give stimulating materials such as toys to their child. Also, for varying reasons many parents don't play with their children. We aim to improve this situation by using a simple intervention called Emotional Stimulation (ES). ES was developed by Play Therapy Africa to help mothers reconnect more fully with their malnourished child. Parents learn simple activities such as games that they can play with their children. In this study, youths and Health Extension Workers (HEW) who staff Health Posts attended by parents of malnourished children will be trained to teach parents ES and Nutritional Education (NE). NE teaches parents important information about their children, such as dietary needs and hygiene. Either ES or NE will be taught to parents alongside the provision of emergency food. The aim of this study is to see whether ES is better than NE at helping children to recover from malnutrition in Ethiopia.

Who can participate?

Children with severe acute malnutrition.

What does the study involve?

Health Posts (intervention sites) are randomly put into one of two groups and patients will receive either ES or NE depending on which Health Post they attend. Health Posts are staffed by a HEW and youths trained to give ES or NE to parents and/or caregivers. Each family participating in the study receives 12 weeks treatment with either ES or NE.

What are the possible benefits and risks of participating?

This study may benefit participants by improving nutrition and family bonding. The results will also be used to see whether ES could be used in the wider populations in East Africa that are severely affected by drought.

Where is the study run from?

Play Therapy Africa (Ethiopia)

When is the study starting and how long is it expected to run for?

February 2012 to August 2012

Who is funding the study?

Pulitzer Foundation (UK)

Who is the main contact?

Prof P Fonagy

p.fonagy@ucl.ac.uk

Contact information

Type(s)

Public

Contact name

Prof Peter Fonagy

Contact details

1-19 Torrington Place

London

United Kingdom

WC1E 7HB

+44 (0) 20 7679 1943

p.fonagy@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Emotional stimulation as a cost-effective addition to emergency food intervention for malnutrition in a low income country: a randomised controlled trial

Study objectives

An Emotional Stimulation (ES) designed to improve mother-child interaction will lead to a greater increase in weight gain in severely malnourished children than Nutritional Education (NE) alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. University College London Research Ethics Committee, 15/09/2011, ref: 3325/001
2. Federal Democratic Republic of Ethiopia Ministry of Science and Technology Ethics Review Committee, 15/11/2011, ref: 310/510/04

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Severe acute malnutrition

Interventions

1. Emotional Stimulation (ES): a brief, structured, intense psychosocial bonding exercise taught to participating mothers
2. Nutritional Education (NE): participating mothers are given information about the link between good nutrition and health based on the Ethiopian Government's information pack drawn up to support mothers with malnourished infants and young children

Intervention Type

Behavioural

Primary outcome measure

1. Body Mass Index (BMI) of infants measured by health extension workers who will record height and weight measurements at weekly intervals for 12 weeks

Secondary outcome measures

Secondary measures will be collected by data collectors at baseline and at 4, 6, 8 and 12 weeks until discharge:

1. Ages and Stages Questionnaire
2. General Health Questionnaire
3. Pearlin and Schoolers' seven-item scale
4. Global Rating Scale
5. Coding Interactive Behaviour Scale
6. Quality of interaction between parent and child (Ainsworth Sensitivity Coding Scale)
7. Parents' perception of the child (qualitative interview)
8. The Bayley Scales will be administered to a sub-sample of randomly identified cases by a supervisor trained in the assessment of infants

Overall study start date

01/02/2012

Completion date

31/08/2012

Eligibility

Key inclusion criteria

1. Age between 6 months and 5 years
2. Severe acute malnutrition defined as 3 SD below WHO published norms of height or forearm skin-fold thickness less than 110mm
3. Pass appetite test
4. Sufficient family involvement to ensure intervention

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

5 Years

Sex

Both

Target number of participants

432

Key exclusion criteria

1. Serious medical complications requiring referral for inpatient treatment
2. Clinically apparent congenital abnormality
3. Preterm birth (<37 weeks gestation) or birth weight > 2SD below weight/gestation limit

Date of first enrolment

01/02/2012

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

Ethiopia

Study participating centre

Play Therapy Africa

Ethiopia

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Sponsor information

Organisation

University College London

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

+44 (0) 20 7679 2000

gradweb@ucl.ac.uk

Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Results and Publications

Publication and dissemination plan

We plan to publish two papers. We hope that papers will appear about the major findings and the follow up in 2016-7. The intended journals are primarily general medical journals given the relevance of the research to the care of malnourished infants.

2016 results in theses: <https://ueaeprints.uea.ac.uk/id/eprint/62988/1/EKnightDCLINPSYfinal.pdf> and <https://discovery.ucl.ac.uk/id/eprint/1532876/>

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other