Evaluating the impact of a community-based intervention using womens groups (WG) to improve communication in Kenyan children with disabilities

Submission date 10/07/2013	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 17/10/2013	Overall study status Completed	 Statistical analysis plan Results
Last Edited 23/10/2019	Condition category Mental and Behavioural Disorders	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

Studies suggest that over 40% of children with disabilities in resource-poor countries have a communication disability. This forms one of the largest sub-groups of disablement, an estimated 2.5% of a total population. Services and support for this population group are almost non-existent in these settings. This study evaluates the impact of a community-based intervention by womens groups (WG), to improve communication and quality of life. The intervention has been developed through a participatory process with WG in Kenya, and also draws on information collected in Uganda and Zimbabwe. The aim is to improve the communication skills and quality of life of children with communication disabilities.

Who can participate?

Active WGs in Kilifi, Kenya will be identified, in an area where a neurological survey has identified children (aged 6-9 years) with communication impairment.

What does the study involve?

These WG will be randomly allocated to one of two groups: an intervention to promote communication in children with disabilities or no intervention at all. The study interacted with existing womens groups and developed skills and awareness about how they could improve the communication skills and quality of life of children with communication disabilities in their community. The intervention encouraged and facilitated participation in everyday activities, sensitised the community, and promoted attendance at school.

What are the possible benefits and risks of participating?

The risk to participants was limited to issues of confidentiality about their impairment status. The successful aspects of the intervention will be identified and used to suggest future interventions and research studies. If the strategy of using WG as agents of change is successful, it can be used as part of Community-based Rehabilitation strategies in other areas of Kenya and in other African countries. Where is the study run from? There was only one centre which is the Centre for Geographical Medicine (Coast), Kilifi Kenya.

When is study starting and how long is it expected to run for? The study took place between 2002 and 2003, with 9 months to deliver the intervention.

Who is funding the study? The project was funded by the Department for International Development and the Wellcome Trust (UK).

Who is the main contact? Professor Charles Newton charles.newton@psych.ox.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Charles Newton

Contact details University of Oxford Dept of Psychiatry Warneford Hospital Oxford United Kingdom OX37JX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

A cluster randomised trial educating womens groups (WG) to improve the communication and quality of life in Kenyan children with disabilities

Study objectives

Womens groups (WG) can improve the communication of children with disabilities by acting as agents of change.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the National Ethical Review Committee of Kenya on 7th March 2002 (KEMRI Scientific Steering Committee No 673)

Study design Cluster randomised trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request information given to the women's groups and patients and their families.

Health condition(s) or problem(s) studied

Communication impairment; Disabilities

Interventions

Random selection of 8 Women's Groups (out of 50 in the area) to participate in the training & intervention & cover 50% of children who had been identified with a communication problem.

These WG will be randomised to receive an intervention to promote communication in children with disabilities, or no intervention at all.

An intervention will be carried out with women from local womens groups (WG) aimed at promoting the development of communication ability through the introduction of simple strategies. These strategies include:

- 1. Raising awareness concerning communication disabilities
- 2. Raising awareness to their potential role in supporting this group of children and their families
- 3. Inclusion of children with communication disability in everyday activities.
- 4. Respite strategies for carers
- 5. Increased opportunity for experiences and communication

Intervention was completed at 9 months. The total duration was 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Improved communication as measured by the Communication Disability Profile, which uses a multi-dimensional theoretical framework, reflecting the new WHO classifications of disablement and a communication disability model based on identification of needs.

Measurements were taken at baseline and at 12 months. Intervention was completed at 9 months.

Secondary outcome measures

Quality of life (QOL) as measured by a locally developed tool, which was based on qualitative data collected from the same 16 Mothers and community groups and the QOL measurement tool for assessing adults in developing countries was also used to inform the development of this questionnaire.

Measurements were taken at baseline and at 12 months. Intervention was completed at 9 months.

Overall study start date

01/07/2002

Completion date

20/12/2003

Eligibility

Key inclusion criteria

 Women's groups (WG) who work in an area in whom children aged 6-9 years of age were identified with communication impairment. The WG had to agree to participate.
 The parents of the children identified with communication impairment gave consent and the the children who reside in the areas where the active WG are located.

Participant type(s) Patient

Age group Child

Lower age limit 6 Years

Upper age limit 9 Years

Sex

Both

Target number of participants 306 children

Key exclusion criteria

1. Women's groups (WG) not active

- 2. Children whose parents refuse consent
- 3. Children whose parents give a negative response to the identification questions.
- 4. Children who do not reside in the area where the active WG are located

Date of first enrolment 01/07/2002

Date of final enrolment 20/12/2003

Locations

Countries of recruitment England

Kenya

United Kingdom

Study participating centre University of Oxford Dept of Psychiatry Oxford United Kingdom OX37JX

Sponsor information

Organisation University of East Anglia (UK)

Sponsor details School of Rehabilitation

Norwich Research Park Norwich England United Kingdom NR4 7TJ

Sponsor type University/education

Website http://www.uea.ac.uk ROR https://ror.org/026k5mg93

Funder(s)

Funder type Charity

Funder Name Department for International Development (DFID) (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