Effectiveness of nutrition training for mid-level providers (MLPs) on feeding practices and nutrition status of HIV-positive children in Tanga, Tanzania

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
09/01/2013		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/02/2013	Completed	[X] Results		
Last Edited 06/04/2017	Condition category Infections and Infestations	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Tanzania is one of the countries devastated by dual burden of HIV/AIDS and child undernutrition. About 5.7 % of the general population in Tanzania is living with HIV/AIDS. Meanwhile, 47.8% of children suffer from stunting (reduction in growth rate), or a chronic form of undernutrition. Even under the treatment with antiretroviral therapy, undernutrition rates among HIV-positive children remains high. The country also suffers from a human resource for health crisis: it has a small number of qualified medical personnel. The doctor to patient ratio remains at 1:30,000. Therefore, less qualified health workers including mid-level providers (MLPs) are left to give health care to patients with high burden, especially in rural and suburban areas. These health workers are trained to treat only limited number of ailments and perform specific and less complex surgical procedures. They may not possess adequate skills to manage patients with complex health problems including HIV-positive children suffering from severe undernutrition. Previous studies have reported improvements on child undernutrition when the trained health providers give nutrition counseling to their caregivers. In Tanzania too, nutrition training for MLPs may improve their nutrition knowledge, counseling, and management skills of undernutrition among HIV-positive children. Successful transfer and translation of nutrition knowledge to caregivers through counseling and treatment may have a positive impact on HIVpositive childrens feeding practices and nutrition status. The aim of this study is therefore to examine the effectiveness of nutrition training of MLPs on feeding practices and nutrition status of HIV-positive children attending Care and Treatment Centers (CTCs) in Tanga, Tanzania.

Who can participate?

Mid-level providers working in CTC facilities for HIV/AIDS and pairs of mothers and their HIV-positive children attending such facilities in Tanga, Tanzania.

What does study involve?

Eight Care and Treatment Centers (CTCs) are randomly allocated to either the intervention or the control group. The nutrition training intervention is given to 16 MLPs in the intervention

group. The training makes use of the specific local determinants of undernutrition. The trained MLPs provide the tailored nutrition counseling and nutrition follow up to caregivers of HIV-positive children attending the selected CTCs. The total of 400 pairs of caregivers and underfive children are assigned and followed up at the intervention group. Similar number and method are repeated for control group.

What are the possible benefits and risks of participating?

MLPs will have improved knowledge in nutrition, management of undernutrition, and counseling skills for caregivers of children at risk of undernutrition using a tailored approach. HIV-positive children with undernutrition will have better feeding patterns and nutrition status and may be sustained. There is no foreseen risk for participating in this study.

Where is the study run from?

The University of Tokyo, Japan in Collaboration with Dar es Salaam based Muhimbili University of Health and Allied Sciences and School of Public Health University of Massachusetts.

When is the study starting and how long is it expected to run for? July 2013 to July 2014

Who is funding the study?

- 1. The University of Tokyo (Japan)
- 2. Muhimbili University of Health and Allied Sciences (Tanzania)

Who is the main contact? Masamine Jimba mjimba@m.u-tokyo.ac.jp

Contact information

Type(s)

Scientific

Contact name

Prof Masamine Jimba

Contact details

University of Tokyo Graduate School of Medicine, Department of Community and Global Health 7-3-1 Hongo, Bunkyo-ku Tokyo Japan 113-0033 +81 (0)3 5841 3697 mjimba@m.u-tokyo.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Effectiveness of nutrition training for mid-level providers (MLPs) on feeding practices and nutrition status of HIV-positive children in Tanga, Tanzania: a cluster randomized control trial

Study objectives

Undernutrition among Human Immune-Deficiency Virus (HIV)-positive children can be controlled if qualified medical personnel counsel caregivers frequently. Such counseling may be beneficial if they focus on local determinants of undernutrition and specific feeding patterns of locally available foods. However, the number of qualified medical personnel is limited especially in Human Resource for Health (HRH) crisis country like Tanzania. Nutrition training of the available mid-level providers (MLPs) mostly found in rural and suburban areas can help to provide such nutrition counseling. Trained MLPs may improve their own nutrition knowledge, management skills of child undernutrition, nutrition monitoring, and counseling skills for mothers of HIV-positive children attending their centers. Counseled mothers will improve feeding practices of their children. This includes feeding frequency, quality and quantity of diet consumed, and dietary diversity. Secondarily, HIV-positive children may have improved nutrition status, anti-retroviral therapy (ART) profile including adherence, CD4 counts, viral load, and general welfare.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Research Ethics Committee of the Graduate School of Medicine of the University of Tokyo, ref: 1007-(1)
- 2. Research Ethics Committee of Muhimbili University of Health and Allied Sciences in Tanzania, 11/02/2013, ref: MU/DRP/AEC/Vol.XVI/88

Study design

Cluster randomized control trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Child nutrition/HIV/AIDS

Interventions

In-service training will be conducted on prevention, diagnosing, and management of undernutrition based on the identified local determinants of undernutrition at the formative research. The training method will be adopted from the standard IMCI nutrition module and Nutrition Assessment and Counseling (NACs) modules. The trained MLPs will provide tailored nutrition counseling and management of undernutrition to HIV-positive children attending the CTCs intervention sites. After the completion of the study, a similar intervention will be made available for the control group after evaluation of results.

The tailored nutrition counseling and management of undernutrition will be provided by MLPs when patients attend CTCs on a monthly basis. Such intervention will continue and be monitored for the entire study duration.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Feeding practices of HIV-positive children attending CTC in Tanga, Tanzania. This includes:

- 1. Feeding frequency
- 2. Dietary diversity
- 3. Quality, and quantity of diets fed to children

Measured at baseline, and monthly for one year

Secondary outcome measures

- 1. Nutrition status (weight, height, and mid upper arm circumference)
- 2. ART profile (adherence, viral load, CD4 count, opportunistic infections)

Measured at baseline, and monthly for one year

Overall study start date

01/07/2013

Completion date

30/07/2014

Eligibility

Key inclusion criteria

Current inclusion criteria as of 16/07/2013:

Children:

- 1. Aged 6 months to 14 years, either sex
- 2. Diagnosed of HIV / acquired immune deficiency syndrome (AIDS); registered at Care and Treatment Centers (CTC) for treatment or care

Caregivers:

Who takes care of the child on a routine basis MLP; classified as Assistant Medical Officers (AMO), Clinical Officers (CO), Nurse assistant

Previous inclusion criteria:

Children:

- 1. Aged 6 months to 5 years, either sex
- 2. Diagnosed of HIV / acquired immune deficiency syndrome (AIDS); registered at Care and Treatment Centers (CTC) for treatment or care

Caregivers:

Who takes care of the child on a routine basis MLP; classified as Assistant Medical Officers (AMO), Clinical Officers (CO), Nurse assistant

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

14 Years

Sex

Both

Target number of participants

A total of 400 pairs of caregivers and their HIV-positive children attending CTC for intervention and 400 pairs for control group.

Key exclusion criteria

- 1. Children too sick to participate in the interview
- 2. Refusal to participate by caregiver
- 3. MLP who are not under formal WHO classification

Date of first enrolment

01/07/2013

Date of final enrolment

30/07/2014

Locations

Countries of recruitment

Japan

Tanzania

Study participating centre University of Tokyo

Tokyo Japan 113-0033

Sponsor information

Organisation

University of Tokyo (Japan)

Sponsor details

Department of Community and Global Health Graduate School of Medicine 7-3-1 Hongo, Bunkyo-ku Tokyo Japan 113-0033 +81 (0)3 5841 3697 mjimba@m.u-tokyo.ac.jp

Sponsor type

University/education

Website

http://www.ich.m.u-tokyo.ac.jp/en/index.html

ROR

https://ror.org/057zh3y96

Funder(s)

Funder type

University/education

Funder Name

University of Tokyo

Alternative Name(s)

The University of Tokyo, , , , Utokyo

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Japan

Funder Name

School of Public Health and Social Sciences of Muhimbili University of Health and Allied Sciences (Tanzania)

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?
<u>Protocol article</u>	protocol	25/10/2013		Yes	No
Results article	results	04/04/2017		Yes	No