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Assessment of a nutrition care and support intervention to prevent wasting in people living with human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) not yet on antiretroviral treatment

Submission date	Recruitment status	[_] Prospectively registered
25/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/07/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2008	Infections and Infestations	[_] Record updated in last year

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
N/A

Study information

Scientific Title
Nutrition care and support for the prevention of weight loss in people living with human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) (PLWHA)

Acronym
PREWAS

Study objectives
The human immunodeficiency virus (HIV) infection is a sexually transmitted disease that causes a severe immunodeficiency and the acquired immune deficiency syndrome (AIDS). There are more than 40.3 million people living with HIV/AIDS worldwide and Malawi is heavily affected by this pandemic with an estimated prevalence rate of 12% in 15 - 49 year olds, resulting in a rise in morbidity and mortality. While the scale-up of the life saving treatment with antiretroviral drugs (ART) is underway worldwide and in Malawi, the role of malnutrition in increasing risk of death for patients on ART has been widely demonstrated. Unfortunately, up to 50% of patients suffering from HIV become wasted and wasting is frequently the first AIDS-defining condition. Thus, identifying an intervention to help prevent malnutrition in people living with HIV and AIDS (PLWHA) to eventually delay ART initiation or improve outcomes of those on ART is of utmost importance.

Hypothesis:
An aggressive two weeks course of nutrition support with ready-to-use therapeutic food (RUTF) after each episode of weight loss will prevent wasting, delay the progression of HIV into AIDS and reduce the prevalence of wasting at initiation of ART.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the National Health Sciences Research Committee based at the Ministry of Health in Malawi on the 11th April 2008 (ref: 528).

Study design
Cluster-randomised unblinded controlled study. Only the statistician performing the analysis will be blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)

Interventions
Intervention group:
Participants of the intervention group will receive nutrition counselling once per month and a disease oriented nutrition counselling plus 1,500 Kcal/day of chickpea sesame ready-to-use therapeutic food (CS-RUTF) for a period of two weeks each time the participants present a significant weight loss.

To ensure that individuals in the intervention group receive their CS-RUTF when needed, each patient will be linked to community volunteers to whom he will report any occurrence of disease. Weight and MUAC will be measured each time the patient reports an occurrence of disease and RUTF prescribed if the weight loss is above 2.5% (table to be created to ease the calculation of 2.5% weight loss).

Control group:
Individuals of the control group will receive nutrition counselling once per month and a disease oriented nutrition counselling after any episode of common or opportunistic infection or significant weight loss.

Both groups:
The programme will ensure that all the episodes of disease are treated by ensuring timely referral to the nearest health facility. The research manager will visit the health facilities prior to commencing the study and seek their permission or collaboration and participation.

Individuals of both groups who develop wasting will be treated using the interim national guidelines for the management of moderate and severe malnutrition for adolescents and adults.

Community volunteers from all participating Positive Living Groups will receive refresher training on nutrition counselling at baseline and every 6 months during follow up. Community volunteers will be carrying out fortnightly visits to collect information on morbidity. Additional visits will be carried out by volunteers at participants' request in case of any disease between volunteer visits. During the visit, volunteers will measure weight and MUAC, collect information on symptoms and signs of diseases using standardised forms translated into the local language.

Total duration of intervention: 24 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be assessed at 12 and 24 months after admission in the programme:
1. Mean monthly CD4 count decrease
2. Mean monthly viral load change
3. Incidence of CD4 count less than 350 cells/ml
4. Incidence of WHO HIV stage 3 or 4 defining event
5. Time to commencing ART
6. Three-monthly MUAC change

Secondary outcome measures
The following will be assessed at 12 and 24 months after admission in the programme:
1. Incidence of short period and long period of weight loss
2. Incidence of wasting defined as a MUAC less than 22 cm for women and less than 23 cm for men
3. Three-monthly weight change
4. Incidence of opportunistic infection
5. Probability of dying within the two years
6. Incidence of WHO clinical stage defining illnesses

Outcomes of interest after discharged from the study for secondary end-point of interest:
7. Probability of dying within the two years
8. Mortality during the first trimester of ART treatment

Overall study start date
01/06/2008

Completion date
31/05/2010

Eligibility

Key inclusion criteria
The study targets both female and male adults aged between 18 years and 59 years of age, already registered by one HIV positive living group. Participants will be recruited among the positive living group members who fulfill the following criteria:
1. Confirmed HIV status (HIV positive)
2. World Health Organization (WHO) stage: no clinical event compatible with stage 3 or 4
3. CD4 count greater than or equal to 350 cells/µL
4. Good nutritional status: absence of oedema, mid-upper arm circumference [MUAC] greater than 220 mm for women and greater than 230 mm for men, body mass index (BMI) greater than 18.5 kg/m^2 and no history of weight loss above 5% of usual weight
5. Physically active (Karnofsky score above 80%)
6. Permanent resident of the catchment area of the positive living group
7. Willingness to participate (signed consent form)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,100 patients (550 per group), to be recruited in 32 clusters (Positive Living groups)

Key exclusion criteria
1. CD4 less than 350 cells/µL
2. Malnutrition (MUAC less than 220 mm for female and less than 230 mm for male, BMI less than or equal to 18.5 kg/m^2, presence of bilateral oedema)
3. On ART
4. Hypertension
5. Diabetes
6. Kidney disease
7. HIV clinical stage 3 or 4
8. Karnofsky score less than 80%

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Malawi

Study participating centre
Valid International
Lilongwe
Malawi
265

Sponsor information

Organisation
Valid International (UK)

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Sponsor type
Research organisation

Website
http://www.validinternational.org

ROR
https://ror.org/00sb6vz77

Funder(s)

Funder type
Research organisation

Funder Name
Valid International (UK) (ref: S-30)

Funder Name
Concern Worldwide (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