Evaluating the use of a novel, low-cost wall chart tool to rapidly identify stunted adolescents in Lilongwe, Malawi

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
24/07/2016		[_] Protocol		
Registration date		[] Statistical analysis plan		
27/07/2016	Completed	[X] Results		
Last Edited 30/08/2023	Condition category Nutritional, Metabolic, Endocrine	Individual participant data		

Plain English summary of protocol

Background and study aims

Stunting is a form of malnutrition where children are too short for their age. It currently affects around 40% of children in Malawi. The current gold standard (best available method) for identifying stunted children involves assessing their height-for-age and comparing that against the reference population (WHO growth standards). This requires accurate height measurement, age assessment, calculation and comparison against reference population (z-score). All these take time and can be difficult in environments such as Malawi where staff numbers, measuring equipment and other resources are limited. As a result, assessing stunting is often of low priority or missed all together, and this vulnerable group of children and adolescents are not identified. Effective identification of stunting in older children and adolescents is the first step towards addressing this public health problem. This project aims to use a new, low-cost tool for the identification of stunted children and adolescents. The aim of this study is to find out whether the stunting chart is able to identify stunting as accurately as the gold standard, and if it is quicker to perform.

Who can participate?

All children and adolescents aged 8 to under 19, who are able to stand up straight for measurement.

What does the study involve?

All participants attend a single study visit at which their stunting status assessed using both the new wall chart and gold standard measurement by health surveillance assistant (HAS, community health workers). The stunting chart is printed on a large canvas and has age bars marked on it showing the correct height-for-age ranges, with colours marking ranges of "normal", "stunted" or "severely stunted". Children stand against the bar corresponding to their age and using a book or piece of paper, the HAS is able to see their stunting status by the colour. The gold standard measurement involves having height and weight measured and used to calculate their z-score to find out their stunting status. The measurements are alternated between visits for fairness, and each procedure is timed. At the end of the study, the results of

the two tests are compared to see how accurate the stunting chart is in comparison to the gold standard. In addition, the time taken to perform the tests are reviewed to see whether the stunting chart is more efficient.

What are the possible benefits and risks of participating? Participants may benefit from increased awareness about the problem of stunting in Malawi. There are no notable risks involved with participating.

Where is the study run from? Malawi Epidemiology and Intervention Research Unit (Malawi)

When is the study starting and how long is it expected to run for? January 2016 to September 2016

Who is funding the study? 1. London School of Hygiene and Tropical Medicine (UK) 2. Wellcome Trust (UK)

Who is the main contact? Dr Marko Kerac marko.kerac@lshtm.ac.uk

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Evaluating the performance (in terms of accuracy and speed) of a novel wall chart, compared to traditional height-for-age measurement, for identifying stunting adolescents in Lilongwe, Malawi

Study objectives

1. Compared to gold standard stadiometer-measured height-for-age-based assessment, the "stunting chart" will have adequate performance for use in the community for identifying stunting

2. The stunting chart will be time-saving compared to traditional HAZ measurement

Ethics approval required

Old ethics approval format

Ethics approval(s)

Malawi's College of Medicine Research and Ethics Committee (COMREC), 30/06/2016, ref: P.06/16/1955
London School of Hygiene and Tropical Medicine Research Ethics Committee, 27/06/2016, ref: 10912

Study design Cross-sectional diagnostic accuracy study

Primary study design Observational

Secondary study design Cross sectional study

Study setting(s) Community

Study type(s) Diagnostic

Participant information sheet See additional files

Health condition(s) or problem(s) studied

Stunted growth (low height-for-age)

Interventions

Participants are purposively sampled, from poorer areas with higher prevalence of stunting and from areas where we have existing contacts with village chiefs. Each participant will have their stunting status (not stunted / stunted / severely stunted) assessed by both stunting chart and height measured using a traditional stadiometer. Each individual will be measured twice by each method, once by a health surveillance assistant (HSA - a community-level healthcare worker in

Malawi) and once by a trained field worker. A different HSA will be used each day (e.g. measure the adolescents in their 'patches') since the aim is to test simplicity of use.

Index test: stunting chart

The stunting chart is a wall chart based on the WHO Standards height-for-age z-scores. This will be developed and printed on large canvas material. Following the Nabarro Thinness chart format, bars showing age (8-19 years), will be plotted along the horizontal axis of the chart. Age bars will be plotted in half-year increments from 8 to 15.5 years, and one-year increments from 16 to 19 years. The vertical axis will show the heights plotted on a 1:1 scale and colour-coded at each z-score interval (orange for z-score -4 to -3, yellow for z-score -3 to -2, green for z-score ≥-2).

Children will stand against the bar corresponding to their age. Using the edge of a book or piece of paper to ensure correct alignment, the colour of the bar behind them will rapidly categorise them as "normal", "stunted" or "severely stunted".

Reference standard: HAZ

According to the WHO, stunting is defined as a height that is more than 2 standard deviations below the WHO Child Growth Standards median, or a HAZ <-2. Each participant's HAZ will be calculated from the mean height obtained from traditional height measurement. This involves height measurement using a standard Leicester stadiometer. Two readings will be obtained to check for agreement as per WHO guidelines. If the two readings are outside a tolerance limit of 0.7cm, both investigators will re-measure until they agree. Stunting status according to HAZ will be used as the reference status to compare the accuracy of stunting chart and traditional height measurement.

Additionally, the HSAs will use the WHO simplified field tables and WHO growth charts to identify whether the participant is "normal", "stunted" or "severely stunted".

There is no follow up for participants. The two tests are conducted consecutively for each participant and the same HSA completes both measurements. The order of the tests is alternated so that there is no bias towards one or the other test.

Intervention Type

Device

Pharmaceutical study type(s) Not Applicable

Phase Not Applicable

Drug/device/biological/vaccine name(s)

MEIRU wall chart

Primary outcome measure

1. Diagnostic test performance of the index test is measured through comparison of sensitivity, specificity, positive predictive value and negative predictive value with the reference standard 2. Total time taken to use each method is measured in seconds (i.e. seconds, minutes) at the beginning and end of each test (i.e. during each test)

Secondary outcome measures

1. Local perceptions of the stunting chart is assessed using a Likert-scale in a purpose-made questionnaire at the end of the study visit

 Performance of field tables and growth charts for classifying stunting status are determined by comparison of its diagnostic test performance against the reference standard
Local views on stunting is assessed using a Likert-scale and short-answer questions in a purpose-made questionnaire at the end of the study visit

Overall study start date

29/01/2016

Completion date

07/09/2016

Eligibility

Key inclusion criteria 1. All children and adolescents aged 8 to under 19 years 2. Able to stand straight for measurement

Participant type(s) Healthy volunteer

Age group Child

Lower age limit 8 Years

Upper age limit 18 Years

Sex Both

Target number of participants 300

Total final enrolment 244

Key exclusion criteria

 Children/adolescents with disability, acute illness or other reason preventing them from standing for height measurement
Inability to obtain informed consent from parents or informed assent/consent from participant

Date of first enrolment 15/07/2016

Date of final enrolment

07/08/2016

Locations

Countries of recruitment Malawi

United Kingdom

Study participating centre Malawi Epidemiology and Intervention Research Unit Community Health Sciences Unit (CHSU) Malawi Mthunthama Road Area 3 Lilongwe United Kingdom

Sponsor information

Organisation London School of Hygiene and Tropical Medicine

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Sponsor type University/education

ROR https://ror.org/00a0jsq62

Funder(s)

Funder type University/education **Funder Name** London School of Hygiene and Tropical Medicine

Alternative Name(s) London School of Hygiene & Tropical Medicine, LSHTM

Funding Body Type Private sector organisation

Funding Body Subtype Universities (academic only)

Location United Kingdom

Funder Name Wellcome Trust

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype International organizations

Location United Kingdom

Results and Publications

Publication and dissemination plan

1. Initial results will be disseminated through a London School of Hygiene and Tropical Medicine (LSHTM) MSc project

2. Findings will be shared with the participating communities via HSAs and field workers who took part

3. Results will be submitted for wider distribution and publication both in Malawi and internationally

2017 results presented at the Action Against Hunger 'Research for Nutrition' Conference in https://www.ennonline.net/attachments/2694/ACF_MEIRU-chart_v.1.3_possible.pdf

Intention to publish date 07/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Participant information sheet	version V5	26/07/2016	28/07/2016	No	Yes
Results article		14/07/2023	30/08/2023	Yes	No