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Growth in adolescence: Potential interventions to improve growth and health and reduce the risks of future non-communicable disease

Submission date
24/08/2016

Recruitment status
No longer recruiting

Registration date
01/09/2016

Overall study status
Completed

Last Edited
18/01/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stunting is defined as having a height-for-age which is much lower than an internationally agreed average. Childhood stunting is a problem all over the world which can cause illness, disrupt development, and result in long-term consequences, including poor physical and cognitive health, and an increased likehood of developing diseases such as diabetes and heart disease later in life. Usually, interventions (treatments or programmes) looking to prevent or reverse stunting focus on the first 2 years of life, also known as the “1st 1000 days of life”. Children who slip through this net or become stunted later in life are therefore left behind. The period of adolescence, where rapid growth and development occur, may represent a “2nd window of opportunity” to optimise growth, development and health. It is also a key time for learning healthy lifestyles which may help prevent non-communicable diseases (NCDs) – such as diabetes or heart disease - in later life. However, little is known about whether steps taken to optimise growth and prevent NCD prevention during this time actually work. Researchers are currently looking to test a way of helping stunted adolescents, but first need to run this formative research (fact finding) project in order to as much information as possible to increase the possibility of success.

Who can participate?
Adolescents aged between 10 and 19 years in 2 different communities: rural Karonga and urban Lilongwe.

What does the study involve?
First of all, adolescents, their parents, and community leaders are all interviewed to ask their opinion of stunting, other diseases, causes of these diseases and how best to combat them. The adolescents also have their height, weight and body circumferences measured and are sked further questions about their health, family history and how their body is developing. Some of the adolescents are also asked to have some tests to see how active they are, how much fat and muscle they have in their body and brain function. These tests include wearing a device that measures how many steps they take each day, playing a computer game for 30 minutes while brain function is measured.

What are the possible benefits and risks of participating?
At this stage the only benefit to the participant is being able to influence the design of a future intervention (treatment) which you may be able to test at a later date. Participants that are found to have health issues are referred to the local health centre. There are no risks of taking part, as this study does not involve any invasive procedures.

Where is the study run from?
The study is run from a Wellcome Trust research site called MEIRU which has 2 locations: Karonga (in rural northern Malawi) and Lilongwe (the capitol city in Malawi)

When is study starting and how long is it expected to run for?
March 2016 to January 2017.

Who is funding the study?
The Wellcome Trust (grant number 200669/Z/16/Z)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

200669/Z/16/Z

Study information

Scientific Title
Growth in Adolescence: Potential interventions to improve growth and health and reduce the risks of future non-communicable disease: a cross-sectional pilot survey and interview study to inform a future RCT

Acronym
GAP study

Study objectives
The aim of this study is to investigate the optimal interventional RCT for improving adolescent growth and health outcomes in Malawi

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. College of Medicine Research Ethics Committee, Malawi (COMREC), 18/08/2016, ref P.06/16/1971
2. London School of Hygiene and Tropical Medicine Ethics Committee, 12/08/2016, ref 11689

Study design
Formative, mixed-methods, pilot study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
1. Stunting
2. Increased risk of future non communicable disease (NCD)

Interventions
This observational research will take place in Karonga (rural site) and a Lilongwe (urban Site) in Malawi and will consist of:
1. Qualitative research: Key informant interviews with future study stakeholders will be

conducted. Mainly individual interviews and some small focus groups. Approx. 20 individuals per study group are expected to achieve data saturation for interviews, and a maximum of 10 focus groups with a minimum of 4 participants.
2. A cross sectional survey: the primary aim of this is determine prevalence of stunting in adolescents in these communities. This will include primary data collection in Lilongwe, recruiting approx. 600 adolescents; and secondary data analysis in Karonga where basic anthropometry for all adolescents is already available
3. A detailed quantitative survey nested within the prevalence survey: More in-depth assessment of approximately 200 adolescents at each site will be conducted, including: a detailed questionnaire asking about possible risk factors for stunting/adverse long term outcomes; detailed anthropometry (following WHO recommended measurement methods); assessment of physical activity (using accelerometers); cognitive function (using CANTAB cognitive testing); and body composition by Bioelectrical Impedance Analysis or BIA (using Bodystat 1500MDD at 50Khz).

Study questionnaires are based on existing validated tools including used in the Global School Heath Survey (GSHS), the Malawi Demographic Health Survey (DHS) and the FAO (Food and Agriculture Organization) 24 hour food recall sheet.

Pubertal stage will be self-assessed using Tanner staging.

The main target population are adolescents aged 10-19 years. In the qualitative sub-study carers /parents; teachers; community healthcare workers; other community leaders will also be interviewed.

Intervention Type
Other

Primary outcome measure
1. Prevalence of stunting defined as height-for-age z score <-2 based on WHO 2007 Growth Standards, in adolescents aged 10-19 years in study communities in Karonga and Area 25 of Lilongwe
2. Views of adolescents on design of a future intervention assessed through qualitative interviews
3. Baseline means and standard deviations for:
3.1. Steps per day measured with Actilife accelerometers worn for 48 hours
3.2. Key CANTAB (cognitive function) outcomes, as dictated by the manufacturers, from a battery of 6 tests: Motor Screening Task (MOT), Paired Associates Learning (PAL), Pattern Recognition Memory (PRM), Reaction Time (RTI), Emotion Recognition Task (ERT) and Spatial Span (SSP)
3.3. Resistance, Reactance, Impedance Index and Phase angle measured by BIA device
3.4. Hand grip strength measured as the best of 3 attempts on each hand

Secondary outcome measures
1. Intra-cluster correlation coefficient for HAZ (height-for-age z-score),steps per day, CANTAB outcomes, BIA outcomes and hand grip strength.
2. Views of parents, community leaders and relevant professionals on the design of a future intervention assessed though qualitative interviews
3. Risk factors for stunting, poor health and NCDs in this population including:
3.1. Blood pressure
3.2. Nutritional intake measured using FAO 24 hour food recall method

3.3. Waist/hip circumference ratio
3.4. Sitting height
3.5. Behaviour and hygiene factors measured using standard questions from WHO Global school-based student health survey (GSHS)
3.6. Socioeconomic status calculated using principal components analysis (PCA) of standard asset questions from the Malawi Demographic Health Survey (DHS)
4. Mean difference between main outcomes (CANTAB outcomes, steps per day, BIA outcomes and handgrip strength) between stunted and non-stunted individuals

Overall study start date
01/03/2016

Completion date
30/01/2017

Eligibility

Key inclusion criteria
1. Adolescents aged 10-19 years
2. Both males and females
3. Living in Karonga district or Lilongwe Area 25

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
780

Key exclusion criteria
1. Visiting adolescents who do not live in the catchment area
2. Adolescents who do not have full consent to participate in the study
3. Adolescents with a disability that means a height measure cannot be obtained

Date of first enrolment
24/08/2016

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
Malawi

Study participating centre
MEIRU (Malawi Epidemiology & Intervention Research Unit)
c/o Community Health Sciences Unit (CHSU)
Lilongwe
Malawi
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (LSHTM)

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ROR
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Funder(s)

Funder type
Government

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. Share findings at local dissemination meetings at Malawi (an aim of which will be to discuss options for and decide final options for a future intervention study)
2. Publish descriptive findings as peer review journal articles

Intention to publish date
30/01/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/09/2016		No	Yes