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Effects of a school-based intervention programme on growth, health and well-being of schoolchildren in three African countries: The KaziAfya project

Submission date
20/07/2018

Recruitment status
No longer recruiting

Registration date
09/08/2018

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ensuring healthy lives and promoting wellbeing among children is a complex and challenging endeavour. In low- and middle-income countries, infectious diseases remain a key public health problem, which negatively impacts on children's physical and cognitive development, resulting in reduced fitness and work productivity.
Additionally, non-communicable diseases (chronic diseases that cannot be passed from person to person) are a rapidly growing public health problem and impose a considerable burden on population health. Consequently, children are at an increased risk of compromised health due to non-communicable and/or infectious diseases, which may hamper their development and wellbeing. In summary, a deprived socio-economic environment can put children at risk of malnutrition and poor growth. Malnutrition has been found to be associated with stunting and poor cognitive development resulting in low IQ and development delays.
One way of addressing this disease burden and disrupting the vicious cycle of poverty and poor health is to incorporate health promotion measures within existing school structures.
The aim of this project is to assess how effective school-based intervention programmes are on communicable diseases, risk factors for non-communicable diseases, health behaviours (beliefs and actions relating to health and wellbeing) and psychosocial health in school-aged children in disadvantaged neighbourhoods in South Africa, Tanzania and Côte d'Ivoire.

Who can participate?
Children in grades 1-4 aged between 6 and 12 years (at baseline)

What does the study involve?
Children will take part in a school-based health promotion program that lasts for 2 consecutive school years. This involves 1 weekly 40 minute lesson of physical education, 1 weekly 40 minute moving-to-music lesson, as well as 3 health education and nutrition education lessons (all 40 minutes long) per school year. Intervention teachers will receive complete lessons plans and additional training/support by a teacher coach during the first study year. In the second year, the

intervention teachers are now asked to implement the contents of the provided lesson plans independently.
Children will also undergo deworming (helminths) using a single dose of albendazole.
Participants will be assessed at baseline (beginning of school year), T1 (end of first intervention school year) and T2 (end of second intervention school year). Measures include physical activity and fitness, multi-micronutrient status, disease history, blood tests, body measurements, parasites (helminths), school grades, life satisfaction, and quality of life. Children with poor chronic conditions (e.g., type 2 diabetes) will be referred to a nearby health facility for treatment and care under experienced medical personnel.

What are the possible benefits and risks of participating?
The possible benefit to participants taking part in this study is that school-based health intervention programs have been shown to have positive effects on children's physical activity levels and being overweight/obese. The planned tests are mostly non-invasive and there are no known risks for these data collection methods. Capillary blood sampling via finger pricks may cause slight discomfort. As a result, children will not be pricked more than twice. Deworming will be done using albendazole, which may have minor adverse effects such as dizziness, but these are usually mild and transient.
All procedures are standardized and follow current WHO guidelines, and medical clinicians will be prepared to treat participants in case of emergencies.

Where is the study run from?
University of Basel, Switzerland
Swiss Tropical and Public Health Institute, Basel, Switzerland
Nelson Mandela University, Port Elizabeth, South Africa
Ifakara Health Institute, Ifakara, Tanzania
Centre Suisse de Recherches Scientifiques, Abidjan, Côte d'Ivoire

When is the study starting and how long is it expected to run for?
January 2018 to December 2021

Who is funding the study?
Fondation Botnar (Switzerland)

Who is the main contact?
Professor Dr Markus Gerber
markus.gerber@unibas.ch

Contact information

Type(s)
Scientific

Contact name
Prof Markus Gerber

ORCID ID
https://orcid.org/0000-0001-6140-8948

Contact details

University of Basel
Department of Sport, Exercise, and Health (DSBG)
Birsstrasse 320B
Basel
Switzerland
4052

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Fondation Botnar Study Nr. 6071

Study information

Scientific Title
Effects of school-based physical activity and multi-micronutrient supplementation intervention on growth, health and well-being of schoolchildren in three African countries: The KaziAfya project

Acronym
KaziAfya

Study objectives
Specific hypotheses for each of our main outcome variables have been formulate, taking into account existing evidence from previous studies, mostly carried out with children living in Western societies:
1. The levels of total physical activity (PA) will increase among children who take part in a school-based PA programme, particularly intra-curricular physical activity
2. Cardiorespiratory fitness will increase among children in the PA and multi-micronutrient supplementation (MMS) + PA condition, independent of children's gender or weight status
3. The PA intervention might be associated with a decreased BMI in overweight or obese children.
4. Children in the multi-micronutrient supplementation intervention and MMS + PA intervention arm will have reduced adiposity and increased free fat mass (FFM)
5. Children in the MMS and MMS + PA group will have significantly increased serum concentrations of the micronutrients included in the supplement and reduced deficiencies
6. PA and MMS + PA will result in increased adiponectin levels, whereas levels of leptin and ghrelin are expected to remain unchanged
7. Children in the MMS and MMS + PA groups will have reduced serum leptin concentrations and increased adiponectin concentrations
8. Children in the PA, MMS and MMS + PA groups will have reduced levels of inflammatory

markers
9. Children in the PA and MMS + PA groups will have decreased blood pressure, improved blood lipid profiles and decreased blood glucose levels
10. Children in the MMS and MMS + PA groups will have reduced cardio-metabolic risk
11. Children in the PA, MMS and MMS + PA groups will have increased executive function and cognitive performance
12. Children in the PA and MMS + PA groups will have improved health-related quality of life and school stress
13. Children in the MMS and MMS + PA groups will have increased health-related quality of life and well-being
14. Children in the MMS and MMS + PA groups will have slower reinfection rates with parasites

Ethics approval required
Old ethics approval format

Ethics approval(s)
We seek ethical approval from the following responsible ethics committees:
Switzerland (submitted Req-2018-00608):
Ethikkommission Nordwest- und Zentralschweiz (EKNZ). Here, we applied for a "declaration of no objection" (Zuständigkeitsabklärung) for our planned project.

South Africa (submitted):
1. Nelson Mandela University in Port Elizabeth, South Africa
2. Department of Health and to the Department of Education of the Eastern Cape Province, South Africa, respectively

Tanzania (submitted):
1. Ifakara Health Institute – Institutional Review Board (IHI-IRB)
2. Tanzania Food and Drugs Authority (TFDA)
3. National Institute for Medical Research (NIMR)

Côte d'Ivoire (approved 02/07/2018):
Institutional Research Commission of the Centre Suisse de Recherches Scientifiques en Côte d' Ivoire (CSRS; Abidjan) and Comité National d'Ethique et de la Recherche (CNER), 100-18/MSHP /CNESVS-km

Study design
Interventional double-blind randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
School-based physical activity and multi-micronutrient supplementation to increase health and improve health-related behaviours

Interventions
3 intervention groups will be compared against one placebo control condition (4 groups in total):
1. Physical activity and placebo
2. Multi-micronutrient supplementation
3. Physical activity and multi-micronutrient supplementation
To ensure allocation concealment, group assingment will be done by a computer-generated code prior to the baseline assessment. This study involves primary school children from grade 1 to grade 4; therefore, each grade level per schoolwill be randomly allocated to one of the 4 groups. To minimise subjective bias, teachers and local study personnel will be blinded regarding whether the tablets are multi-micronutrients or the placebo.
Physical activity will involve 1 40 minute physical education lesson per week and 1 40 minute moving-to-music lesson per week. Additionally, a physical activity-friendly school environment will be developed. Groups 1 and 3 will receive this.
Multi-micronutrient supplementation will involve provision of multi-micronutrient tablets to participants on school days. Groups 2 and 3 will receive this.
Group 1 and the control group will be given placebo tablets.
All groups will receive health education - a series of classroom-based lessons designed to increase awareness of intestinal parasite infections amongst schoolchildren and educate them on treatment and prevention methods, including proper hygiene and sanitation habits and the importance of consuming clean water and food.
All groups will also receive nutritional education - a series of classroom-based lessons designed to increase awareness of the importance of health nutrition.
Additionally, all participants will receive deworming treatment and, if required, referral to local clinics.

Intervention Type
Supplement

Primary outcome measure
The following will be assessed at the baseline, 12 and 24 months post-intervention:
1. Physical activity:
1.1. Self-reported physical activity, assessed using the following:
1.1.1. Single-item tool, taken from the Health-Behaviour in School-Aged Children (HBSC) questionnaire: "Physical activity is any activity that increases your heart rate and makes you get out of breath some of the time. Physical activity can be done in sports, school activities, playing with friends or walking to school. Some examples of physical activity are running, brisk walking, biking, dancing, skateboarding, swimming, soccer, basketball, rugby, cricket. For this next question, add up all the time you spent in physical activity each day. Over the past 7 days, on how many days were you physically active for a total of at least 60 minutes per day?”
1.1.2. 6 items from the Physical Activity Questionnaire for Children (PAQ-C)
1.2. 7 day physical activity measured by actigraphy
2. Physical fitness:
2.1. Cardiorespiratory fitness, assessed using the 20 m shuttle run test from the Eurofit Fitness

Testing Battery
2.2. Grip strength, assessed using a grip strength test on both the right and left hands with the Saehan hydraulic hand dynamometer
3. Multi-micronutrient status, assessed using capillary blood sampling via finger prick)

Secondary outcome measures

The following will be measured at the baseline and 12 and 24 months after the intervention:
1. Disease history of child and parents, assessed using a socio-economic and demographic profile questionnaire
2. Subjective health complaints, assessed by the nurse and a questionnaire
3. Haemoglobin concentration (Hb), measured using Haemocue
4. Blood pressure (SBP, DBP), assessed using oscillometry with a digital blood pressure monitor
5. Blood lipids (TC, HDL-C, LDL-C, TG, Non-HDL, C-HDL ratio), measured using the Alere Afinion AS100 analyser
6. Blood glucose (HbA1c), measured using the Alere Afinion AS100 analyser
7. Status of the following, assessed using dried blood spot samples (DBS):
7.1. Vitamin A
7.2. Vitamin D
7.3. Zinc
7.4. Transferrin
7.5. Cytokines (IL-6)
7.6. Leptin
8. Body weight and height, assessed using bioelectrical impedance analysis (BIA)
9. Body composition (body fat), assessed using BIA
10. Waist/hip ratio, assessed using BIA
11. Body Mass Index, assessed using BIA
12. Soil-transmitted helminths (A. lumbricoides, hookworm, T. trichiura), assessed using the Kato-Katz technique
13. Schistosoma mansoni, assessed using the Kato-Katz technique
14. Executive function, assessed using a computer-based version of the Flanker test
15. School grades - end of year results in mathematics, home language and the first additional language
16. Health-related quality of life, assessed using the KIDSCREEN-10 questionnaire
17. Perceived stress, assessed using the Health Behaviours in School Age Children (HBSC) questionnaire
18. School satisfaction, assessed using the HBSC questionnaire
19. Perceived academic competence, assessed using the HBSC questionnaire
20. Sleep, assessed using the following:
20.1. Insomnia Severity Index (ISI)
20.2. Pittsburgh Sleep Quality Index (PSQI)
20.3. Sleep environment

Control variables, assessed via questionnaire at the baseline and 12 and 24 months after the intervention:
21. Age
22. Sex
23. Socioeconomic status
24. Ethnicity
25. Home language

26. School
27. Grade
28. Country

Overall study start date
01/01/2018

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Attending grade 1 to 4
2. Aged 6 to 12 years (corrected 30/04/2019)
3. Written informed consent by parent/guardian
4. Not participating in other clinical trials
5. Not receiving multi-micronutrient supplements
6. Not suffering from clinical conditions that prevent participation in physical activity, as determined by qualified medical personnel

Participant type(s)
Other

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
4000

Key exclusion criteria
1. Congenital or acquired alteration of the gastrointestinal tract, which could impair absorption of the multi-micronutrient supplements
2. Taken vitamin and mineral supplements in the past 6 months.
3. Fetal alcohol syndrome

Date of first enrolment
15/10/2018

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
Côte d'Ivoire

South Africa

Tanzania

Study participating centre
Ifakara Health Institute
Plot 463, Kiko Avenue Mikocheni P.O. Box 78 373 Dar es Salaam Tanzania
Dar es Salaam/Ifakara
Tanzania
78373

Study participating centre
Nelson Mandela University
PO Box 77000 Nelson Mandela University
Port Elizabeth
South Africa
6031

Study participating centre
CSRS- Centre Suisse de Recherches Scientifiques en Cote d'Ivoire
Yopougon, Abidjan -
01 BP 1303 Abidjan
Abidjan
Côte d'Ivoire
01 BP 1303

Sponsor information

Organisation
Fondation Botnar

Sponsor details
St.Alban Vorstadt 56
Basel
Switzerland
4052

+41 61 201 04 74
info@fondationbotnar.org

Sponsor type
Other

Website
https://www.fondationbotnar.org/contact

Funder(s)

Funder type
Not defined

Funder Name
Fondation Botnar

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 28/04/2021:
We aim to publish our:
1. Study protocol on 30/09/2018
2. Baseline data on 01/01/2021
3. 12-month follow-up data on 31/12/2021
4. 24-month follow-up data on 30/06/2022

Previous publication and dissemination plan:
We aim to publish our:
1. Study protocol on 30/09/2018
2. Baseline data on 01/07/2019
3. 12 months follow-up data on 01/07/2020
4. 24 months follow-up data on 01/07/2021

Intention to publish date
30/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/01/2020	08/01/2020	Yes	No
Other publications	baseline data	21/02/2021	27/04/2021	Yes	No
Other publications	baseline data	19/08/2021	08/10/2021	Yes	No
Other publications	baseline data on socioeconomic status and cardiorespiratory fitness	25/06/2021	28/01/2022	Yes	No
Other publications		06/06/2022	07/06/2022	Yes	No
Other publications		16/04/2021	06/09/2023	Yes	No
Other publications		03/05/2021	06/09/2023	Yes	No
Results article		27/01/2022	06/09/2023	Yes	No
Results article	Prevalence and determinants of undernutrition	23/06/2022	06/09/2023	Yes	No
Results article		25/04/2024	17/09/2024	Yes	No
Results article	body composition	03/07/2025	07/07/2025	Yes	No