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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
20/07/2018		[X] Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
09/08/2018		[X] Results			
Last Edited 07/07/2025	Condition category	[] 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

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Contact details

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

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 Reg-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

Study type(s)

Prevention

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(s)

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)

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 years

Upper age limit

12 years

Sex

Αll

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

Funder(s)

Funder type

Not defined

Funder Name

Fondation Botnar

Results and Publications

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?
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
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
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes