

Effects of a school-based health intervention programme in Port Elizabeth, South Africa: the KaziBantu project

Submission date 09/07/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/07/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/06/2025	Condition category Other	<input checked="" type="checkbox"/> 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 that negatively impacts on children's physical and cognitive development. Additionally, non-communicable diseases (chronic diseases that cannot be passed from person to person) are a rapidly growing public health problem, and are a considerable burden on population health. Research has revealed that African populations have moved towards a disease profile similar to Western countries, with an increasing proportion of deaths attributed to chronic, lifestyle-related diseases and being overweight, replacing undernutrition as a risk factor. Consequently, children are at an increased risk of compromised health due to a dual burden of diseases, which could affect their development and wellbeing and constitutes a challenge for health systems in African countries.

Although children are mainly affected by infectious diseases, they may at a young age develop risk factors that make them more likely to develop non-communicable diseases in early adulthood. One way to address this problem and disrupt the vicious cycle of poverty and poor health is to incorporate health promotion measures within schools.

The goal 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 Port Elizabeth, South Africa. Additionally, we aim to develop and pilot-test a workplace health intervention for primary school teachers.

Who can participate?

Children in grades 1-6 aged between 6 and 16 years. All teachers from the study schools are involved in the implementation of the school-based health promotion programme.

What does the study involve?

For children:

Children will take part in a school-based health promotion programme that lasts for 32 school weeks. This involves 1 40 minute long physical education lesson per week, 1 40 minute moving-

to-music lesson per week, and 3 health education and 3 nutrition education lessons (all 40 minutes long) across the study period. Children will also undergo deworming (helminths) using a single dose of albendazole or mebendazole. Participants will be assessed at the beginning and after 12 months, and assessment measurements will include physical activity and fitness, disease history, blood tests, body measurements, parasites (helminths), school grades and 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.

For teachers:

Teachers will take part in a 6-month workplace health promotion programme. There will be a baseline assessment including measurements relating to perceived health, disease history, blood tests, body measurements, physical activity, mental health and stress and quality of life. Following this, teachers will receive a personal health profile providing an overview of cardiovascular and mental health that is used to estimate their health risks, along with brief information on how to interpret this.

The workplace health programme will last for 20 weeks and involve individually tailored lifestyle coaching workshops.

What are the possible benefits and risks of participating?

The possible benefit for child participants of taking part is that prior research has shown that interventions such as this school-based health programme have positive outcomes on children's physical activity levels and being overweight/obese. For teachers, the benefit of taking part is that they will receive a free health screening and gain behavioural skills that are helpful for achieving personal health goals through behavioural change.

For both children and teachers, most of the planned tests and methods used for assessment are non-invasive and there are no known risks for these data collection methods. Capillary blood sampling (for haemoglobin concentration, blood lipids and blood glucose) and the finger prick required for this may be slightly uncomfortable. As a result, the procedure has been planned so that participants are only pricked once. For children, albendazole and mebendazole, which will be used for deworming, may have minor adverse effects such as dizziness, but these effects are usually mild and transient.

All procedures are standardised and follow current WHO guidelines, and medical clinicians will be prepared to treat participants in case of emergencies.

Where is the study run from?

1. University of Basel, Switzerland
2. Nelson Mandela University, Port Elizabeth, South Africa
3. Swiss Tropical and Public Health Institute, Basel, Switzerland

Who is funding the study?

Novartis Foundation, Basel, Switzerland

Who is the main contact?

Professor Dr Uwe Pühse
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Study website

<http://www.kazibantu.org>

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R-2018-00048

Study information

Scientific Title

Effects of a school-based health intervention programme in marginalized neighbourhoods of Port Elizabeth, South Africa: the KaziBantu project

Acronym

KaziBantu

Study objectives

A 12-month school-based health promotion programme in physical activity, health and nutrition education and deworming/referral to local clinics will contribute to improving clinical parameters among children from primary schools located in disadvantaged areas in Port Elizabeth, South Africa, taking into account adjustment to baseline covariates. A 6-month workplace health promotion programme will help enhance clinical parameters among teachers.

The planned study will provide basic insights regarding the efficacy and effectiveness of school-based health promotion measures to increase children's and teachers' health and health-related behaviours. While we have pilot-tested the intervention toolkit for children, additional evidence is needed to scale-up the intervention programme. The present study will also provide new insights into the possibility of the protective effects of physical activity and cardiovascular fitness against the negative consequences of high perceived stress. This work is of potential public health importance since previous studies have shown close links between perceived stress and risk for cardiovascular diseases as well as premature mortality. The involved organizations will obtain important information regarding the health state and the interest of South African children and primary school teachers in health promotion programmes. Finally, new knowledge will be gained regarding the relationship between physical activity and both infectious diseases and risk-factors for non-communicable diseases among South African children. Furthermore, evidence regarding the health benefits of a physically active lifestyle, compared to Western countries, is generally limited among African populations. This applies particularly to studies using accelerometry to objectively assess participants' physical activity levels.

Children of the intervention schools will take part in a school-based health promotion programme, which consists of four components (physical activity, health and nutritional education, deworming/referral to local clinics). Prior research suggests that such interventions have positive outcomes on children's physical activity levels and overweight/obesity. Our pilot tests (from the DASH study) support these findings.

Teachers of the intervention and control schools will receive a free health screening, and behavioural skills will be fostered that are helpful to achieve personal health goals through behavioural change. Established clinical cut-off values will be used to create the personalized health risk profiles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nelson Mandela University (NMU) Ethics Committee, Port Elizabeth, South Africa, 26/03/2018, H18-HEA-HMS-001

Eastern Cape Department of Education, Port Elizabeth, South Africa, 09/05/2018,

Eastern Cape Department of Health, Bhisho, South Africa, 5/06/2018, EC_201804_007
The study is registered at ethical review board of Northwestern and Central Switzerland (EKNZ),
01/03/2018, R-2018-00047

Study design

Interventional randomized controlled trial with a duration of 12 months for child participants and 6 months for teacher participants (pilot phase)

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

The planned study will provide basic insights regarding the efficacy and effectiveness of school-based health promotion measures to increase children's and teachers' health and health-related behaviours.

Interventions

Children:

1. Regular physical activity opportunities, including incorporation of one 40 minute physical education lesson per week and one 40 minute moving-to-music lesson per week into the main school curriculum. Additionally, a physical activity friendly school environment will be developed.
2. Health education - a series of classroom-based lessons to increase awareness of intestinal parasite infections among schoolchildren and educate them on treatment and prevention methods, including proper hygiene and sanitation habits and the importance of consuming clean water and food.
3. Nutritional education - a series of classroom-based lessons to help increase awareness of the importance of healthy nutrition. The school feeding programme will also be analysed to identify ways to improve the healthiness of the current diet. School cooks will be trained in basic nutrition and hygiene during preparation of school meals.
4. Deworming and referral to local clinics.

There will be an intervention and a control group and schools are randomly assigned to the intervention or control group. In each school, classes are randomly selected to participate.

Teachers:

Teachers will have the opportunity to participate in a 20 week workplace health promotion programme. Individually tailored lifestyle coaching workshops will be organised at the two intervention schools. In case of increased health risks, participants will be recommended to contact a general practitioner for further medical clarifications and possible medical action.

There will be an intervention and a control group and schools are randomly assigned to the intervention or control group. In each school, all teachers are invited to participate in the study.

Intervention Type

Other

Primary outcome measure

Children:

The following will be measured/assessed at the baseline and after 12 months:

1. Physical activity:

1.1. Self-reported physical activity assessed by Health-Behaviour of School-Aged Children (HBSC) questionnaire

1.2. 7 day physical activity measured by actigraphy

2. Physical fitness:

2.1. Cardiorespiratory fitness measured using VO₂ max estimates from 20 m shuttle run (Children run back and forth on 20 m course following the pace of sound signals, starting with a running speed of 8.5 km/h. The frequency of signal increases every minute by 0.5 km/h. When a child fails to follow the pace in two consecutive intervals, the stage and distance completed fully will be record. The age of the child and the speed at which the child stopped running is converted into VO₂ max estimates

2.2. Grip strength measured by grip strength test with Saehan hydraulic hand dynamometer

Teachers:

Subjectively perceived health is assessed at the baseline and after 6 months:

1. General perceived stress assessed using the German version of the Perceived Stress Scale (PSS4)

2. Work-related stress assessed using the Effort-Reward Imbalance (ERI) model

3. Mental health (mental distress or minor psychiatric morbidities) assessed using the General Health Questionnaire (GHQ-12)

Secondary outcome measures

Children:

The following will be measured/assessed at the baseline and after 12 months:

1. Disease history of children and parents assessed by face-to-face interview by a professional nurse based on a self-developed questionnaire

2. Subjective health complaints (15 items) assessed by Health-Behaviour of School-Aged Children (HBSC) questionnaire

3. The following are measured using a finger prick test to generate a blood sample for analysis (performed following standardisation protocol of WHO (2010):

3.1. Haemoglobin concentration (Hb)

3.2. Blood lipids (TC, HDL-C, LDL-C, TG)

3.3. Blood glucose (HbA1c)

4. Blood pressure (systolic and diastolic) measured three times after the child has been seated for 5 minutes using a validated oscillometric Omron® digital blood pressure monitor

5. Body composition (percentage body fat and thickness of skinfolds) measured by anthropometry

6. Waist-to-hip ratio measured by anthropometry

7. Body mass index measured by anthropometry

8. Soil-transmitted helminths (*Ascaris lumbricoides*, hookworm, *Trichuris trichiura*) assessed using Kato-Katz method

9. Execute function assessed using Flanker test

10. School grades, obtained directly from the school/teachers
11. Health-related quality of life assessed using KIDSCREEN-10 questionnaire
12. School satisfaction assessed using one item from Health-Behaviour of School-Aged Children (HBSC) questionnaire
13. Academic self-concept assessed using one item from Health-Behaviour of School-Aged Children (HBSC) questionnaire

The following control variables will be measured/assessed using a self-developed questionnaire at the baseline and after 12 months:

14. Age
15. Sex
16. Socioeconomic status
17. Ethical background
18. Home language
19. School
20. Grades

Teachers:

The following will be measured at the baseline and after 6 months:

1. Disease history assessed by face-to-face interview by a professional nurse based on a self-developed questionnaire
2. The following are measured using a finger prick test to generate a blood sample for analysis (performed following standardisation protocol of WHO (2010):
 - 2.1. Haemoglobin concentration (Hb)
 - 2.2. Blood lipids (TC, HDL-C, LDL-C, TG)
 - 2.3. Blood glucose (HbA1c)
3. Blood pressure (systolic and diastolic) measured three times after the child has been seated for 5 minutes using a validated oscillometric Omron® digital blood pressure monitor
5. Body composition (percentage body fat) measured by dual-energy X-ray absorptiometry (DXA scan)
6. Waist-to-hip ratio measured by anthropometry
7. Body mass index measured by anthropometry
8. Self-reported physical activity assessed by questionnaire objectively and by self-report
9. Objectively assessed physical activity assessed using actigraphy
10. Grip strength measured using grip strength test with Saehan hydraulic hand dynamometer
11. General perceived stress assessed by PSS questionnaire
12. Work-related stress assessed by ERI questionnaire
13. Work-family conflict assessed by WAFCS questionnaire
14. Burnout symptoms measured by SMBM questionnaire
15. Health-related quality of life assessed by GHQ-12 questionnaire
16. Sleep complaints assessed by ISI questionnaire

The following control variables will be measured/assessed using a self-developed questionnaire at the baseline and after 6 months:

17. Age
18. Sex
19. Educational status
20. Smoking
21. Alcohol consumption
22. Caregiving
23. Children at home
24. Employment rate

- 25. Shift status
- 26. Years working
- 27. Use of medication
- 28. Previous cardiac disorders
- 29. Previous psychiatric disorders

Overall study start date

01/07/2018

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Children:

1. Grade 1-6
2. Aged 6-14 years
3. Written informed consent by parent/guardian
4. Not participating in other clinical trials
5. Not suffering from medical conditions that prevent participation in physical activity

Teachers:

1. Involved in implementation of the school-based health promotion programme
2. Tick all questions with "yes" in the Physical Activity Readiness Questionnaire to be able to take part in the cardiorespiratory fitness test

Participant type(s)

Learner/student, Mixed

Age group

Mixed

Sex

Both

Target number of participants

Target: Approx. 720 children and 80 teachers. Final: 974 children and 146 teachers

Total final enrolment

1120

Key exclusion criteria

Children:

1. Suffering severe malnourishment (as diagnosed by a study nurse following national guidelines. In this case, children will be referred to local clinics)

Teachers:

1. Acute or chronic medical conditions that prevent participation in a submaximal fitness test (if uncertain, participant will be asked to consult a general practitioner and provide a doctor's

certification before he/she is included in the study)

2. Temporary illness such as a cold or fever (to participate in cardiorespiratory fitness test)

3. Minimum 50% employment rate for at least 6 months

Date of first enrolment

01/01/2019

Date of final enrolment

24/05/2019

Locations

Countries of recruitment

South Africa

Study participating centre

Nelson Mandela University

PO Box 77000

Port Elizabeth

South Africa

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Sponsor information

Organisation

Novartis Foundation

Sponsor details

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Sponsor type

Industry

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ROR

<https://ror.org/04f9t1x17>

Funder(s)

Funder type

Industry

Funder Name

Novartis Foundation

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Publication and dissemination plan

The principal investigators will coordinate the international dissemination of the study results through presentations at national and international conferences and publications in peer-reviewed literature (primarily open-access).

All intervention materials will be made available to the control schools so that the whole community can benefit from this project. Workshops will be offered to the control schools to prepare teachers to implement the school-based health promotion programme. Teachers of the control schools will have the possibility to take part in the lifestyle coaching programme after the second measurement occasion.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The raw datasets generated and/or analyzed during the ongoing study will be available upon completion of the study and may be obtained on request from Nelson Mandela University or Basel University study staff.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/11/2017		Yes	No
Results article		15/03/2018		Yes	No
Results article		04/04/2018		Yes	No
Results article		08/11/2018		Yes	No
Protocol file	version v2.0	13/12/2018	13/12/2018	No	No
Results article	version v11	15/01/2019		Yes	No
Protocol file		21/01/2019	22/01/2019	No	No
Protocol article		11/07/2019	15/07/2019	Yes	No
Dataset	Hypertension in school-aged children	21/07/2022	26/07/2022	No	No
Dataset	Metabolic syndrome in teachers	24/03/2025	04/04/2025	No	No
Results article		06/06/2025	10/06/2025	Yes	No