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Long-term effects of a lifestyle intervention on the health of children and teachers at cardiovascular risk in schools of disadvantaged communities in South Africa

Submission date
15/04/2020

Recruitment status
No longer recruiting

Registration date
17/04/2020

Overall study status
Completed

Last Edited
03/04/2024

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
The burden of non-communicable diseases (NCDs) is rapidly increasing, especially in low- and middle-income countries (LMICs), and has been recognized as one of the biggest public health challenges of our era. While physical activity plays an important part in the prevention of NCDs in adulthood, low levels have been shown in South African youths. Children in disadvantaged communities are at particular risk of compromised health and underdevelopment. Promoting healthy lifestyles through health interventions in educational settings has proven effective at reducing the risk for NCDs. Furthermore, teachers' own health in these communities is also poor and their collaboration as role models is essential for a successful implementation of such lifestyle interventions. In this context, a concerted community-health programme called KaziBantu was designed to enhance literacy and health of both children (KaziKidz) and teachers (KaziHealth) and was implemented in schools of marginalized communities in Port Elizabeth. Preliminary results are positive regarding the intervention but also showed that some children and teachers were at risk of developing non-communicable diseases. At the same time, discontinuation of these programmes after the end of funding is high. Therefore, this study will follow-up the KaziBantu intervention in these schools to assess its sustained implementation and the achievement of health effects under real-world conditions. The first aim of this study is to first examine long-term improvement and preservation of health effects on metabolic risk factors for NCDs in at-risk children and teachers. The second aim is to evaluate long-term feasibility, acceptance, adoption, implementation, maintenance and dissemination of the both KaziKidz and KaziHealth interventions at an individual, community, organizational and institutional level in Port Elizabeth. The third aim is to explore correlations between health effects, health behaviours and adoption and implementation level.

Who can participate?
Children in 5th – 7th grades aged 9 to 14 and teachers aged 21 to 65 from the 8 schools that participated in the KaziBantu study and who were identified for having risk factors for cardiometabolic disease (e.g. obesity, high blood pressure, diabetes)

What does the study involve?
Children and teachers will be followed-up over a 2-year period, during which measurements of health status and disease history, blood tests and body composition, physical activity and nutrition will be assessed at two different time points. Teachers and parents of the children participating in the study, school principals from the eight participating schools and authorities from the Education department will be interviewed at two different time points in order to evaluate the feasibility, acceptance, implementation and maintenance of both KaziKidz and KaziHealth interventions.

What are the possible benefits and risks of participating?
Children will be assessed physically (by a professional school nurse) and clinically in terms of cardiovascular health risks and evidence of malnutrition (by qualified biokineticists) twice during the two-year period. These children would have the benefit of having their parents alerted to any red flag(s) identified during the assessment and they will be encouraged to take their child to the nearest clinic for a medical examination. They will also receive a referral letter providing details of the identified issue of concern. The child participants will also have the continued benefit of exposure to a school-based health promotion programme that their teachers were trained to implement and are hopefully successfully implementing on their own. Teachers will benefit as they will receive two free health assessments and a personalised health profile based on internationally established clinical cut-offs over the two-year period of the study. Additionally, the teachers will have the opportunity to participate in an online course on self-assessment of personal health to educate themselves on health and wellness knowledge. Furthermore, teachers presenting with severe chronic diseases (e.g., type 2 diabetes, obesity, high blood pressure) will receive a referral letter that they could present to their medical doctor, or a nearby health clinic. However, the cost of the latter consultations will be for their own account. Most measurements are non-invasive without specific risks involved. Blood lipids, haemoglobin and blood glucose levels are assessed with a finger prick blood test. The capillary blood sampling method is minimally invasive and, therefore, only involves minimal risks.

Where is the study run from?
1. University of Basel (Switzerland)
2. Nelson Mandela University (South Africa)
3. Swiss Tropical and Public Health Institute (Switzerland)

When is the study starting and how long is it expected to run for?
April 2020 to November 2021

Who is funding the study?
Swiss National Science Foundation (SNF) (Switzerland)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Swiss National Science Foundation (SNF) No. 320030_192651

Study information

Scientific Title
Sustainability of a school-based health promotion intervention in children and teachers at risk for non-communicable diseases in marginalised communities in Port Elizabeth, South Africa

Study objectives
The study aims at following-up an established school-based health promotion intervention in order to strengthen the evidence for its effectiveness in promoting long-lasting positive lifestyle changes that ultimately seek to improve cardiovascular risk factors such as obesity, hypertension, dyslipidemia and hyperglycemia among children and teachers in selected schools of marginalised areas of Port Elizabeth, South Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/07/2020, human research ethics committee (REC-H) from the Nelson Mandela University (PO Box 77000, Nelson Mandela University, Port Elizabeth, 6031, South Africa; +27 (0) 41 504 1111; info@mandela.ac.za), ref: H20-HEA-HMS-001
2. Approved 12/05/2020, Swiss ethics committee (Ethikkommission Nordwest- und Zentralschweiz, EKNZ, Hebelstrasse 53, 4056 Basel, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: Req-2020-00430
3. Approved 07/12/2020, Eastern Cape Department of Education (Private Bag X0032, 5605 Bhisho, South Africa; +27 (0)40 608 4200/8; viwe.mkona@ecdoe.gov.za)

Study design
Observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Non-communicable diseases: obesity, hypertension, diabetes, dyslipidemia

Interventions
Current interventions as of 10/03/2021:

A cohort of identified at-risk children and at-risk teachers from 8 quintile 3 primary schools in Port Elizabeth, South Africa, will be followed-up during a 2-year period.

Assessments of health outcomes and behaviours of both children and teachers will be collected at two time points.

Community feasibility and acceptance, as well as organizational and institutional implementation and dissemination levels, will also be enquired.

A comprehensive evaluation of these parameters will follow the RE-AIM framework and its proposed dimensions – (i) Reach, (ii) Efficacy, (iii) Adoption, (iv) Implementation and (v) Maintenance.

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Previous interventions:

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Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 10/03/2021:

Assessed 1 and 2 years post KaziBantu intervention:
1. Body weight, assessed using a digital weighing scale
2. Body height, assessed using a stadiometer
3. Body mass index, calculated as weight (kg)/height (m)2
4. Waist and hip circumference, assess using a tape
5. Body fat percentage, assessed using bioelectrical impedance analysis (BIA)
6. Self-reported health status, assessed by questionnaire
7. Blood pressure (systolic and diastolic), assessed using oscillometry with a digital blood pressure monitor
8. Blood lipids (TC, HDL-C, LDL-C, TG, Non-HDL, C-HDL ratio), measured using the Alere Afinion AS100 analyser
9. Blood glucose (HbA1c), measured using the Alere Afinion AS100 analyser
10. Haemoglobin concentration, assessed using the HemoCue Hb 301 system
11. Objectively measured physical activity, assessed using an ActiGraph accelerometer
12. Self-reported physical activity, assessed via the Health-Behaviour of School-Aged Children (HBSC) questionnaire
13. Self-reported diet, assessed via the 24-hour recall questionnaire
14. General health assessment, assessed for teachers via online seminar
15. Implementation status, assessed via questionnaire
16. Feasibility and acceptability, assessed via semi-structured interviews and focus group discussions

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Previous primary outcome measure:

Assessed 1 and 2 years post KaziBantu intervention:
1. Body weight, assessed using a digital weighing scale
2. Body height, assessed using a stadiometer
3. Body mass index, calculated as weight (kg)/height (m)2
4. Waist and hip circumference, assess using a tape
5. Body fat percentage, assessed using bioelectrical impedance analysis (BIA)

6. Physical examination, assessed face-to-face by a professional nurse
7. Self-reported health status, assessed by questionnaire
8. Blood pressure (systolic and diastolic), assessed using oscillometry with a digital blood pressure monitor
9. Blood lipids (TC, HDL-C, LDL-C, TG, Non-HDL, C-HDL ratio), measured using the Alere Afinion AS100 analyser
10. Blood glucose (HbA1c), measured using the Alere Afinion AS100 analyser
11. Haemoglobin concentration, assessed using the HemoCue Hb 301 system
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14. Self-reported diet, assessed via the 24-hour recall questionnaire
15. General health assessment, assessed for teachers via online seminar
16. Implementation status, assessed via semi-structured interviews
17. Feasibility and acceptability, assessed via focus group discussions once in the fall of 2021

Key secondary outcome(s))
The following control variables will be assessed via questionnaire 1 and 2 years post KaziBantu intervention:
1. Age
2. Sex
3. Socioeconomic status
4. Ethnicity
5. Home language
6. School
7. Grade

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/12/2020:
1. Children and teachers from the KaziBantu study population
2. Children aged approximately 10–13 years old (4th to 7th grade)
3. Teachers aged approximately 21–65 years old
4. Children identified for being at high-risk for non-communicable diseases defined as presenting at least:
4.1. Pre- or hypertension
4.2. Pre- or diabetes
4.3. Borderline or hypercholesterolemia
4.4. Overweight or obesity
5. Written informed consent by parent/guardian for children and by teachers

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4.1. Pre- or hypertension
4.2. Pre- or diabetes
4.3. Borderline or hypercholesterolemia
4.4. Overweight or obesity
5. Written informed consent by parent/guardian for children and by teachers

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
10 years

Upper age limit
65 years

Sex
All

Total final enrolment
459

Key exclusion criteria
1. Participation in another clinical trial
2. Lack of written informed consent

Date of first enrolment
15/02/2021

Date of final enrolment
15/03/2021

Locations

Countries of recruitment
South Africa

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

Sponsor information

Organisation
Swiss National Science Foundation

ROR
https://ror.org/00yjd3n13

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 17/11/2021:
The individual de-identified participant data generated during and/or analysed during the current study will be stored in the publically available repository https://zenodo.org. Consent from participants was obtained, by what access criteria the data will be shared including with whom, for what types of analyses, and by what mechanism. Data is composed of a range of quantitative and qualitative data including: anthropometric (body weight, height, waist and hip circumferences), clinical (blood pressure, blood lipid profile, HbA1c), physical activity (sports participations, type and amount of physical activity), diet behaviour (type and amount of food), intervention feasibility, acceptance and implementation. Data will become available 36 months after the end of the study for at least 10 years.

Previous individual participant data (IPD) sharing statement:
All participant level data will be stored in Excel and Pdf form in the publicly accessible Zenodo Data Repository (https://zenodo.org), which represents a non-profit storage and sharing solution for data compliant with the funding agency requirements (SNF FAIR Data Principles). 300 datasets will be collected at two different time points with an estimated volume of 100 GB. All participants - or children guardians - will sign a consent form submitted to and approved by the responsible ethics committee. The consent forms will authorize future sharing and usage of the data. Anonymity of the participants is guaranteed, as the researchers will not deposit raw files in order not to compromise this guarantee. Instead, anonymized transcripts of data files will be deposited. All identifying information will be kept in a locked filing cabinet and not stored with electronic files.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/05/2023	25/05/2023	Yes	No
Protocol article	protocol	05/10/2021	21/10/2021	Yes	No
Other publications	Qualitative descriptive study	01/04/2024	03/04/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes