ISRCTN68411960 https://doi.org/10.1186/ISRCTN68411960

Impact of disease burden and setting-specific interventions on schoolchildrens cardio-respiratory physical fitness and psychosocial health in Port Elizabeth, South Africa

Submission date
15/08/2014

Recruitment status
No longer recruiting

Registration date
01/10/2014

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
An unhealthy diet, high in sugar and salt, and a lack of exercise are both leading risk factors for ill-health. Together, they account for 10% of the global burden of disease (i.e. health-related costs, deaths and disabilities), as expressed in disability-adjusted life years (DALYs). The DALY measures overall disease burden by looking at the number of years lost due to ill-health, disability and early death. Studies have shown that the South African population now have a disease profile (i.e. the population are exposed to similar risk factors and develop similar diseases) similar to that of Western countries, with increasing numbers of deaths and DALYs attributed to chronic diseases. Yet, infectious diseases that are known to be caused by poor living conditions and poverty continue to occur in marginalized communities, such as school-aged children in poor neighbourhoods. The term dual burden is being used to describe this issue of growing public health concern. In-depth studies looking at this provide new insights into their impact on childrens physical fitness and psychosocial health. In turn, such insights are required to tailor setting-specific interventions (treatments or programmes) to improve childrens health and wellbeing. We want to look at the burden and distribution (for example, which neighbourhoods) of communicable diseases (e.g. intestinal protozoa and helminth infections) and non-communicable chronic conditions (e.g. type 2 diabetes and malnutrition) among school-aged children in selected schools in Port Elizabeth, South Africa, and to assess their impact on childrens physical fitness and psychosocial health.

Who can participate?
All primary schoolchildren from grade 4 (age range: 9-12 years) from selected disadvantaged schools.

What does the study involve?
All participants are tested for parasites and anaemia, their body measurements are taken, their physical fitness assessed and their cognitive performance tested (memory, attention span etc). For the intervention, treatment against soil-transmitted helminthiasis and schistosomiasis is

given, using a single dose of albendazole (400 mg) and praziquantel (40 mg/kg), respectively. Treatment is given to all study participants directly after the assessments at the beginning of the trial (baseline assessments) and then after 1 and 2 years. Reassessment of parasitic infection, presence of anaemia, body measurements, physical fitness and cognitive performance also take place after 2 years.

What are the possible benefits and risks of participating?
There are no specific risks associated with this study. Some participants may find giving stool and urine samples embarrassing but we try to avoid that by telling them why the samples are necessary and important to the study. Fingerprick tests are used to take blood samples. This is a minimally painful and usually well accepted procedure. Albendazole and praziquantel are widely used for preventive chemotherapy. These drugs might result in some side effects, but these are usually mild and dont last for long. Trained medical personnel involved in this study will take care of the children in case of medical emergencies. All participating children benefit from repeated de-worming with albendazole and praziquantel, two drugs that are recommended by the World Health Organization to control soil-transmitted helminthiasis and schistosomiasis.

Where is the study run from?
Historically black primary schools in the Port Elizabeth township of South Africa

When is the study starting and how long is it expected to run for?
September 2014 to August 2017

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

Who is the main contact?
Professor Uwe Pühse
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Impact of disease burden and setting-specific interventions on schoolchildrens cardio-respiratory physical fitness and psychosocial health in Port Elizabeth, South Africa: a cross-sectional epidemiological survey and cluster randomized controlled trial

Study objectives
1. The dual burden of communicable diseases and non-communicable chronic conditions in school aged children in selected schools near Port Elizabeth, South Africa, has a negative influence on the childrens cardio-respiratory physical fitness, cognitive performance and psychosocial health.
2. The burden of communicable and non-communicable chronic disease is differently distributed among schools and students with different social and demographic background.
3. Specific health interventions (e.g. lifestyle interventions and deworming) can improve children s health and wellbeing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee (Human) from the Nelson Mandela Metropolitan University (NMMU), Port Elizabeth, South Africa, 04/07/2014, ref. H14-HEA-HMS-002
2. Ethics Committee northwest/central Switzerland, 01/08/2014, ref. 2014-179

Study design
1. Cross-sectional clinical epidemiological survey
2. Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Communicable diseases (e.g. intestinal protozoa and helminth infections) and non-communicable chronic conditions (e.g. type 2 diabetes and malnutrition)

Interventions
The following intervention toolbox is proposed but the specific combination of interventions to be used will be governed by the key findings from the initial cross-sectional baseline survey: Physical fitness programmes, health education and administration of nutritional supplements or treatments. All participants of the study will be treated against soil-transmitted helminthiasis and schistosomiasis with a single dose of albendazole (400 mg) and praziquantel (40 mg/kg), respectively, at baseline, 1 year and 2 years (follow-up assessment) after launch of the study.

Intervention Type
Mixed

Primary outcome measure
1. The prevalence of communicable diseases (e.g. intestinal protozoa and helminth infections) and non-communicable chronic conditions (e.g. type 2 diabetes and malnutrition).
2. Differences (non-infected vs. infected) and changes (before and after treatment) in physical fitness levels, psychosocial health and cognitive performance.

Secondary outcome measures
1. Reduction of infection prevalence and intensity of soil-transmitted helminths and schistosomiasis.
2. Differences and changes in disease-related morbidity measures (malnutrition and anaemia).

Treatment will be administered to all study participants directly after baseline assessments, 1 year and 2 years after baseline. Reassessment of parasitic infection, anthropometric and haemoglobin measurements, clinical examination, physical fitness and cognitive performance will take place at the end of the study follow-up, 2 years after baseline.

Overall study start date
01/09/2014

Completion date
31/08/2017

Eligibility

Key inclusion criteria
1. Willing to participate in the study
2. Be in possession of a written informed consent by a parent/guardian on behalf of the child
3. Not participating in other studies
4. Being a primary school child aged 9-12 years, male or female
5. Absence of ill-health condition (e.g. severe anaemia, respiratory disease or other major illnesses), as assessed by a medical doctor at baseline.

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Approximately 1,000 schoolchildren

Key exclusion criteria
1. Children below the age of 9 years or above 12 years
2. Not having a written informed consent or no parental/legal guardians permission to participate
3. Suffer from medical conditions which prevent participation in the study, as determined by qualified medical personnel
4. Attending other clinical trials during the study period.

Date of first enrolment
01/09/2014

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
South Africa

Switzerland

Study participating centre
University of Basel
Basel
Switzerland
4052

Sponsor information

Organisation
University of Basel

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Department of Sport, Exercise and Health (DSBG)
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Sponsor type
University/education

Website
https://dsbg.unibas.ch/

ROR
https://ror.org/02s6k3f65

Organisation
Nelson Mandela Metropolitan University (South Africa)

Sponsor details
Department of Human Movement Science
Port Elizabeth
South Africa
-

Sponsor type
University/education

Organisation
Swiss Tropical and Public Health Institute (Switzerland)

Sponsor details
-
Basel
Switzerland
-

Sponsor type
Research organisation

Funder(s)

Funder type
Government

Funder Name
Swiss National Science Foundation (SNSF) (reference no. IZLSZ3_149015) (Switzerland)

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, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/12/2015		Yes	No
Results article	results	05/09/2016		Yes	No
Other publications	situational analysis	01/09/2017	08/04/2020	Yes	No
Results article	observational results	08/05/2017	08/04/2020	Yes	No
	results				

Results article		27/11/2017	08/04/2020	Yes	No
Results article	results	08/11/2018	08/04/2020	Yes	No
Results article	results	01/10/2017	08/04/2020	Yes	No
Results article	results	15/01/2019	08/04/2020	Yes	No
Results article	results	01/11/2016	08/04/2020	Yes	No
Results article	results	01/01/2018	08/04/2020	Yes	No
Results article	results	15/03/2018	08/04/2020	Yes	No
Results article	results	01/07/2018	08/04/2020	Yes	No
Results article	results	10/09/2020	22/10/2020	Yes	No