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Development and implementation of an evidence-based nutrition education programme for orphans and vulnerable children in Soweto, South Africa

Submission date
04/01/2019

Recruitment status
No longer recruiting

Registration date
14/01/2019

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Safeguarding healthy lives and promoting general well-being of orphans and vulnerable children (OVC) is a complex and challenging endeavour. In low and middle-income countries such as South Africa, little is known about the quality of life (QoL) and food intakes of the OVC. Nutrition remains a key public health problem, which negatively impacts on OVC's physical and cognitive performance. This may result in poor academic performance, future productivity and fitness. Children exposed to insufficient or unvaried diets are more likely to show academic snags. Some of the existing research that examined the relationship between quality of food intake and academic performance reported that there is a link between quality of food intake and academic performance. Quality of food intake has also been reported to be associated with learning capability, physical activities and QoL of children. One way of addressing this is to promote nutrition education programme (NEP) among OVC and their caregivers. The aim of this study is to explore factors that can make the OVC more vulnerable to untimely death. The information will be used in designing an effective nutrition education intervention tailored to the needs of the participants. The study also plans to measure the effects of the NEP on QoL, dietary intakes, physical activities, academic performance and body measurements of the OVC.

Who can participate?
Orphans and vulnerable children aged 12-17 and their caregivers

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. The caregivers of the OVC in the intervention group are given a brochure and 12 weeks of nutrition education teaching (using trainers manual, workbook and flipcharts). The control group only receive a brochure without nutrition education teaching. QoL, dietary intake, body composition and measurements, physical activity, academic performance, nutrition knowledge, attitude, and practices of the caregivers are measured at the start of the study, week 12 and week 24.

What are the possible benefits and risks of participating?
The possible benefit of taking part in this study is that NEP has been shown to have positive effects on children's QoL, academic performance and physical activity. None of the planned measurements are invasive and there are no known risks for the data collection methods. All procedures are standardized.

Where is the study run from?
University of Johannesburg (South Africa)

When is the study starting and how long is it expected to run for?
April 2019 to July 2020

Who is funding the study?
National Research Foundation (South Africa)

Who is the main contact?
1. Dr TK Bello
2. Prof. Pillay Jace

Contact information

Type(s)
Scientific

Contact name
Dr TK Bello

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An evidence-based nutrition education programme for orphans and vulnerable children: protocol on the development of nutrition education intervention for orphans in Soweto, South Africa using mixed methods research

Study objectives
It is hypothesised that the intervention group will show significant improvements in their primary and secondary outcomes compared to the control group at week 12 and week 24 (post-intervention).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Education Research Ethics Committee of the University of Johannesburg, B Ring 403, Tel: 011 559 2585; Email: davidr@uj.ac.za, ethical clearance number: 2018-035. The application has been submitted to Gauteng Department of Education

Study design
Interventional quasi-experimental design

Primary study design
Interventional

Secondary study design
Quasi experimental design

Study setting(s)
Other

Study type(s)
Quality of life

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
Orphans and vulnerable children

Interventions
The OVC and their caregivers will take part in the NEP. The caregivers of the OVC in the intervention group will be given a brochure and 12 weeks of nutrition education teaching (using trainers manual, workbook and flipcharts). Selected constructs of the Social Cognitive theory (SCT) and Health Belief Model (HBM) will be incorporated into the contents of the nutrition education materials to enhance learning and positive changes in attitudes and dietary behaviour. This will help to improve QoL, dietary diversity, physical activities anthropometric status and academic performance of the OVC. The intervention will entail the implementation of the NEP at the orphanage homes. The intervention participants will receive nutrition education materials and the 12 week NEP. The NEP is proposed to consist of: (i) an NE trainer's manual (ii) a participant's workbook to be used at home by the intervention participants to revise the topics that will be taught. This is expected to enhance participants' confidence in performing acquired knowledge and skills (iii) flipcharts for pictorial demonstration; so that participants will compile evidence through visual literacy (iv) a leaflet summarising the NEP for self-learning.

The control group will only receive a brochure without nutrition education teaching.

Primary (QoL) and secondary (dietary intake, body composition and anthropometric and measurements, physical activities measurements, academic performance, nutrition knowledge, attitude, and practices of the caregivers) outcomes will be measured at baseline, week 12 and week 24.

Intervention Type
Behavioural

Primary outcome measure
Quality of life of the orphans and vulnerable children, assessed using Kidscreen health-related quality of life questionnaire for children and adolescents at baseline, week 12 and week 24

Secondary outcome measures
Assessed at baseline, week 12 and week 24:
1. Dietary intake: The method of data collection here will be emancipatory participatory approach using photovoice and photo-assisted focus group discussions. There will be no pictures of people but pictures of foods and environment only. A single day no-quantified 24-hr recall of OVC will be obtained from the participants via their caregivers/families
2. Body composition and anthropometric and measurements: Tanita Dc-430 Body Composition Analyser (BCA) will be used. Participants will be allowed to stand on the BCA without shoes or socks. Participants' age, gender, and height will be entered manually into the BCA for calculations. Weight will be captured when the participants stand on the BCA. Height will be obtained using portable stadiometer
3. Physical activity measured using accelerometer
4. Academic performance obtained from standardized source via the participants' school administrators or national academic records
5. Nutrition knowledge, attitude, and practices (KAP) of the caregivers of the OVC, assessed using an interviewer-administered validated nutrition KAP questionnaire

Overall study start date
01/04/2019

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Are within the age range of 12-17 years
2. Lost one or both parents
3. Give both oral and written consent

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
520 orphans and vulnerable children

Key exclusion criteria
1. Below age 12 and above age 17 years
2. Has not lost one or both parents
3. Refuses to give both oral and written consent

Date of first enrolment
01/04/2019

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
South Africa

Study participating centre
University of Johannesburg
Faculty of Education University of Johannesburg
Soweto Campus
GNA 119, Robert Sobukwe Building
Johannesburg
South Africa
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Sponsor information

Organisation
National Research Foundation

Sponsor details
Physical Address:
NRF Building
South Gate
CSIR Complex
Meiring Naudé Road
Brummeria
Pretoria
South Africa
Postal Address:
Box 2600
Pretoria
0001
South Africa
Pretoria
South Africa
0001

Sponsor type
Government

Website
https://www.nrf.ac.za/content/nrf-contact-details

ROR
https://ror.org/05s0g1g46

Funder(s)

Funder type
Government

Funder Name
National Research Foundation

Alternative Name(s)
South Africa's National Research Foundation, National Research Foundation (South Africa), NRF

Funding Body Type
Government organisation

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

Location
South Africa

Results and Publications

Publication and dissemination plan
1. Study protocol: January 2019
2. Needs assessment data: October 2019
3. Baseline data, week 12 (intervention) and week 24 (follow-up) data: January to December 2020

Intention to publish date
01/12/2020

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	14/03/2019	06/01/2021	Yes	No