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Can nutrition education reduce undernutrition and disease severity in adolescents with sickle cell disease?

Submission date
05/12/2018

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Sickle cell disease (SCD) is an inherited genetic blood disorder that causes the normally disc-shaped red blood cells that carry oxygen throughout the body to be crescent-shaped. These cells are not as flexible as healthy red blood cells and can get stuck in small blood vessels to create blockages. The blockages can cause severe pain and organ failure if an organ is deprived of oxygen. The sickle cells are also not as long-lived as healthy red blood cells and so a person with SCD often suffers from anemia. SCD is most common in people of African ancestry, and sub-Saharan Africa carries almost 80% of the global burden of the consequences of the disease. Adolescents with SCD in sub-Saharan Africa tend to have inadequate food intake, poorer growth and nutrition compared with healthy peers. This has a negative impact on their growth, development and disease severity. Previous studies support the need for nutritional education to help reduce the risk of malnutrition and disease worsening. Currently, a number of hospitals with specialized SCD clinics in Ghana promote the need for increased fluid intake and supply adolescents with folic acid (vitamin B9) supplements routinely. Although studies have clearly shown this is not enough, there is however, no evidenced-based nutrition programme to guide caregivers and their adolescents on the best food selection to promote optimal health.
This study aims to assess the impact of a nutrition education programme on the nutritional status and disease severity of adolescents with SCD. In addition, the nutrition knowledge, attitude, and practices (KAP) of adolescents with SCD and their families will be explored. It is expected that participants will have increased nutrition knowledge that translates into increased fat-free body mass and reduced disease severity. This study will contribute evidence to support the importance of including evidence-based nutrition education in the comprehensive management of SCD in adolescents in Ghana.

Who can participate?
Adolescents with currently stable SCD who are not taking medications that affect growth.

What does the study involve?
Hospitals will be randomly assigned to either the intervention or control group. Adolescents with SCD who attend a hospital in the intervention group will receive the SCeDi (Sickle Cell

Disease) Nutrition Programme. This will provide age-appropriate nutrition education through individual and group counselling, which will last 6 months. At the start and end of the intervention, the participants' weight, height and body composition will be measured. Participants' and families' KAP around nutrition will be assessed using focused group discussions and in-depth interviews. Dietary intake will be assessed using a questionnaire.

What are the possible benefits and risks of participating?
This research will help healthcare professionals to understand the specific nutrition messages and delivery methods that will help to reduce how often young people with SCD get sick and reduce the complications that come with the disease. This will also help other parents and children in Ghana and elsewhere to get the appropriate nutrition information that they need to grow well. Each participant in the intervention group will receive the SCeDi Nutrition book and nutrition fact sheet, as well as the nutrition education and advice.
The potential risks are that participants may feel discomfort or pain during the taking of body measurements and blood samples. The researchers who do this will be fully trained and will follow a standard method designed to make participants comfortable and prevent any possible infection.

Where is the study run from?
The Department of Nutrition and Food Science, University of Ghana, Legon, Ghana

When is the study starting and how long is it expected to run for?
May 2016 toDecember 2020 (updated 20/07/2020, previously: August 2019).

Who is funding the study?
Carnegie-University of Ghana BANGA Project

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
37MH-IRB IPN 248/2018

Study information

Scientific Title
Sickle Cell Nutrition (SCeDi) Project: Effect of a nutrition education programme on nutritional status and disease severity of adolescents with sickle cell disease

Acronym
SCeDi

Study objectives
Participants in the intervention group are expected to have increased Fat-Free Mass (3 kg for boys and 1.7 kg for girls); 30% increase in nutrition-related Knowledge, Attitude, Practices and Perception (KAPP) and reduced disease severity (SI <6) compared with the control group at the end of 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. 37 Military Hospital Institutional Review Board, 19/11/2018, (Neghelli Barracks, Accra, Ghana; +233 302 769667; irbmilhosp@gmail.com), ref: 37MH-IRB IPN 248/2018
2. Korle Bu Teaching Hospital Institutional Review Board, (P O Box LG1195, Legon, Accra, Ghana; ethicscbas@ug.edu.gh), ref: KBTH-IRB/00088/2018
3. The University of Ghana, Ethics Committee of the College of Basic and Applied Sciences - ref: ECBAS 054/17-18

Study design
Multi-center cluster-randomised controlled trial (RCT)

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Sickle cell disease

Interventions
Adolescents attending the four selected hospitals will be randomized into either an intervention or control group. Every adolescent and their caregiver who meets the inclusion criteria will be contacted via phone using the clinic attendance register for their consent to join the study. Those who give their consent will be recruited to join the study. An equal number of participants from each hospital will be recruited to be in the control group.
Participants will be 470 adolescents with SCD (235 Intervention and 235 Control) attending hospital at Korle-Bu Teaching and the 37 Military Hospitals. The hospitals will be randomly assigned to either an intervention or control group. Adolescents with confirmed diagnosis of

SCD and who are appropriately described to be "in a steady state" will be included in the study. Those whose treatment has a direct impact on growth e.g. hydroxyurea will be excluded. The SCeDi (Sickle Cell Disease) Nutrition Programme will provide age-appropriate nutrition education through individual and group counselling, which will last 6 months.

In the intervention groups, adolescents and their caregivers assigned will receive personal (one-on-one) nutrition information and counseling. In addition, these adolescents and their caregivers will receive group nutrition education on appropriate, affordable, and safe food choices. The intervention will be designed to increase the daily energy intakes of the children by up to 40% with up to 35% of which will be from protein (Hyacinth et. al., 2013), compared with the Recommended Nutrient Intake for their healthy peers. For the non-intervention groups, adolescents will receive the regular basic nutrition education/counseling that is delivered at their clinics. The nutrition education plan will be repeated every month for 6 months.
1. SCeDi Nutrition Group Education
This entails
1.1. 30 minutes of general nutrition education to be delivered by a nutritionist who is part of the research team on the following topics:
i. Nutrition and its importance to the adolescent with SCD
ii. Meeting the energy and nutrient needs of adolescents with SCD
iii. Meeting the fluid needs of the adolescent with SCD
iv. Factors to consider when making food choices (including timing, quantity and food groups as recommended by the Food and Agriculture Organization of the United Nations [FAO])
v. Hygiene practices
1.2. 10 minutes question time for caregivers and adolescents
1.3. Participants to play the indoor Nutrition Feedback Board Game in a group of 2-8 adolescents. This is designed to reinforce learning and get feedback on lessons learnt from the group education (20 minutes).
1.4. Each participant will be also given a 1-page summarised nutrition information fact sheet.
2. SCeDi Nutrition One-on-One counseling Sessions
Estimated to be for 20 minutes per adolescent/caregiver pair in a private room to ensure confidentiality. This will be done by a registered dietician (RD) using the Healthy Teens Counseling Approach (Olson et. al., 2008). This motivational interviewing patientcentered approach is designed to encourage the adolescent to make informed decisions on food choices. The counseling process entails that the RD accounts for the energy and nutrient needs, and preferences of the individual participant (Gabel and Herrman, 2016). This will entail a process of constructive negotiation, to develop a shared agreement that is more likely to result in positive dietetic outcomes.
3. For easy reference once they return home, each participant will be given the SCeDi Nutrition book which will contain information discussed during the group session and also example local food recipes.

Qualitative data will be analyzed using the NVivo v.10 Software to generate themes to further inform the nutrition education programme for the intervention group. Children's body composition will be analyzed using the bioelectrical impedance analyzer device (Omron (BF511) and the Fourier-transform Infrared Spectroscopy Instrument which determines the percentage fat and fat-free mass. Weight (kg) and height (cm) will be measured to generate indices of stunting, wasting and underweight using the WHO AnthroPlus software. Dietary data from a 24-hour recall and Food Frequency Questionnaire will be analyzed using the Esha FPro 3.2 and RIING database to determine the estimated nutrients as well as the dietary diversity of all participants. Estimates will be compared to the Recommended Nutrient Intake (RNI) to determine adequacy (to be categorized as below, normal or above the RNI). Clinical measures (number of recurrence over the past 6 months, laboratory values and disease complications) will

be translated using the disease Severity Index (SI). Those with an index score of <6 will be classified as mild and those with ≤6 will be classified as severe. These quantitative data (socio-demographic, clinical data and nutritional status) will be summarized by means, and standard deviations using the SPSS v.20. Unadjusted and adjusted comparison of means (continuous variables) and percentages (binary variables) will be performed using general linear model (continuous variables) and logistic regression (binary variables).

Intervention Type
Behavioural

Primary outcome(s)
Percentage change in fat-free mass assessed using a bioelectrical impedance analyzer device (Omron (BF511) and the Fourier-transform infrared spectroscopy instrument, which determines the percentage fat and fat-free mass at baseline and 6 months

Key secondary outcome(s))
1. Knowledge, Attitude, Practices and Perception (KAPP) scores of all the adolescents using the FAO KAPP questionnaire
2. Disease Severity Index Scores calculated from number of recurrences (frequency of painful crises, hospitalization and blood transfusion over the past 6 months), laboratory values (haemoglobin level, bilirubin level, proportion of foetal haemoglobin (HbF), lactate dehydrogenase (LDH) level and leucocyte count) and disease complications (acute chest infection/syndrome, leg ulcers, gallstones, stroke, avascular osteonecrosis, osteomyelitis, enuresis, priapism, retinopathy, and deep vein thrombosis)
3. Stunting (height for age) assessed using using WHO AnthroPlus software
4. Wasting (weight for height) assessed using using WHO AnthroPlus software
5. Underweight (weight for height) assessed using using WHO AnthroPlus software
6. Nutrient intake and dietary diversity scores assessed using 24-hour recall and Food Frequency Questionnaire analyzed using the Esha FPro 3.2 and RIING database
All outcome measures were measured at baseline and endline (6 months).

Completion date
30/12/2020

Eligibility

Key inclusion criteria
1. Adolescents aged 10-19 years
2. Confirmed diagnosis of SCD and who are appropriately described to be ‘in a steady state’ (no history of stroke or long-term transfusion therapy for at least 4 weeks before the intervention, no hospitalization or intercurrent illness that required emergency or hospitalization 4 weeks before the study)
3. No other chronic disorder

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Child

Lower age limit
10 years

Upper age limit
19 years

Sex
All

Key exclusion criteria
Receiving any treatment that has a direct impact on growth e.g. hydroxyurea

Date of first enrolment
06/11/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Ghana

Study participating centre
Korle-Bu Teaching Hospital
Guggisberg Ave
Accra
Ghana
N/A

Study participating centre
37 Military Hospital
Neghelli Barracks
Accra
Ghana
N/A

Study participating centre
Tema General Hospital
Tema
Tema
Ghana
N/A

Study participating centre
Police Hospital
Accra
Ghana
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Sponsor information

Organisation
Carnegie-University of Ghana BANGA Project

ROR
https://ror.org/01r22mr83

Funder(s)

Funder type
University/education

Funder Name
Carnegie-University of Ghana BANGA Project

Funder Name
Hershey Project

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?

Interim results article	Knowledge and nutrition-related practices among caregivers	06/03/2023	19/05/2023	Yes	No
Participant information sheet			02/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes