Ten2Twenty-Ghana

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26929

Source
NTR

Brief title
Ten2Twenty-Ghana

Health condition

Anaemic girls

Sponsors and support

Primary sponsor: Wageningen University and Research and University for Development Studies
Source(s) of monetary or material Support: Edema-Steernberg Foundation (research money), Dr Judith Zwartz Foundation (fellowship, sandwich PhD), Nutricia Foundation (research grant) and Sight & Life (treatment product for RCT)

Intervention

Outcome measures

Primary outcome

Changes in micronutrient status
 Hb
 Serum ferritin (SF)
 Serum transferrin receptor (sTfR),

 Retinol-binding protein (RBP)
 Serum zinc
 Serum folate
 Vitamin B12

Secondary outcome

 Anthropometric indicators (e.g. attained height, height-for-age z-score, body-mass-index-for-age z-score) and body composition (bio-electric impedance)
 Cognitive development/skills
 Academic performance
 Perceptions and aspirations (qualitative)

Study description

Background summary

Adolescence with its rapid growth and maturation provides a unique window of opportunity to address nutritional problems highly prevalent among Ghanaian female adolescents. Investing in nutrition is vital for improving adolescent girl's health and development and that of their future offspring. However, limited knowledge on dietary intakes, nutrient gaps as well as type, timing and efficacy of needed interventions hampers progress. Nutrition is interwoven with social and economic life trajectories, and changes in nutrition may have synergies as well as trade-offs in health, education, family formation and labour participation. However, very few studies address the multiple trajectories and their interactions or interrelations. The overall aim of the research project proposed is to examine the interrelations between nutritional, social and economic trajectories of optimising nutrition of female adolescents for better health, family formation, education and labour participation in Ghana

Rationale: Stunting and underweight are prevalent among adolescent girls in Ghana and anaemia is a severe public health problem particularly among adolescent girls in the rural Northern Savannah agro-ecological zone of Ghana. Girls are more disadvantaged in household food distribution and resource allocation, more at risk of sexual violence and less educated compared to boys in Ghana. Moreover, during this life stage, changes in social status, duties and gender roles take place in differing social, cultural and physical contexts resulting in different challenges. These deprivations predispose adolescent girls in Ghana to malnutrition and undermine their development into adulthood. Malnutrition blocks not only girls' potential in important life domains, but also the health and well-being of future generations.
1. Irrespective of the increasing evidence of poor micronutrient status among adolescent girls, nutrition initiatives in Ghana have commonly focused on children and women neglecting adolescents. Consumption of food fortified with vitamin A, iron and multiple-micronutrients significantly increases haematologic markers and serum micronutrient concentrations among children and adolescents. However, whether to intervene before or after menarche to

achieve the most benefit remains unknown, and there is a paucity of data on dietary practices, nutrient intakes and behaviour of adolescent girls in low and middle-income countries including Ghana. Furthermore, little is known about the consequences of malnutrition during adolescence and the trade-offs in the social and economic trajectories when optimising nutrition during adolescence. According to the WHO, the lack of age and sex-specific data on health and nutritional status of adolescents at the national level is the primary underlying reason for widespread lack of policies and programmes for improving the health and nutritional status of adolescents. Hence, the proposed study aims to examine the interrelations between nutritional, social and economic trajectories of optimising nutrition of female adolescents for better health, family formation, education and labour participation in Ghana. In a randomised controlled trial (RCT), the study will evaluate the effect of consuming multiple-micronutrient fortified biscuits compared to unfortified biscuits (UB) five days/week for 26-weeks on micronutrient status and vertical growth of female adolescents, and how this is related to the timing of intervention (before or after menarche) and changes in health, education and fertility.

Study objective

1. Compared to unfortified biscuits (UB), consumption of multiple-micronutrient fortified biscuits five days/week for 26-weeks will improve micronutrient status and vertical growth of female adolescents
2. The timing of intervention (before or after menarche) with multiple-micronutrient fortified biscuits will result in different changes in health, education and fertility of adolescent girls.
3. There is an association between nutritional status and the social and economic trajectories (quality of life, cognitive ability, educational attainment, aspirations, life satisfaction, self-esteem, self-efficacy, quality of life, family formation and labour participation) of the adolescent girls

Study design

Baseline (Time 0) and End-line (Time 1)

Intervention

Participants in the treatment arm of the RCT will receive an multiple-micronutrient fortified biscuits (MMB) enriched with 11 vitamins (vitamins B1, B2, B6, B12, A, D, K1, E, niacin, folate and ascorbic acid) and 7 minerals (Zn, Ca, Fe, Cu, I, Se and Mg) whereas prticipants in the placebo arm of the RCT will receive unfortified biscuits (UB) similar in appearance to the MMB. Field assistants will supervise intake of the biscuits with the support of school teachers. Both the MMB and UB will weigh 40g and look similar in appearance, but different colours are used in the packaging without any labels to blind both the researchers and participants. Both biscuits (MMB and UB) will provide 477.3Kcal per 100g of energy (190.92Kcal for the 40g biscuit). The manufacturer keeps the colour keys and only discloses this to the researchers after the end-line data collection.

Contacts

Public
Wageningen University and Research
Fusta Azupogo

+233246280485
Scientific
Wageningen University and Research
Fusta Azupogo

+233246280485

Eligibility criteria

Inclusion criteria

1. Must be an adolescent girl in either age cohort (Pre-menarche: 10-13 years or post-menarche:14-17 years).
2. Apparently healthy without any visible any visible sign(s) of poor health, non-pregnant and non-lactating
3. Must have Hb ≥ 80g/L using a HemoCue in the field (will be referred to hospital if Hb <80g/L)
4. Not taking medication (medical drug use) or nutrient supplements (e.g. iron) at time of enrolment
5. Not currently participating in another intervention study with food, supplement or drug
6. Willing to consume biscuits from Monday-Friday (5 times per week) as a snack at school for 26 weeks
7. Must have no history of medical or surgical events that may significantly affect the study outcome
8. No sign of chronic infection or metabolic disorder
9. No Mental status that is incompatible with the proper conduct of the study
10. Not afraid to donate approximately 12ml of blood (~2.5 teaspoons) on 2 different occasions during the study
11. Willing to participate and informed consent of parent/guardian obtained

Exclusion criteria

1. Having a history of medical or surgical events that may significantly affect the study outcome.
2. Severely anaemic (Hb < 80g/L); excluded from the study and referred to the hospital.

3. Medical drug use.
4. Any sign of chronic infection or metabolic disorder.
5. Currently participating in another intervention study with food, a supplement or drug
6. Clinical signs of vitamin A deficiency (cornea ulceration, night blindness) and clinical signs of iodine deficiency (visible goitre).
7. Severely underweight (BAZ < -3 SD).
8. Have any known food allergy to biscuits.
9. Not willing or afraid to give up blood donation during the study.
10. Refusal of parents.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-02-2019
Enrollment:	620
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data will be handled confidentially and coded. When it is necessary to trace data of an individual subject, a subject identification code list will be used to link the data to the subject. The code will not be based on the subject's initials and birth-date. The principal investigator will safeguard the key to the code for the period of the trial including publication of findings. An independent person will be appointed to safely keep the code to the data in case the data or human material is kept for a more extended period. All study results will be reported in aggregated form so that participants will remain anonymous. Only members of the clinical team will have access to participant's records. Field staff will sign a written statement to

maintain the confidentiality of any personal information from (potential) trial participants to which they may become acquainted. Treatment effects of the fortified biscuits on micronutrient status will be analyzed using analysis of covariance (ANCOVA). The primary analysis of treatment effect will be per protocol analysis (compliance ≥ 80%); however, since this can lead to selection bias, we will also explore intention-to-treat analysis. The analysis will adjust for any socio-demographic and socio-economic related variables that differ between the fortified and unfortified biscuits group at baseline.

For continuous secondary outcome variables, mixed model analysis will be used with pre-defined contrast, i.e. time 2 vs 1. However, Cox proportional hazard models will be fitted for categorical outcome variables.

Ethics review

Positive opinion

Date:	01-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7487
Other	Navrongo Health Research Centre Institutional Review Board (NHRC-IRB) : NHRCIRB323

Study results

Summary results

Results will be reported in peer-reviewed international journals according to established guidelines about authorship (International Committee Of Medical Journal Editors) and reporting of randomised controlled trials and longitudinal studies. The principal investigator will authorise all publications and presentations relating to the study. Other named authors will include others who have played supervisory roles on the research (principal and co-principal investigators and field supervisor). In addition, research results will be shared through a workshop with invited participants from international organisations and fora for advocacy and technical support (e.g. UNICEF, USAID, GAIN.), national policy makers (e.g. Ghana Ministry of Health), and local research institutions (e.g. University for Development Studies and Navrongo Health Research Centre).