# Evaluation of an educational nutritional curriculum among adolescent girls in Zambia

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
26/02/2018	No longer recruiting	☐ Protocol		
<b>Registration date</b> 04/06/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
13/08/2021	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Background and study aims

Adolescence is a critical period in the lives of young people, and potentially a time to reap lasting benefits from interventions that improve general, nutritional, sexual, reproductive, and maternal and child health. Undernutrition in adolescent girls can have a direct impact on their immune function and susceptibility to infectious diseases, as well as increase mortality risk during childbirth. Micronutrient deficiencies, including iron, Vitamin A, and zinc deficiency, frequently result in lethargy and depression, and are associated with decreased cognitive function and productivity. Anemia is a critical health concern among pregnant adolescents who, if anemic, have an increased risk of death. Data from national surveys in Zambia indicate a high prevalence of deficiencies in both macro and micronutrients. The aim of this study is to assess the impact of an adolescent girls' empowerment program that includes a nutritional educational component on nutritional knowledge, behaviors and health outcomes. A broader objective is to provide evidence for the Zambian national government ministries to set policy priorities and develop strategic plans for scaling up cost-effective programs that address nutritional deficiencies in adolescent girls. The findings will also inform stakeholders and civil society working on nutrition and nutrition-sensitive interventions. A final aim is to inform donors about cost-effective approaches that increase the impact of nutrition interventions. Additionally, the study contributes to the knowledge base of nutritional research and effective methods for addressing anemia and other nutritional deficiencies in adolescent girls and their children.

#### Who can participate?

Vulnerable, never married adolescent girls aged 10–19, selected among all girls participating in a girls' empowerment program conducted over 2 years in urban and rural areas in four provinces of Zambia. In urban areas girls are selected from high-density housing compounds in the cities of Lusaka, Kabwe, Ndola and Kitwe. In rural areas, girls are selected from multiple adjacent villages or chiefdoms in Central, Copperbelt and Northwestern provinces. The empowerment program identified and targeted the most vulnerable girls living in selected program areas.

## What does the study involve?

The program areas are randomly allocated to receive the empowerment program or to not receive the program. Girls participating in the empowerment program's weekly girls' groups are additionally randomly allocated to receive, or not, the educational curriculum guided sessions on

nutrition. All girls selected to participate in the curriculum learn about general topics about food, micro and macro nutrients, and anemia; older adolescents 15–19, receive additional information on nutrition during pregnancy and proper infant and child feeding behaviors. All girls in the empowerment program girls' groups, regardless of whether they additionally receive the nutritional education component, participate in mentor-led sessions on the topics of sexual and reproductive health, life skills and financial education.

What are the possible benefits and risks of participating?

The benefits of participation are information regarding proper nutrition and anemia for themselves and their children, sexual reproductive health, life skills and financial education. Additionally, girls who participate in the research are tested for anemia, counselled on the results and referred to health services if found to be severely anemic. There are very minimal risks to the participant. The risks include any sensitivities to answering questions about themselves and, for those tested for anemia, from infection to the puncture of the finger prick.

#### Where is the study run from?

The study is community-based with interviews conducted at households within selected urban and rural areas of four provinces of Zambia

When is the study starting and how long is it expected to run for? November 2012 to July 2018

Who is funding the study?

Department for International Development (UK)

Who is the main contact? Dr Karen Austrian kaustrian@popcouncil.org

#### Study website

http://www.popcouncil.org/research/adolescent-girls-empowerment-program

# Contact information

# Type(s)

Public

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#### Scientific

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

Population Council Protocol 581; University of Zambia, Biomedical Research Ethics Committee protocol 008-11-12

# Study information

#### Scientific Title

Evaluation of the impact a randomized educational nutritional intervention on nutritional knowledge, dietary intake and anthropometric outcomes for girls 10-19 years of age participating in a The Adolescent Girls' Empowerment Program in Zambia

# **Study objectives**

- 1. The intervention will improve nutritional knowledge among exposed participants compared to unexposed participants
- 2. The intervention will improve dietary intake among exposed participants and their children compared to unexposed participants and their children
- 3. The intervention will improve anthropometric outcomes among exposed participants and their children compared to unexposed participants and their children

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

- 1. Population Council, Institutional Review Board, 24/10/2013, ref: 581
- 2. University of Zambia, Biomedical Research Ethics Committee, ref: 008-11-12

#### Study design

Two-arm randomized cluster evaluation

#### Primary study design

Interventional

#### Secondary study design

Cluster randomised trial

#### Study setting(s)

Community

#### Study type(s)

Prevention

#### Participant information sheet

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

#### Health condition(s) or problem(s) studied

Insufficient dietary intake, stunting, thinness, underweight, overweight, obesity, anemia

#### **Interventions**

Participants in this study included vulnerable, never married adolescent girls aged 10–19. The girls were selected among all girls participating in a girls' empowerment program conducted over two-years and implemented urban and rural areas in four provinces of Zambia. In urban areas girls were selected from high-density housing compounds in the cities of Lusaka, Kabwe, Ndola and Kitwe. In rural areas, girls were selected from multiple adjacent villages or chiefdoms in Central, Copperbelt and Northwestern provinces. The empowerment program identified and targeted the most vulnerable girls living in selected program areas. A random selection process determined whether girls in the pre-selected programs areas would be invited to participate in the empowerment program or would be assigned to non-program areas (control).

The Adolescent Girls Empowerment Program targeted adolescent girls drawn from lower-income backgrounds and invited them to participate in mentor-led weekly girls group meetings over the course of two years. Three curricula guided the meetings, including health and life skills, financial education and nutrition for adolescent girls. Half of the weekly girls' groups (mentors) were randomly assigned to an arm that included the nutritional curriculum, while half of the girls' groups (mentors) were randomly assigned to an arm that did not implement the nutritional curriculum.

All girls selected to participate in the nutritional curriculum learned about general topics about food, micro and macro nutrients, and anemia; older adolescents 15–19, received additional information on nutrition during pregnancy and proper infant and child feeding behaviors.

All girls in the empowerment program girls' groups, regardless of whether they additionally received the nutritional education component, participated in mentor-led sessions on the topics of sexual and reproductive health, life skills and financial education.

#### Intervention Type

Behavioural

#### Primary outcome measure

Survey data was collected annually, with Round 1 starting in 2013:

- 1. Nutritional knowledge: health/unhealthy foods; causes and signs and symptoms of anemia; proper infant and child feeding practices measured through survey interviews annually (Round 3-Round 5)
- 2. Nutritional behavior: dietary diversity, eating of nutrient rich foods, infant and child feeding practices measured through survey interviews annually (Round 1-Round 5)

#### Secondary outcome measures

- 1. Nutritional outcomes (stunting, thinness, underweight, overweight, obesity) using anthropometric measurements (Round 1-Round 5)
- 2. Anemia measured using point-of-care anemia testing (Round 3-Round 5)

#### Overall study start date

14/11/2012

#### Completion date

30/07/2018

# Eligibility

#### Key inclusion criteria

- 1. Residing in areas covered by the intervention program
- 2, Aged 10-19 at baseline
- 3. Assigned to a program girls group (mentor)
- 4. Sampled for the AGEP program evaluation

# Participant type(s)

Other

# Age group

Mixed

#### Sex

Female

# Target number of participants

2,660

#### Total final enrolment

2660

#### Kev exclusion criteria

1. Currently or formerly married at baseline

#### Date of first enrolment

07/01/2013

#### Date of final enrolment

# Locations

#### Countries of recruitment

Zambia

Study participating centre Lusaka Province, Zambia Zambia

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# Sponsor information

## Organisation

Population Council

#### Sponsor details

One Dag Hammarskjold Plaza New York United States of America 10017 12123390500 pubinfo@popcouncil.org

## Sponsor type

Research organisation

#### Website

www.popcouncil.org

#### **ROR**

https://ror.org/03zjj0p70

# Funder(s)

## Funder type

Government

#### **Funder Name**

Department for International Development, UK Government

## Alternative Name(s)

**DFID** 

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

**United Kingdom** 

# **Results and Publications**

#### Publication and dissemination plan

Manuscript submission to a peer-reviewed journal is expected in quarter 3 of 2018.

2018 results in https://www.popcouncil.org/uploads/pdfs/2018PGY\_AGEP-NutritionBrief.pdf

#### Intention to publish date

01/10/2018

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Paul C. Hewett (phewett@popcouncil.org); Karen Austrian (kaustrian@popcouncil.org). Type of data: individual level survey data, biomarker data, anthropometric data. Availability of data: currently available, no end date of availability. Criteria: user must complete a data use agreement form to access the data and obtain approval for use; there are generally no restrictions on the data use for program or research purposes, an exception is when there is a conflicts with other researchers and/or investigators who planned to publish on certain topics; these are evaluated on a case-by-case basis. Mechanism: the data and instruments are downloadable. Written informed consent (adults) or parental/guardian consent and minor assent (aged < 18 years) was obtained for all aspects of study participation and data collection. The data publicly available has been de-identified to protect the confidentiality of study participants. The data can be used only for non-commercial purposes.

# IPD sharing plan summary

Available on request

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results		01/01/2018	13/08/2021	No	No
Results article		22/07/2020	13/08/2021	Yes	No