

Evaluation of the Nia Project

Submission date 16/08/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/09/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The start of puberty and menstruation (menarche) is a specifically vulnerable time for girls, during which they begin to show interest in the opposite sex, while becoming exposed to many external pressures, including sexual coercion or harassment from boys and men, expectations to marry from their families, and the need to perform well in primary school in order to qualify for secondary school. These pressures can be increased by girls' lack of knowledge of their bodies, their rights, and the implications of their decisions, and by their inability to manage puberty and adolescence safely and comfortably with appropriate menstrual health and hygiene management (MHM) products. The aim of this study is to assess the effect of distributing Nia brand sanitary pads and providing reproductive health education (i.e., facilitated sessions and the Nia Teen magazine) on girls' education and reproductive health.

Who can participate?

Girls attending Class 7 in 140 schools in the Ganze, Kaloleni and Magarini sub-counties of Kilifi County in Kenya

What does the study involve?

Participating schools are randomly allocated to one of the following four groups:

1. Control group
2. Sanitary pad distribution
3. Reproductive health education
4. Sanitary pad distribution and reproductive health education

In groups 2 and 4, each girl receives a packet of 10 ZanaAfrica's Nia Teen brand disposable sanitary pads each month for the entire study period, and also receive two pairs of underwear at the start of the study and an additional pair at the start of each subsequent term. Groups 3 and 4 receive reproductive health education, comprised of facilitated health education sessions (FHE) and a health magazine developed by ZanaAfrica. The 25-session curriculum is delivered by trained facilitators during bi-monthly girls-only health clubs held during time allocated for extra-curricular activities in school for the duration of the study. ZanaAfrica's health magazine, Nia Teen, is distributed at the start of each term for the five-term period. Each issue corresponds directly to the topics covered in the Nia Yetu curriculum that term. The magazines are designed to appeal to adolescent girls and include activities, interviews with role models and a comic with characters. The control group receives the standard government/Ministry of Education provided life skills education and distribution of sanitary pads.

What are the potential risks and benefits of participating?

Participants may benefit by receiving sanitary pads and/or reproductive health education. There are no potential risks involved.

Where is the study run from?

This study is run by the Population Council in their Nairobi Office. The Nia Project is led by ZanaAfrica and they are partnering with Plan International to implement the interventions in Kilifi.

When is the study starting and how long is it expected to run for?

November 2016 to August 2019

Who is funding the study?

Bill and Melinda Gates Foundation (USA)

Who is the main contact?

1. Dr Karen Austrian

kaustrian@popcouncil.org

2. Dr Eunice Muthengi

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Study website

<http://www.popcouncil.org/research/evaluating-the-nia-project>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Identify the effect of menstrual health management interventions on girls' well-being and education in Kilifi County

Study objectives

1. Consistent distribution of pads will result in improved school attendance and participation/engagement in class.
2. Reproductive health education and training will result in improved Sexual and Reproductive Health and Rights (SRHR) knowledge, attitudes and norms.
3. Combining distribution of pads with reproductive health education will result in a greater improvement in school attendance, participation/engagement in class and SRHR knowledge, attitudes and norms.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Population Council Institutional Review Board, 06/10/2016, ref: 788
2. AMREF Ethical and Scientific Review Committee, 08/11/2016, ref: P292/2016

Study design

Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

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

Adolescent reproductive health

Interventions

The Nia Project interventions are implemented by ZanaAfrica. Girls enrolled in Class 7 at the start of the 2017 school year are the beneficiaries, receiving interventions over a period of 5

school terms, from May 2017 to December 2018. Before program implementation, a total of 140 schools in three rural Kilifi sub-counties (Magarini, Kaloleni and Ganze) were stratified by sub-county and randomly assigned to one of the following four study arms:

1. Control group
2. Sanitary pad distribution
3. Reproductive health education
4. Sanitary pad distribution + reproductive health education

Sanitary Pads

For the Nia Project, each girl receives one packet of 10 ZanaAfrica's Nia Teen brand disposable sanitary pads each month, for the entire project period. Project beneficiaries also receive two pairs of underwear at the start of the intervention, and an additional pair at the start of each subsequent term.

Reproductive Health Education

The Nia Project reproductive health education intervention is comprised of facilitated health education sessions (FHE) and a health magazine developed by ZanaAfrica. Nia Yetu, the curriculum for the FHE sessions, was developed by ZanaAfrica (2017) with many elements adapted from the Tuko Pamoja: Adolescent Reproductive Health and Life Skills Curriculum developed by PATH and Population Council as part of the Kenya Adolescent Reproductive Health Program (KARP). The 25-session curriculum is delivered by trained facilitators during bi-monthly girls-only health clubs held during time allocated for extra-curricular activities in school for the duration of the project period. ZanaAfrica's health magazine, Nia Teen, is distributed at the start of each term for the five-term period. Each issue corresponds directly to the topics covered in the Nia Yetu curriculum that term. The magazines are designed to appeal to adolescent girls and include activities, interviews with role models and a comic with characters.

The control group receives the standard government/Ministry of Education provided life skills education and distribution of sanitary pads.

Intervention Type

Mixed

Primary outcome measure

1. School attendance, assessed daily by staff members for a period of 4 weeks per term, starting in September 2017 through December 2018.
2. School participation/engagement, assessed using survey data at baseline in the first quarter of 2017 and after the intervention period in the first quarter of 2019
3. Sexual and reproductive health and rights (SRHR) knowledge, attitudes and norms, assessed using survey data at baseline in the first quarter of 2017 and after the intervention period in the first quarter of 2019

Secondary outcome measures

1. School retention and performance
2. Timing of pregnancy and birth
3. Timing of sex and sexual behavior

Assessed using survey data at baseline in the first quarter of 2017 and after the intervention period in the first quarter of 2019

Overall study start date

08/11/2016

Completion date

31/08/2019

Eligibility

Key inclusion criteria

Girls enrolled in class 7 in 140 project schools

Participant type(s)

Other

Age group

Child

Sex

Female

Target number of participants

Target is 25 girls per school, in 140 schools, therefore 3,500 girls

Total final enrolment

3489

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

22/02/2017

Date of final enrolment

09/05/2017

Locations

Countries of recruitment

Kenya

Study participating centre

Population Council, Nairobi Office

Avenue 5, 3rd Floor

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PO Box 17643 - 00500

Sponsor information

Organisation

Population Council

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.popcouncil.org/>

ROR

<https://ror.org/03zjj0p70>

Funder(s)**Funder type**

Charity

Funder Name

Bill and Melinda Gates Foundation

Alternative Name(s)

Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Publication and dissemination plan

Study protocol will be published in the last quarter of 2017. Planned publication of results in a high-impact peer reviewed journal by August 2020.

Intention to publish date

31/08/2020

Individual participant data (IPD) sharing plan

During the project, data will be shared only among collaborators from the study. At the conclusion of the project, anonymized versions of these data may be of general interest to the research community. All data will be deposited by August 2020 – the expiration of the award. The project data and metadata will be submitted to the Population Council's Dataverse public repository for providing broad access. Once these data have been submitted for archiving, the repository will have primary responsibility for long-term data curation and access control. The data available will be the quantitative data from the baseline and endline surveys, as well as qualitative transcripts. Informed consent will be obtained from study participants at end-line for use of de-identified data.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/12/2018		Yes	No
Results article	Intra-school-grade variability results	13/07/2020	04/03/2021	Yes	No
Results article	Outcome measure results	31/08/2021	21/09/2023	Yes	No