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Measuring the medium-term impact of school-based interventions as girls transition into adulthood

Submission date 19/12/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/12/2022	**Overall study status** Ongoing	
Last Edited 13/05/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Studies have been conducted to evaluate the benefits of keeping girls in school on their sexual and reproductive health and productivity. These suggested that most improvements occur if girls complete secondary education, with additional gains in child marriage and pregnancy for each extra year of school attended. They also noted that girls completing secondary school earn up to 5-fold more, have a one-third reduction in total fertility, increased contraception use by a third, and a ~25% reduction in child stunting compared with girls with no education. However, few follow-up studies have examined these effects and whether they have any longer-term effect as AGYW reach adulthood. There are conflicting results on lasting effects of school-based interventions when girls are followed up for about 2 years after finishing school, with one study showing a continued reduction in pregnancy rates, while another shows no difference in HIV rates compared with girls who had not received any school-based intervention. Our UK funded trial among 4,137 Kenyan secondary schoolgirls, providing cash, a menstrual cup, or both, examined if interventions reduce school dropout, HIV, HSV-2, and SRH harms compared with girls not provided interventions. As this trial has finished, we aim to follow-up prior trial participants to evaluate if previous school interventions have any effects on their health and social equity as they transition to adulthood and measure the cost benefits of the prior trial interventions.

Who can participate?

Girls who took part in the prior trial can participate.

What does the study involve?

The study will follow-up girls between July 2022 and October 2025, with two surveys with additional data captured through health facility record reviews. We will use a socio-behavioural survey questionnaire, ask some questions on their mental health, and offer HIV/HSV-2 testing to participants who previously tested negative, through individual follow-up of consenting girls (at home or in select community locations of their choice). We will examine if girls who previously received interventions have better decision making on health access, better SRH and mental health, if they have had less children, and if their children have been healthy, compared with girls

who received no interventions in the past trial. We will also conduct interviews and have discussion groups with girls, and with stakeholders to understand whether they perceived the past school interventions were of value.

What are the possible benefits and risks of participating?
Participants will receive items in the CCG2 Members Pack. Participants knowledge of their health status (HIV, HSV-2) will contribute to their improved health and social outcomes. Participants are thought likely to benefit from improving their self-esteem and autonomy by contributing to the study. Risks involve the taking of blood for HIV and HSV-2 tests, upset over some questions e.g., relating to personal history or violence, breaches of confidentiality. These will be mitigated where possible with uptake of safeguarding mechanisms, training, availability of counselling, signposting to services, and safe keeping of all documentation.

Where is the study run from?
Kenya Medical Research Institute, Kisumu, Kenya

When is the study starting and how long is it expected to run for?
April 2022 to October 2025

Who is funding the study?
Medical Research Council, United Kingdom

Who is the main contact?
Prof Penelope Phillips-Howard, Liverpool School of Tropical Medicine
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Contact information

Type(s)
Principal Investigator

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Prof Penelope Phillips-Howard

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LSTM REC: 22-030

Study information

Scientific Title
Cups or Cash for Girls Follow-up Study

Acronym
CCG2

Study objectives
As the cohort follow-up study is exploratory in nature it does not have a pre-specified hypothesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2022, Liverpool School of Tropical Medicine Research and Ethics Committee (Pembroke Place, Liverpool, L3 5QA, UK; lstmrec@lstmed.ac.uk; +44 151 702 9396) Ref: #22-030

Study design
Single site longitudinal study following up a cohort of participants in a prior school-based trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

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

Potential reduction in sexual and reproductive health and mental health harms as schoolgirls transition out of school into adulthood

Interventions
Prior trial interventions:
1. One reusable menstrual cup
2. Cash transfer pocket money (~$15 per school term)
3. Menstrual cup plus cash transfer
4. Control; cup provided at end of prior trial
The prior trial is registered at https://clinicaltrials.gov/ct2/show/NCT03051789

The present trial is a follow up survey of participants from the prior trial.

Intervention Type
Mixed

Primary outcome measure
No one primary outcome, as this is exploratory comprising health and social equity (see below for all outcomes)

Secondary outcome measures
1. Health
1.1. Number of participant deaths measured using mobile alert system and survey
1.2. Reported PHQ-9-A score measured using questionnaires at survey
1.3. Number of and incidence of intimate partner violence measured using questionnaires at survey
1.4. Other mental health scores (GAD, PCL) measured using questionnaires at survey
1.5. Number and prevalence of cigarette smokers measured using questionnaires at survey
1.6. Number and prevalence of alcohol drinkers measured using questionnaires at survey
1.7. BMI score and weight status (underweight[<18.5], healthy[18.5-24.9], overweight[25-29.9], obese[30>]) measured using anthropometric measurement at survey
1.8. Number and prevalence of clinically obese measured using anthropometric measurement at survey
1.9. Number and prevalence of anaemia measured using hospital records
2. Sexual health:
2.1. Number of and incidence of HIV measured using questionnaires at survey
2.2. Number of and incidence of HSV-2 measured using questionnaires at survey
2.3. Age sexual debut measured using questionnaires at survey
2.4. Number of sex partners measured using questionnaires at survey
2.5. Age at time of first born measured using questionnaires at survey
2.6. Age at marriage measured using questionnaires at survey
3. Reproductive health:
3.1. Number of and incidence of pregnancies measured using questionnaires at survey
3.2. Number and incidence of live births measured using questionnaires at survey, mobile alert system, hospital records
3.3. Number and incidence of stillbirths measured using questionnaires at survey, mobile alert system, hospital records
3.4. Number and incidence of abortions measured using questionnaires at survey, mobile alert system, hospital records
3.5. Number and incidence of neonatal, post-natal, infant deaths measured using questionnaires

at survey, mobile alert system, hospital records
3.6. Number and incidence of low birth weight (LBW) babies measured using hospital records
3.7. Number and incidence of infant / child stunting measured using hospital records
4. Health seeking, health care
4.1. Number of ANC visits during pregnancy using questionnaires at survey, hospital records
4.2. Place of delivery of offspring using questionnaires at survey, mobile alert system, hospital records
4.3. Number and prevalence of offspring with infant vaccinations given using questionnaires at survey, mobile alert system, hospital records
4.4. Resorts to health care if sick (Index depicting healthcare-seeking behaviour) using questionnaires at survey, mobile alert system, hospital records
5. Covid-19
5.1. Number and prevalence having covid-19 vaccine using questionnaires at survey
5.2. Number and incidence of covid infections using questionnaires at survey
5.3. Number and proportion who have been vaccinated using questionnaires at survey
5.4. Number and prevalence of AGYW reporting covid-related changes in behaviours using questionnaires at survey
5.5. Number and prevalence of AGYW reporting covid-related changes in income and employment using questionnaires at survey
6. Prior intervention prospective measures and social equity
6.1. Number and prevalence of menstrual cup use using questionnaires at survey
6.2. Number and prevalence of prior dropouts who returned to school using questionnaires at survey
6.3. Attainment (KCSE grade) using school records
6.4. Participant educational level reached (incomplete secondary, completed secondary, tertiary) using questionnaires at survey
6.5. Partner or husbands' education level (grade reached) using questionnaires at survey
6.6. Employed (occupation; part-time, full time) using questionnaires at survey
6.7. Annualised own / family income using questionnaires at survey

Overall study start date
01/04/2022

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Adolescent girls and young women who were enrolled as schoolgirls in the prior CCG trial
2. Stakeholders who live and/or work in the area of the prior CCG trial

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
4137 secondary schoolgirl participants that were enrolled into the prior school trial; plus ~72 stakeholders

Key exclusion criteria
1. Adolescent girls and young women not participating in the prior trial
2. Adolescent girls and oung women in prior trial who refuse consent
3. Stakeholders who do not have daughters, or who do not work with adolescent girls and young women

Date of first enrolment
09/02/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Kenya

Study participating centre
Kenya Medical Research Institute
Centre for Global Health Research
Kisian Campus
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Sponsor information

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ROR
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Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
In country dissemination will be conducted at community, regional and national level as part of the research development process. Community feedback will include to the participants and their parents and guardians. Research publications will be completed and published through open-access journals. We will maximise research uptake through the Ministry who will contribute to study design, health service linkage, interpretation of findings and support policy planning. Findings will be shared with Kenya's Technical Working Group on adolescent health, SRH, and mental health to support updates on policy, strategy and guidelines for school-based interventions for AGYW, and whether other interventions are required post-school attendance. We will prepare topics for dissemination across different actors and stakeholders, utilising existing platforms e.g. coalitions, hubs and weblinks. Findings will be shared with SRH, maternal, HIV, COVID-19, and public health academics and other groups and via meetings, presentations, and publications.

Intention to publish date
01/01/2026

Individual participant data (IPD) sharing plan

Data for this study will be available upon request, after obtaining written approval for the proposed analysis from the KEMRI SERU. Their application forms and guidelines can be accessed at https://www.kemri.org/seru-overview. To request these data, please contact the KEMRI SERU at seru@kemri.org.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.5	10/07/2022	19/12/2022	No	No