

BMC Public Health

Menstrual cups and cash transfer to reduce sexual and reproductive harm and school dropout in adolescent schoolgirls: study protocol of a cluster-randomised controlled trial in western Kenya

--Manuscript Draft--

Manuscript Number:	PUBH-D-19-00698R3	
Full Title:	Menstrual cups and cash transfer to reduce sexual and reproductive harm and school dropout in adolescent schoolgirls: study protocol of a cluster-randomised controlled trial in western Kenya	
Article Type:	Study protocol	
Section/Category:	Global Health	
Funding Information:	UK-Medical Research Council/Department for International Development/Wellcome Trust/Department of Health and Social Care (MR/N006046/1)	Dr. Penelope A. Phillips-Howard
Abstract:	<p>Background: Adolescent girls in sub-Saharan Africa are disproportionately vulnerable to sexual and reproductive health (SRH) harms. In western Kenya, where unprotected transactional sex is common, young females face higher rates of school dropout, often due to pregnancy, and sexually transmitted infections (STIs), including HIV. Staying in school has shown to protect girls against early marriage, teen pregnancy, and HIV infection. This study evaluates the impact of menstrual cups and cash transfer interventions on a composite of deleterious outcomes (HIV, HSV-2, and school dropout) when given to secondary schoolgirls in western Kenya, with the aim to inform evidence-based policy to improve girls' health, school equity, and life-chances.</p> <p>Methods: Single site, 4-arm, cluster randomised controlled superiority trial. Secondary schools are the unit of randomisation, with schoolgirls as the unit of measurement. Schools will be randomised into one of four intervention arms using a 1:1:1:1 ratio and block randomisation: (1) menstrual cup arm; (2) cash transfer arm, (3) cups and cash combined intervention arm, or (4) control arm. National and county agreement, and school level consent will be obtained prior to recruitment of schools, with parent consent and girls' assent obtained for participant enrolment. Participants will be trained on safe use of interventions, with all arms receiving puberty and hygiene education. Annually, the state of latrines, water availability, water treatment, handwashing units and soap in schools will be measured. The primary endpoint is composite of incident HIV, HSV-2, and all-cause school dropout, after three years follow-up. School dropout will be monitored each term via school registers and confirmed through home visits. HIV and HSV-2 incident infections and risk factors will be measured at baseline, mid-line and end-line. Intention to treat analysis will be conducted among all enrolled participants. Focus group discussions will provide contextual information on uptake of interventions. Monitoring for safety will occur throughout. Discussion: If proved safe and effective, the interventions offer a potential contribution toward girls' schooling, health, and equity in low- and middle-income countries.</p>	
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Response to Reviewers:	<p>16 August 2019</p> <p>Dear Editors at BMC Public Health,</p> <p>We were so pleased to have our manuscript entitled "Menstrual cups and cash transfer to reduce sexual and reproductive harm and school dropout in adolescent schoolgirls: study protocol of a cluster-randomised controlled trial in western Kenya" reviewed by you and your reviewers. We very much appreciate the time and effort put into considering this paper. We have responded to the raised points below and incorporated all changes into our manuscript as described.</p> <p>1. Please remove Appendix 1 from the file inventory, as it contains personal information. Please also remove all references to it in the text.</p> <p>Thank you for noting this. We have removed Appendix 1 (Full protocol) from the file inventory and have replaced it with Appendix 1 (SPIRIT checklist).</p> <p>Reference to Appendix 1 (Full protocol) has been removed from the main body of the text (see lines 105, 424, 490, and 551).</p> <p>Reference to Appendix 1 (Spirit checklist) has been added to line 115.</p> <p>Please do not hesitate to contact me with any additional feedback or questions.</p> <p>Kind Regards,</p> <p>Ms. Garazi Zulaika</p>

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Cups or Cash for Girls Trial (CCG) v8 16Aug19

1 Title

2 Menstrual cups and cash transfer to reduce sexual and reproductive harm and school dropout in
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31 **Abstract**

32 **Background:** Adolescent girls in sub-Saharan Africa are disproportionately vulnerable to sexual and
33 reproductive health (SRH) harms. In western Kenya, where unprotected transactional sex is
34 common, young females face higher rates of school dropout, often due to pregnancy, and sexually
35 transmitted infections (STIs), including HIV. Staying in school has shown to protect girls against early
36 marriage, teen pregnancy, and HIV infection. This study evaluates the impact of menstrual cups and
37 cash transfer interventions on a composite of deleterious outcomes (HIV, HSV-2, and school
38 dropout) when given to secondary schoolgirls in western Kenya, with the aim to inform evidence-
39 based policy to improve girls' health, school equity, and life-chances.

40 **Methods:** Single site, 4-arm, cluster randomised controlled superiority trial. Secondary schools are
41 the unit of randomisation, with schoolgirls as the unit of measurement. Schools will be randomised
42 into one of four intervention arms using a 1:1:1:1 ratio and block randomisation: (1) menstrual cup
43 arm; (2) cash transfer arm, (3) cups and cash combined intervention arm, or (4) control arm.

44 National and county agreement, and school level consent will be obtained prior to recruitment of
45 schools, with parent consent and girls' assent obtained for participant enrolment. Participants will
46 be trained on safe use of interventions, with all arms receiving puberty and hygiene education.
47 Annually, the state of latrines, water availability, water treatment, handwashing units and soap in
48 schools will be measured. The primary endpoint is composite of incident HIV, HSV-2, and all-cause
49 school dropout, after three years follow-up. School dropout will be monitored each term via school
50 registers and confirmed through home visits. HIV and HSV-2 incident infections and risk factors will

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be measured at baseline, mid-line and end-line. Intention to treat analysis will be conducted among all enrolled participants. Focus group discussions will provide contextual information on uptake of interventions. Monitoring for safety will occur throughout.

Discussion: If proved safe and effective, the interventions offer a potential contribution toward girls' schooling, health, and equity in low- and middle-income countries.

Trial registration: ClinicalTrials.gov NCT03051789, 15th February 2017

Keywords: Sexual and reproductive health; adolescence; equity; HIV; HSV-2; pregnancy; school dropout, clinical trial, menstruation, Kenya, study protocol.

Background

Young persons aged 10-24 years (yr) make up a quarter of the worlds' population, contributing 1.8 billion persons of whom approximately 90% live in low or middle-income countries (LMIC). Adolescence is a critical time of psychological and biological change, and advocacy has increased to identify interventions that protect young peoples' lives (1). These interventions include ways to protect against sexual and reproductive health (SRH) harms, which are disproportionately high among adolescent girls in sub-Saharan Africa (SSA) (2, 3). Each year an estimated 14 million girls aged 15-19yr give birth (2). Maternal causes kill more girls in this age group than any other cause (2). Thus, delaying pregnancy to adulthood is important for women's reproductive health and infants survival as well as their economic and social empowerment (4). In much of east and southern Africa including western Kenya, where unprotected transactional sex is common, young females are highly vulnerable to sexually transmitted infections (STIs), including HIV which may result in mother-to-child transmission (2, 3). The burden of young female SRH harms is high for individuals, and on their communities and health services, yet sustainable preventive interventions are lacking. Evidence of a positive association between girls' education, and their health and economic potential, has strengthened international resolve to improve educational opportunities for adolescent girls. While SRH education has not been

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76 demonstrated to have a large impact on SRH harms (5), staying in school has shown to protect girls
77 against early marriage, teen pregnancy, and HIV infection, with schoolgirls reporting less frequent sex,
78 and fewer partners with less age disparity (6-8). Building on the Millennium Development Goals
79 (MDG), which focused on primary school attendance, the post-2015 Sustainable Development Goals
80 encourage investment in secondary, tertiary and vocational education to build human capital,
81 encourage innovation and spur economic growth (9).

82
83 Intervention studies using cash transfer (CT) have demonstrated a protective effect on girls SRH
84 (including HIV, HSV-2) and school indicators (8, 10, 11), although results in other studies have been
85 inconclusive (12, 13). Dropout before secondary school completion is partly explained by girls'
86 vulnerability once they engage in premarital sex, which is often a precursor to unintended pregnancy
87 or early marriage (7, 14, 15). Studies have illustrated adolescent girls' vulnerability to transactional
88 or coercive sex, to obtain necessities such as soap, sanitary products, and underwear (16-19).
89 Products for menstrual hygiene management (MHM) are one such necessity, and their accessibility
90 remains a pervasive problem in LMIC. A lack of MHM materials, awareness, and facilities, as well as
91 stigma, negatively impact girls' school-life (20, 21), and can be a driver of girls' vulnerability to
92 coercive sex. In western Kenya, 10% of 15yr old girls self-reported they obtained money through sex
93 to purchase sanitary products (22). To better understand girls MHM needs in western Kenya, a pilot
94 study in rural primary schools was conducted measuring girls' menstrual practices, uptake, and
95 safety of a reusable menstrual cup (MS Pilot Study) (23, 24). The pilot results demonstrated
96 acceptability of the menstrual cup (25), with a lower prevalence of STI and bacterial vaginosis found
97 at 9 and 12 month follow-up among girls using the cup when compared to controls (26), and good
98 clinical safety (16). Prevalence of school dropout after 12 months was lower but inconclusive due to
99 the small sample (26).

101 To verify the results of the MS Pilot Study and examine the efficacy, safety, and cost-effectiveness of
102 different school-based interventions in improving girls' SRH, schooling, and life-chances in rural
103 western Kenya, a randomized controlled trial was designed with a larger population and follow-up
104 duration. The study is designed to inform evidence-based policy to improve girls' health, school
105 equity and their life-chances which is summarised in this article.

107 **Methods**

108 **Design Overview**

109 This study is a single site, open-label, 4-arm, school-cluster randomised controlled superiority trial
110 taking place in Siaya County, western Kenya. Schools are the unit of randomisation (clusters), with
111 girls as the unit of measurement. Schools will be randomly allocated into 4 arms using a 1:1:1:1 ratio
112 and block randomisation to minimise bias. Enrolment will open in the first school term of 2017 after
113 trial registration and continue until we reach the necessary sample. Girls will be followed-up through
114 graduation and into employment or up to 10 academic terms to determine if they complete
115 secondary school (Form 4), see Appendix 1: Spirit Checklist.

117 **Primary objective**

118 To determine the impact of menstrual cups or CT alone, or in combination, on a composite of
119 deleterious outcomes (HIV, HSV-2, and school dropout) when given to secondary schoolgirls in
120 western Kenya.

122 **Secondary objectives**

- 123 1. To measure the age-specific differences in the acquisition of HIV and HSV-2 infections in
124 secondary schoolgirls and risk factors for incident HIV and HSV-2 infections.

- 125 2. To determine the risk, risk factors and reasons for dropout and other school indicators among
126 secondary schoolgirls examining the influence of social, epidemiological, and/or health
127 characteristics.
- 128 3. To determine the cost benefit of menstrual cup and CT programmes for schoolgirls by assessing
129 the cost savings of outcomes averted, for individual and combined interventions, and resulting
130 societal impact.
- 131 4. To determine the safety of menstrual cup use, including risk of cup contamination over time,
132 serious adverse events, and identify factors that increase or modify this risk.
- 133 5. To determine factors affecting how adolescent girls spend CT money, and what training is
134 required to support their financial literacy and decision-making.
- 135 6. To determine any adverse outcomes associated with CT and evaluate ways to mitigate risk.
- 136 7. To determine the impact of the interventions on girls' sexual behaviours, including age of sexual
137 début, coerced sex, number of partners, age of partners, pregnancy, condom use and use of
138 contraception.
- 139 8. To examine programme implementation for interventions in schools, working with beneficiaries
140 and stakeholders to develop programme implementation packages.

142 **Design Considerations**

143 *Why secondary schoolgirls?*

144 Among schools located in our proposed study area, the dropout rates are higher among girls in
145 secondary when compared to primary school girls. Unpublished school enrolment data for 2015 in
146 the study location shows that only 26% of primary school girls drop out of primary school compared
147 to 36% who drop out of secondary school (local school enrolment data, unpublished). These high
148 dropout rates for secondary schoolgirls exert a high burden on the national economy, with lifetime
149 cost of dropout estimated to be 48% of GDP (4). Our pilot study found that following the abolition of
150 primary school fees 6 years ago, girls complete primary at a younger age (<15yr). Thus, fewer girls in

151 primary school reach menarche and sexual debut. While prevalence of HIV was low in our primary
152 school cohort (<1%), health studies in the same study area have documented very high HIV
153 incidence for secondary school-aged girls, who range in age from 13-30. In one study, HIV prevalence
154 was 8.8% in 15-19yr olds, sharply rising from 1.3% among 13-14yr olds to 3.3% in 16yr olds and
155 12.8% in 18yr olds (27). A similar steep increase by age was seen in HSV-2 prevalence (27). A high
156 prevalence of STIs was detected in 15-19yr old girls in neighbouring Kisumu (28). In pilot study focus
157 group discussions (FGDs), when asked about reasons for drop out, girls voiced reasons linked to
158 exposure to sexual activity (resulting from alcohol, funeral parties, needs for money, and coercive
159 sex), and these were more frequently stated among older girls (17). During these FGDs, girls were
160 able to vocalise their concerns about pregnancy risks, and issues around lack of money for school
161 and personal needs. They reported that their menstrual needs were unmet but a high priority and at
162 times compelled them to have sex to obtain money to buy pads (17). In a separate study in the same
163 area, 10% of 15yr olds surveyed reported they had sex for money in order to purchase sanitary pads
164 (22).

165

Justification for a composite endpoint

167 The primary composite endpoint will include incident HIV, HSV-2, and school dropout in girls sero-
168 negative or for both HIV and HSV-2 on enrolment or undetermined sero-status at enrolment
169 (conservatively the sample size allows for 20% refusal for testing at baseline). The presence of HIV or
170 HSV-2 at enrolment precludes the components from contributing to the primary composite
171 endpoint. Thus, among HIV-negative girls who were HSV-2 positive on enrolment only incident HIV
172 infection and school dropout would contribute to the primary endpoint; among girls who are both
173 HIV and HSV-2 positive on enrolment, only school dropout would contribute. This endpoint
174 represents the key drivers compromising girls' health and life chances into adulthood. The rationale
175 behind this composite endpoint is to increase the power for a given sample and to build a single
176 outcome across all girls regardless of their independent HIV and/or HSV-2 status at enrolment.

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178 *Justification for cumulative school dropout*

179 The cumulative risk of school dropout among secondary schoolgirls is an acute problem in western
180 Kenya; 36% of girls drop out before the start of the fourth and final year of secondary school due to
181 teen-age pregnancy, lack of school funds, illness, work or family commitments, or viewing school as
182 unnecessary (17). The need for MHM is also perceived as a constant stressor impacting school-life
183 given that traditional MHM items (rags, paper, etc) leak, cause odour and discomfort, and cause girls
184 to habitually miss school and fall behind. Some evidence suggests that poor MHM even leads some
185 to engage in transactional sex for essential 'luxuries' such as pads and soap (17, 22). During the pilot
186 study (23-25), we found that use of MHM products (reusable menstrual cups or pads) for at least 1
187 year had the potential to prevent school dropout (26). CT programs also have shown potential for CT
188 improving the odds of being enrolled in and attending school, improving household socio-economic
189 status (SES) and quality of life, and reducing early marriage (29, 30). In the trial, we define dropout
190 as not attending school consecutively for at least 1 term or longer. Girls who attended part or all of
191 Form (class) 4, but then do not sit the final national Kenya Secondary Certificate of Education (KSCE)
192 exams will be considered a dropout in that final term. Other secondary school indicators such as
193 grade repetition will also be documented. Girls who return to school after being classified as a
194 dropout will be classified as re-enrolled.

195

196 *Justification for cumulative risk of incident HIV and HSV-2*

197 Risky sexual exposure can cause harm to a girl's sexual and reproductive health and negatively affect
198 her life-chances even while remaining in school. The pilot showed high prevalence of laboratory
199 confirmed STIs in this rural area in western Kenya even among primary schoolgirls (28% of girls had
200 reproductive tract infections, predominantly bacterial vaginosis) (26, 31). Community surveys in the
201 pilot site found an HIV prevalence of 11% among females under 30yr, rising from 1% in 15yr to 20%
202 by age 29 (22, 27), and a reported 52% of girls in this area engaging in transactional sex for money,

203 gifts or services (32). HSV-2 is the most common cause of genital ulcer disease worldwide, the most
204 prevalent STI in sub-Saharan Africa, and a well-established biomarker for sexual risk behaviour (8,
205 33, 34). Evidence suggests HSV-2 prevalence in girls in the study area increases from 10% in 13-14yr
206 to 28% in 15-19yr, and 70% among the 20-24yr (27, 35).

207
208 A trial in Malawi that provided CT to school girls aged 13-22yr found that HIV and HSV-2 prevalence
209 were 33% and 70% lower respectively in CT recipients after 18m intervention when compared to
210 controls (8). Results were supported with reduced frequencies of self-reported sexual activity and
211 less age discordant sex (8). The impact of menstrual cups on HIV or HSV-2 has not been evaluated,
212 but when assessed during the pilot study, cups were associated with a lower prevalence of STIs and
213 bacterial vaginosis (26), both important risk factors for HIV acquisition and transmission (36-38). This
214 information corroborates reported narratives that control-arm girls most acutely felt the need to
215 have sex to obtain sanitary pads (24, 25). Laboratory confirmation of infections is essential, however,
216 as girls and young women's reported symptoms are poorly predictive of infection (31, 39-43).

217
218 **Study setting**

219 The study will be conducted in in schools in Siaya County in rural western Kenya, extending to
220 contiguous areas that include Kisumu County if needed. The site is in a health and demographic
221 surveillance system (HDSS) positioned 400 km west of Nairobi, with its southernmost point reaching
222 Lake Victoria (44). The population are mostly members of the Luo ethnic group, and are mainly
223 subsistence farmers (45). Siaya is an impoverished area, with previous studies estimating households
224 have a mean annual income approximating \$600 to \$700 (46). An estimated four out of ten child
225 learners miss school daily in Siaya County (47). Gender equity seen in primary school falls during
226 adolescence, with between 25%-33% more boys than girls attending secondary school by age 18 (48,
227 49). The disease burden typifies rural African communities (44), with mortality in adolescents and
228 young adults attributed to communicable diseases, injuries (50), and maternal causes (51). Advances

229 in antiretroviral therapy (ART) access have been associated with reducing adolescent and young
230 female mortality by half (50, 52). Physical and sexual violence against females is one of the highest in
231 Kenya, with 12% of women reporting their first sexual intercourse was coerced (53), rising up to 45%
232 among adolescent girls (54). The former pilot study evaluating menstrual interventions was
233 conducted in one of the three sub-divisions within the study area, with water, sanitation, and
234 hygiene (WASH) observations illustrating presence of latrines and water, but not soap in schools
235 (23). The menstrual care among the population was examined and illustrate girls' and young
236 women's preference for commercial pads over traditional items; with 10% of 15yr olds reporting
237 they had sex for money to purchase sanitary pads (22). Schools and health facilities have been geo-
238 located (see Figure 1, below).

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240 *Figure 1 – Map of Siaya County Public Health Facilities and 96 CCG Study Schools*

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242 **Eligibility criteria: schools**

243 *Inclusion criteria for schools*

- 244 • Secondary school within study area
- 245 • Girls or co-educational school
- 246 • Day school
- 247 • Approval by Head Teacher

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249 *Exclusion criteria for schools*

- 250 • Boys only school
- 251 • Boarding schools
- 252 • Special needs schools (i.e. for the blind)

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254 **Eligibility criteria: participants**

255 *Inclusion criteria for participants*

- 256 • Attend secondary day schools in the study area
- 257 • Resident of the study area
- 258 • Have a history of established menses (≥ 3 times)
- 259 • Have no disability preventing participation
- 260 • Assent to participating in the study and have received parent or guardian consent

261 *Exclusion criteria for participants*

- 262 • Attend boarding schools
- 263 • Visibly pregnant or declare pregnancy at baseline (girls who don't declare pregnancy but whose
264 delivery dates confirm pregnancy started prior to enrolment will be excluded from the analysis.)

266 **Trial interventions**

267 Schools will be randomised to one of 4 arms:

- 268 1. One menstrual cup with training on safe use and care, with handwash soap termly.
- 269 2. Cash transfer (CT) Ksh 1500/term plus financial literacy training.
- 270 3. Combined menstrual cup and CT with training on financial literacy and cup safe use and care.
- 271 4. 'Usual practice' control (control arm), with handwash soap termly.

272 All participants regardless of school cluster will receive puberty and hygiene education.

274 *Menstrual cup*

275 The menstrual cup is a medical grade silicone bell shaped container which is inserted into the vagina
276 to collect menstrual flow, and requires emptying at regular intervals (4-8 hours) (55). Cleaning by
277 boiling is recommended at the end of each cycle. The Mooncup® will be used in the t/rial (56), selected
278 because it has been tested in the UK (57, 58) and internationally (26, 59), is produced to ISO
279 13485:2003 standards, and registered by the U.S. Food and Drug Agency of Medicines (FDA;
280 Registration Number 3009117944); and was successfully used in the pilot study (54). Further, its' white

281 colour when new, changing to brown after use, allows physical observation of use (26). Girls will
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3 282 receive school-based training on safe cup use and care (including insertion, emptying, re-insertion,
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5 283 cleansing, and storage). The trial will document girls' use over time.
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9 285 *Cash transfer pocket money*

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11 286 Cash transfer (CT) programmes are a popular social protection tool in developing countries that aim,
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14 287 among other things, to improve education outcomes and reduce risky sexual behaviour (8, 10, 11, 60,
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16 288 61). A sum of US\$5 per month (~Ksh500; exchange December 2015) was recommended for future
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19 289 studies. CT programmes which were conditional on attendance have been shown to improve school
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21 290 outcomes more than unconditional or non-monitored (29). This trial will provide Ksh1500 (US\$15) per
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23 291 term (3 terms per school year) for up to 10 academic terms. Conditionality for CT receipt will be based
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26 292 on 80% or more school attendance in the previous term, in line with other studies (8, 61-64). After
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28 293 assent, participants in the CT arms will receive school-based financial literacy training and a bank card.
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31 294 For this trial, Equity Bank pre-paid cash cards will be used for minors after obtaining guardian consent.
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33 295 Girls must provide a birth certificate and a guardian ID to receive a bank card. Precautions will be taken
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35 296 to ensure girls have direct access to their accounts but maintain low visibility to minimize the risk of
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38 297 theft, harassment, or violence. School registries will be assessed retrospectively per term to verify
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40 298 school attendance, with spot-checks conducted to minimise risk of falsification of registries. The trial
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42 299 will document girls' use and spending choices over time.
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47 301 **Endpoints / Outcome measures**

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49 302 *Primary outcome:*

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52 303 Composite: incident HIV, HSV-2, all-cause school dropout by the end of the study.
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57 305 *Secondary outcomes:*

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- 307 • HSV-2 incidence
 - 308 • HIV incidence
 - 309 • Reported sexual behaviour indicators (including age at sexual debut, age-discordance of partners,
310 coercive sex, number of sexual partners, pregnancy, condom use, and use of modern
311 contraceptives)
 - 312 • School performance indicators (Kenya Certificate of Secondary Education [KCSE] results, grade
313 repetition, prevalence of re-enrolment, and absenteeism)
 - 314 • Quality of life using EuroQoL and PEDSQL
 - 315 • Cost-effectiveness of interventions from the societal, including girls', perspective

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317 *Safety endpoints*

- 318 • Tolerability: any adverse events assessed in a general reproductive health questionnaire
- 319 • Primary Safety:
 - 320 ○ Toxic Shock Syndrome
 - 321 ○ Violence associated with interventions provided
- 322 • Secondary Safety:
 - 323 ○ *E. coli* growth on sampled cups
 - 324 ○ Other emergent harms that may occur with provision of cash pocket money or cups.

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326 **Sample Size estimates**

327 Original trial design sample size estimate: Sample size and power calculations were performed for the
328 minimum number of schoolgirls needed in the proposed 4-arm trial using sample size calculation
329 software (NCSS/PASS); calculations were validated using SAS based simulation studies. Five primary
330 comparisons of the primary endpoint were tested: (1) menstrual cup vs usual practice, (2) CT vs usual
331 practice, (3) combined CT and cup vs usual practice, (4) combined CT and cup vs menstrual cup only,
332 and (5) combined CT and cup vs CT only. Calculations were based on a 2-sided alpha of 0.01 to allow

333 5 primary comparisons of interest, assuming an ICC value of 0.008. Taking a target of mid-late Form-1
334 of schools in the study area gives a sample size average of 46 girls, a 1yr enrolment period, a 5% overall
335 refusal to take part in the study, 20% refusal at enrolment to consent to HIV testing among
336 participating girls, an average of 10 terms (~3.3yr) follow-up through the end of Form-4, and 20% loss
337 to follow-up or refusal to provide biological samples at the end of the study period. Of 46 enrolled
338 girls/school, on average, 35 ($0.95 \times 0.80 \times 46$) will contribute to the primary analysis; we assume that 6.9
339 will be HSV-2 or HIV positive on enrolment (24.7% of 28 girls who agree to testing) and the remaining
340 28.1 will be HSV-2/HIV negative ($n=21.1$) or of unknown HSV-2/HIV sero-status ($n=7$) because no
341 assent/consent was provided for testing at enrolment. With these assumptions, a trial with 4 arms of
342 21 schools per arm (84 schools total) enrolling 46 girls/school (i.e. 966/arm; 3864 girls total) with 35
343 girls/school contributing to analysis, will have 90% power to detect a 25% reduction (Relative Risk
344 [RR]=0.75) in the 3.3yr incidence risk of the primary endpoint from 44.1% in the control group to 33.1%
345 with either intervention, and 80% power to detect a 22.2% reduction (RR=0.778) to 34.3% (both at
346 $\alpha=0.01$).

347
348 *Source data:* The ICC value of 0.008 was the observed ICC value for the composite endpoint of school
349 dropout and STIs in our previous pilot study, and 0.0084 for school dropout alone (26). The anticipated
350 effect sizes of 25% (RR=0.75) for the primary endpoint is based on a model combining the impact and
351 event frequency of the 3 components of the primary endpoint in the three strata: HSV2/HIV negative
352 girls (60.2% of the overall sample), HSV-2 or HIV positive girls (19.8% of the sample), and girls for
353 whom the sero-status is unknown (20% of the sample). The model predicts that a 25% (RR=0.75)
354 overall reduction from 44.1% to 33.1% with single interventions, or from 33.1% to 24.8% with the dual
355 intervention can be achieved with the following combination of relative risk reductions for school
356 dropout and HIV and HSV-2 incidence respectively: 30% and 25.7%; 25% and 34.2%; or 20% and 43.0%.
357 The anticipated minimum reduction of 30% in dropout is based on an average 31% reduction in a
358 meta-analysis comparing controls against cash transfer (29), and is more conservative than a 58%

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359 reduction observed with menstrual cups in year-2 of the pilot (26). The 48.8% reduction in HIV and
360 HSV-2 incidence is based on a 51.9% reduction observed in year-2 of the pilot study, adjusted for the
361 fact that baseline HSV2-HIV status would not be available for 12 of 60 girls/school (20%) on enrolment,
362 3 to 4 of whom may have undetected HSV-2 or HIV on enrolment. The observed relative risk reduction
363 in the HIV and HSV-2 incidence was 48.8% (based on a 43.4% reduction in STI prevalence by the end
364 of the previous pilot in 2014) (26).

365 (2) Blinded sample size re-estimation

366
367 A blinded sample size re-estimation was conducted in 2017 using the baseline data from all arms
368 pooled to validate the assumptions made during the original sample size estimations in the trial design
369 phase. The average number of girls per school and the baseline prevalence of HSV-2/HIV (a proxy for
370 the anticipated incidence) were lower than anticipated. A sample size re-estimation with pooled data
371 demonstrated that a total of 96 school clusters (24/arm) are required with an anticipated average of
372 41.25 girls per cluster to obtain 90% power to detect a 25% (RR=0.75) reduction in the primary
373 endpoint from 39.3% in the control arm to 29.5% in any of the 3 intervention arms (alpha=0.0167
374 allowing for 3 primary comparisons against the control arm), with an ICC of 0.008 and allowing for
375 20% loss to follow-up. This yields a full sample of 3,960 overall, 3,168 of whom are expected to
376 contribute to the primary endpoint, 33 per cluster. This same sample size provide 80% power to detect
377 a 25.7% (RR=0.743) reduction from 29.5% in any of the single intervention arms to 21.9% in the
378 combined intervention arm (alpha=0.025). The total sample size may exceed 3,960 if the average
379 cluster enrolled has more eligible girls than anticipated as the intention is to give every eligible girl in
380 each secondary school the opportunity to participate.

381 **Assignment of interventions**

382 *Allocation*

1 384 School clusters are the unit of randomisation and girls the unit of measurement. A census of secondary
2 385 schools in the area will be used to select the eligible schools. The trial statistician will produce block
3
4 386 randomized groupings of four schools (blocks) using a 1:1:1:1 ratio and based on location and size,
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6
7 387 including larger schools (e.g. with more than 20 target girls) for logistical reasons. Arm allocation of
8
9 388 schools to intervention arms will be achieved using community ceremonies. During a public ceremony,
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11 389 head teachers representing their respective school will be called up with the rest of their blocks for
12
13 390 balanced randomization. The head teachers will each simultaneously pick 1 of 4 coded items, and once
14
15 391 all blocks have completed this process and all schools have been randomly allocated, study arm will
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17 392 be displayed by opening sealed envelopes and breaking the code. This methodology was informed by
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19 393 the pilot study where randomisation ceremonies with head teachers were successful (26).
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26 395 *Blinding*

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28 396 Participants cannot be masked to their treatment arm due to the nature of interventions provided.
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30 397 Laboratory personnel testing for HIV and HSV-2, investigators, and trial statisticians will be blinded
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32 398 to the study arm. Field staff will be masked as much as feasible, including those who conduct home
33
34 399 visits to confirm dropout. Bias will also be minimised by use of block randomisation stratified by
35
36 400 school size. An independent person will prepare the sealed envelopes with the study arm allocation.
37
38 401 Study arm allocation will not be recorded in the central database to ensure the trial statistician and
39
40 402 data managers remain blinded throughout the study. This information will be recorded separately
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42 403 and only be merged with the main database following approval of the statistical analysis plan (SAP),
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44 404 closure of the databases and submission of a copy to the independent statistician of the Data
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46 405 Monitoring and Ethics Committee (DMEC).
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54 407 **Participants' timeline**

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56 408 *Overview*
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409 The participant's timeline will commence after pre-recruitment preparations, including ministry,
410 school, and community stakeholder meetings and approvals. Parent consent for their daughters'
411 participation will follow the school cluster randomisation ceremonies. Participants' meetings for
412 assent, pre-screen enrolment and baseline screening, mid-line screening (second study year), and
413 end-line screening (third study year) will be held as 'Health Days' in randomised schools.

414
415 *Figure 2-Flowchart of Randomization and Study Design*

416
417 *Pre-screen Enrolment, Assent and Baseline Screening*

418 The school enrolment register will be used as the sampling frame to define all target girls in the
419 study schools. Parents of all girls will be approached at the end of the school information meeting to
420 request informed consent for (1) the main study, (2) HIV testing and counselling, and (3) blood
421 storage. Signing will be private and one-to-one with a trained member of the study team. The
422 enrolment list will be updated at the meeting to record girls transferring out or into the school and
423 missed parents will be followed up at home for consent. Reasons for non-consent will be
424 documented.

425
426 Girls whose parents have consented to their participation in the study will be informed of the study
427 purpose and procedures. Each girl will individually be asked to give her assent to participate and asked
428 key eligibility criteria questions (see eligibility criteria: participants, above). Girls who meet the
429 eligibility criteria will then be invited to participate in the study.

430
431 Participants will privately self-administer a combined demographic, social, behavioural and quality of
432 life/wellbeing questionnaire using tablets during the 'Health Day'; absent girls will be invited to
433 participate at a subsequent 'Health Day' when logistically feasible. All relevant information will be
434 captured in the survey questionnaire. Baseline questions around demographics, use of menstrual

1 435 items, and access to cash and personal bank account will be asked, as well as other secondary
2 436 outcomes. Wellbeing will be assessed using the adolescent (12-18yr) 23-item PedsQL™ 4.0 (Paediatric
3
4 437 Quality of Life Inventory; <http://www.pedsq.org/>), and will measure physical, emotional, social, and
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7 438 school functioning of children, core dimensions as delineated by WHO (65).
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11 440 A baseline clinical survey will be conducted to define pre-intervention HIV and HSV-2 prevalence, and
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13 441 height, weight, and waist measures of participants. Documentation of population HIV prevalence is
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16 442 important to understand frequency of mother-to-child transmission of HIV, noted in a Zimbabwean
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18 443 schoolgirl CT study which only evaluated HIV and HSV-2 at endline (30). However, refusal to have an
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21 444 HIV or HSV-2 test at baseline will not preclude participants from joining the study. School ‘Health Days’
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23 445 will be operated with a trained mobile team at a location at or close to their school. All sample
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25 446 collection and HIV counselling will be conducted by a team of trained HIV Testing and Counselling
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27 447 (HTC) staff. Results will not be given then, but separately to participants on an individual level at the
28
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30 448 health clinics with trained counsellors and testing and counselling and care facilities. Participants can
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33 449 visit clinics individually without peer pressure and are encouraged but not obligated to ask their
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35 450 parents to accompany them. If consent/assent has been obtained for blood collection, girls will
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37 451 provide 600uL of blood for HIV and 1.5ml for HSV-2 with any blood not used for these two tests stored
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39 452 as dried blood spots for future testing of other STIs or vaccine preventable infections, if funding allows.
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42 453 Blood will be collected through fingerpick and stored and transported in Microtainer EDTA tubes to
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44 454 KEMRI laboratories for analysis. Blood will be stored for a maximum of 5yr, after completion of the
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47 455 trial, after which it will be destroyed.
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52 457 *Midline screening*
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54 458 All participants will be invited to participate in a mid-study behavioural survey to update socio-
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56 459 behavioural characteristics, including marriage status, sexual exposures, and document patterns of
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59 460 intervention use, problems encountered, and any possible safety issues. Midline HIV/HSV-2 testing
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461 will be conducted mid-study. These tests and follow-up counselling and treatment will follow the
462 same methodologies used at baseline. These measurements will allow closer examination of
463 incidence over time and offer the opportunity to test and counsel participants who exit the study
464 before the endline survey. Baseline consents and assents include this assessment. Participants are
465 reminded they have the freedom to withdraw or refuse testing.

467 *End study screening*

468 Similar to the baseline Health Day, participants will attend an end of study Health Day to complete
469 an endline behavioural survey to document changes in socio-behavioural characteristics (including
470 risky sexual behaviours, quality of life/wellbeing measures) and intervention use, problems
471 encountered, and any perceived harms. Outreach activities to survey enrolled girls who have left
472 school or dropped out will be conducted if funding is available. HIV and HSV-2 serostatus will be
473 assessed at this same Health Day to determine incidence among those testing negative at enrolment
474 and during interim follow-up testing. Careful consideration and coordination with head teachers will
475 be needed to secure the dates for the final survey to ensure no disruption for girls in Form 4 while
476 they take final exams. Endline HIV/HSV-2 testing will be conducted on Health Days in safe spaces
477 among all enrolled girls to protect the confidentiality of baseline HIV positive participants.
478 Participants are reminded they have the freedom to withdraw or refuse testing.

479

480 *Unscheduled visits*

481 School dropout will be assessed every term until the study end. Regular monitoring of school
482 registers will be conducted to determine dropout among participating girls. Girls who dropout will
483 be followed-up with an unscheduled visit to the home to understand reasons for dropout and
484 confirmation of the same, and to identify those that have migrated to a different area who may still
485 attend school (e.g. are classified as loss to follow-up). An unannounced annual WASH survey will be
486 conducted at all participating schools, to observe the presence and state of latrines, water

1 487 availability, water treatment, handwashing units and soap. At any time, participants displaying
2 488 adverse events will be assessed by a study nurse, with a triage form evaluating seriousness and
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4 489 potential relationship with the interventions and tailored AE and SAE forms to document relevant
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7 490 details (see Appendix 2: SAE Report Form).
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11 492 *Focus group discussions*

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14 493 FGDs will be held pre-intervention, annually (interim) during the trial, and at the end of the study.
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16 494 Feedback from these will document participant and other beneficiaries understanding of the
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19 495 interventions, use, impact and any problems arising.
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23 497 **Laboratory Procedures**

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25 498 *Clinical testing*

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28 499 HIV testing will be conducted in accordance to Kenyan national guidelines(66). HSV-2 will be examined
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30 500 using Kalon gG2 ELISA test kits (Kalon Biologicals Ltd, Guilford, UK), with quality assurance performed.
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33 501 Any additional blood collected at baseline, interim, or end of study will be stored for future testing of
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35 502 other STIs or vaccine preventable infections, if funding allows.
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40 504 *Cup contamination*

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42 505 A register of all participants receiving cups will be used to randomly select a swatch of used cups by
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44 506 duration of provision. This will exclude girls who received a replacement cup due to loss, theft, or
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47 507 damage. Randomly selected participants will be traced and asked if they are willing to swap their
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49 508 existing cup for a new one, to allow laboratory examination of their cup. Each used cup will be
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52 509 placed in a separate lock- bag labelled with participant ID and transported to the laboratory and
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54 510 tested for *E coli* growth. Cups will be swabbed using polyester tipped swabs moistened in normal
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57 511 saline and inoculated into both MacConkey (MAC) agar and blood agar (BA) and incubated for 18-24
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59 512 h at 37°C. After incubation, colony types will be visualized for characteristic morphology of *E.coli* and
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2 513 others from the MAC plates, and subjected first to analytical profile index (API) testing for suspected
3 514 *E coli* growth(67), then incubated for 18-24 h at 37°C. The results will be interpreted using API
4 software(68).
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9 517 **Statistical methods**

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11 518 A study statistical analysis plan will be developed during the course of the study for the final analysis.
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13 519 This will be completed prior to the unblinding of data at database lock.
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19 521 *Screening failures*

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21 522 A participant who gives informed assent (after parental consent) and is provided with a study ID, but
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23 523 then is found not to fulfil the eligibility criteria, will be classified as a screening failure and excluded
24
25 524 from the intention-to-treat (ITT) and the per protocol (PP) analysis. Pregnant girls who do not
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27 525 declare pregnancy at enrolment will be excluded from analysis after the dates of normal (or
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29 526 otherwise) deliveries confirm that the current pregnancy was ongoing at enrolment.
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35 528 Intention-to-treat (ITT) population

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37 529 The intention-to-treat population (the full analysis population) is defined as all participants who
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39 530 provided parental consent, themselves assented, and were enrolled into the study. These girls will be
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41 531 included in the intention-to-treat analysis regardless of whether they have completed all endline
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43 532 evaluations.
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49 534 Per protocol (PP) population

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51 535 The per-protocol population within the menstrual cup groups is defined as all participants receiving
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53 536 the cup with evidence it changed colour showing actual use. For cash transfer, 'per protocol'
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55 537 constitutes all girls receiving the cash intervention until dropout or reaching the endpoint.
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59 538 Participants documented to have crossed over between school clusters will be excluded.
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2 540 *Cost-effectiveness analyses*
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4 541 An economic evaluation will be conducted to provide evidence for the cost-effectiveness of the
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7 542 three interventions. This will be used to estimate the societal cost consequences and efficiencies of
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9 543 the intervention packages to inform health service delivery and future policy decisions.
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14 545 *Safety outcomes*
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16 546 Adverse events (AEs) and serious adverse events (SAEs) will be monitored, managed and recorded
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19 547 during the study (see Appendix 2: SAE Report Form). AEs will be reported and tabulated for each
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21 548 treatment arm, overall, and according to body system on a per protocol basis. Intervention
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23 549 emergent AEs are defined as adverse events that had an onset on the day of the intervention, or
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26 550 thereafter. AEs that have missing onset dates will be considered to be treatment emergent. No
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28 551 formal statistical testing will be undertaken. All laboratory data will be listed and summarised.
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33 553 **Ethics approval and consent to participate**
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35 554 This protocol, the informed parent consent and participant assent documents, and participant
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38 555 information sheets have been reviewed and approved by the Research Ethics Committees at the
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40 556 Kenya Medical Research Institute, Nairobi, Kenya (KEMRI protocol #3215) and the Liverpool School
41
42 557 of Tropical Medicine, Liverpool (LSTM protocol #15-005). The Centers for Disease Control and
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45 558 Prevention gave approval for reliance on the KEMRI IRB (2016-136). Registry approval for trailing
46
47 559 menstrual cups was given by the Kenyan Poisons and Pharmacy Board (ECT_16_07_06). Annual
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50 560 renewal of approvals by KEMRI, LSTM, and KPPB are required based on reporting of trial activities in
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52 561 the prior year.
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57 563 **Discussion**
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564 In this study we are hypothesizing that, as a result of receiving the trial interventions, participating
565 adolescent girls' health and schooling will improve. Prior studies have illustrated that the provision
566 of a menstrual cup can lower rates of reproductive tract and sexually transmitted infections (26);
567 and that the provision of cash transfer impacts positively on girls' schooling outcomes (8, 13).
568 Moreover, evidence is building that enrolment and consistent attendance in school acts as a social
569 vaccine with multiple benefits for girls(6, 15). This trial will determine if provision of a menstrual
570 solution alone, or in combination with cash transfer directly to schoolgirls can improve their life
571 chances, in terms of reducing their risk of HIV, STI (HSV-2), and school dropout. In our trial, we
572 postulate the interventions tested (cups alone, CT alone, or cups and CT) will lead to a reduction in
573 schoolgirls' exposure to sexual and reproductive harms, while increasing their opportunity to
574 complete their schooling, compared with controls. Enrolment, intervention and follow-up of
575 participants across a wide geographical area in rural Africa requires a strong collaboration with
576 schools, communities and organisations. The collaboration in western Kenya between KEMRI, LSTM,
577 SWAP, CDC and government of Kenya (GoK) provides this. Parallel small group sessions evaluating
578 programme fidelity and uptake will inform and strengthen the development of programmatic
579 materials for implementation, should the trial show positive outcomes.

580 Our research will be communicated to the UK and Kenyan public, Kenyan local, county and national
581 ministries, NGO and aid agencies, national and international universities, research groups,
582 international development and aid agencies, donor organizations, and international agencies setting
583 global policy. We will use multiple communication strategies to target information to the correct
584 audience, as appropriate. Much will be through face-to-face interactions at workshops, meetings,
585 local forum presentations, and international conferences. Communication through technology
586 transfer will be used to disseminate more widely to a broader audience, through online networks,
587 webinars, online news, blogs, and publication portals.

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589 We hope that if the interventions prove to be successful and our communication strategy sound, this
590 trial could contribute to improved retention of adolescent girls in school, and could have multiple
591 benefits for health and education services, and national and global level development. This growing
592 evidence base must be used to help girls complete their educations and become financially
593 independent adults, better manage their own menstrual hygiene, and reduce the negative psycho-
594 social pressures and stigma leading to sexual exploitation, violence, illness, premature marriage, and
595 death during childbirth. Cascading benefits may include that communities will benefit from an
596 increase in social capital, and a reduction in resources required to support unemployed, sick, and
597 pregnant girls. Evidence-based-policy will lead to schools being beneficiaries, by improving girls'
598 experience of menstrual care in school; and teachers will benefit from girls' improved attention in
599 class and equitable teaching. As more girls complete education, there will be greater opportunity for
600 training female teachers, redressing the gender imbalance. More engaged pupils will increase
601 teachers' job satisfaction and better grades will raise school profiles. Partnerships between
602 education and the health sector will be strengthened. Economic benefits would translate nationally;
603 for example, researchers estimate that in Kenya, if all 1.6m adolescent girls were able to complete
604 secondary school, and the ~220,000 girls who were pregnant and delivered could be educated, there
605 would be a cumulative effect adding up to £2.1 billion towards Kenya's gross income per year (4).
606 Implementation of successful interventions globally will increase the number of girls completing
607 school, reducing the current global estimate of 44m adolescent girls out of school. Implementing
608 interventions that retain girls through secondary school will have global economic benefits, as it is
609 estimated that countries growth rates would increase on average by ~1% annually if girls' education
610 was raised one level higher (i.e. secondary status). Interventions will reduce the prevalence of teen
611 births and poor maternal outcomes, and the rate of new HIV infections in adolescence which
612 currently account for ~40% of new infections. This will decrease the burden of HIV programme costs
613 for antiretroviral drugs and antenatal care to prevent mother to child transmission.

615 **List of abbreviations**

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3	95% CI	95 percent Confidence Interval
4	AE	Adverse event
5	AIDS	Acquired Immunodeficiency Syndrome
6	ART	Antiretroviral therapy
7	CDC	Centers for Disease Control and Prevention
8	CHW	Community Health Worker
9	CRF	Case Record Form
10	CRO	Contract Research Organization
11	CT	Cash transfer
12	DfID	Department for International Development, UK
13	DHSC	UK Department of Health and Social Care
14	DMEC	Data Monitoring and Ethics Committee
15	DSMB	Data Safety Monitoring Board
16	ELISA	Enzyme linked immunosorbent assay
17	ERC	Ethics Research Committee
18	FDA	Food and Drug Administration
19	FGD	Focus group discussions
20	GCP	Good Clinical Practice
21	GEE	Generalised Estimating Equation
22	GMP	Good Manufacturer Practice
23	HDSS	Health and Demographic Surveillance System
24	HIV	Human immunodeficiency virus
25	HTC	HIV testing and counselling
26	HSV-2	Human simplex virus type 2
27	IDI	In-depth interviews
28	IRB	Institutional Review Board
29	ITT	Intention to Treat
30	JGHT	Joint Global Health Trials
31	KEMRI	Kenya Medical Research Institute
32	LSTM	Liverpool School of Tropical Medicine
33	MHM	Menstrual hygiene management
34	MoEST	Ministry of Education, Science and Technology
35	MoH	Ministry of Health
36	MRC	Medical Research Council, UK
37	PCR	Polymerase Chain Reaction
38	PE	Protective efficacy
39	PP	Per protocol
40	RCT	Randomised Controlled Trial
41	REC	Research Ethics Committee
42	RR	Relative risk
43	RTI	Reproductive tract infections
44	SAE	Serious adverse event
45	SAP	Statistical Analysis Plan
46	SOP	Standard Operating Procedure
47	SRH	Sexual and reproductive health
48	STI	Sexually transmitted infections
49	SWAP	Safe Water and AIDS Project
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tCTU Tropical Clinical Trials Unit
TSC Trial Steering Committee
WASH Water, sanitation and hygiene
WHO World Health Organization

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617 **Declarations**

618 **Ethics approval and consent to participate:**

619 This protocol, the informed parent consent and participant assent documents, and participant
620 information sheets have been reviewed and approved by the Research Ethics Committees at the
621 Kenya Medical Research Institute, Nairobi, Kenya (KEMRI protocol #3215) and the Liverpool School
622 of Tropical Medicine, Liverpool (LSTM protocol #15-005). These ethics approvals cover all 96
623 participating Siaya schools. The Centers for Disease Control and Prevention gave approval for
624 reliance on the KEMRI IRB (2016-136). Registry approval for trailing menstrual cups was given by the
625 Kenyan Poisons and Pharmacy Board (ECT_16_07_06). Annual renewal of approvals by KEMRI, LSTM,
626 and KPPB are required based on reporting of trial activities in the prior year. Written parent consents
627 and written participant assents were collected. In the case that a parent was illiterate and could not
628 read, verbal consent with a witnessing literate adult of the parents choosing was collected.

629

630 **Consent for publication**

631 Not applicable

632

633 **Competing interests**

634 The authors declare no conflict of interests.

635

636 **Availability of Data and Materials**

637 Not applicable: Out manuscript does not contain any data or related findings.

638

639 **Funding**

640 This study is funded by the Joint Global Health Trials Initiative (UK-Medical Research
1
2 641 Council/Department for International Development/Wellcome Trust /Department of Health and
3
4 642 Social Care, grant MR/N006046/1). The funders have or will have no role in the design of the study,
5
6
7 643 the collection, analysis, and interpretation of data, or in writing the manuscript.
8

9 644

11 645 **Authors' contributions**

12 646 PPH and FtK conceived the study. PPH, FtK, DK, DW, EZG, LM, AE, LN, AvE, and CO wrote the grant.

13
14 647 PPH, GZ, FtK, DK, EN, EZG, LM, AvE, CO, JJ, EK, MM, DO, BO, and GB drafted the protocol. DW and TC

15
16 648 provided statistical guidance in the protocol, IN provided ministry and policy expertise, CH guided

17
18 649 drafting of trial governance, and CP drafted the safety monitoring procedures. All investigators

19
20 650 contributed to the refinement of the study protocol and approved the final version. GZ, PPH, AvE,

21
22 651 FtK, LM, DK, TC, EZG, and DW drafted the manuscript. All authors read and approved the final

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24 652 manuscript prior to submission.
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32 654 **Acknowledgements**

33 655 We are most grateful for the valuable advice and comments of the independent Trial Steering

34
35 656 Committee members (Robert Bailey, Sarah Baird, Marni Sommer, Sassy Molyneux, Caroline Kabiru,

36
37 657 Christian Borja-Vega, Jo Mulligan), and of the Data Monitoring and Ethics Committee members

38
39 658 (Michelle Hindin, Helen Weiss, and Jackton Omoto). We would also like to thank the LSTM

40
41 659 programme manager (Cheryl Giddings), research management services, and research governance

42
43 660 teams. Further thanks to Mooncups[®] Ltd, UK, for supplying the menstrual cups at a discounted rate;

44
45 661 and Equity Bank, Kenya for advice and support of the cash dispersal system. Additional thanks to the

46
47 662 dedicated field, lab, admin, and office staff; to the Ministry of Health and Education partners,

48
49 663 administrative leaders, schools, and communities, and importantly to the girls and their families in

50
51 664 Siaya County. This paper is published with the permission of KEMRI Director. The findings and
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665 conclusions in this paper are those of the authors and do not necessarily represent the official
666 position of the Centers for Disease Control and Prevention.

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18 19 20 849 **Figure Legends**

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23 850 Figure 1: Map of Siaya County Public Health Facilities and 96 CCG Study Schools

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26 851 Figure 2: Flowchart of Randomization and Study Design

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29 30 853 **Appendices**

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33 854 Appendix 1: SPIRIT Checklist

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36 855 Appendix 2: SAE Report Form
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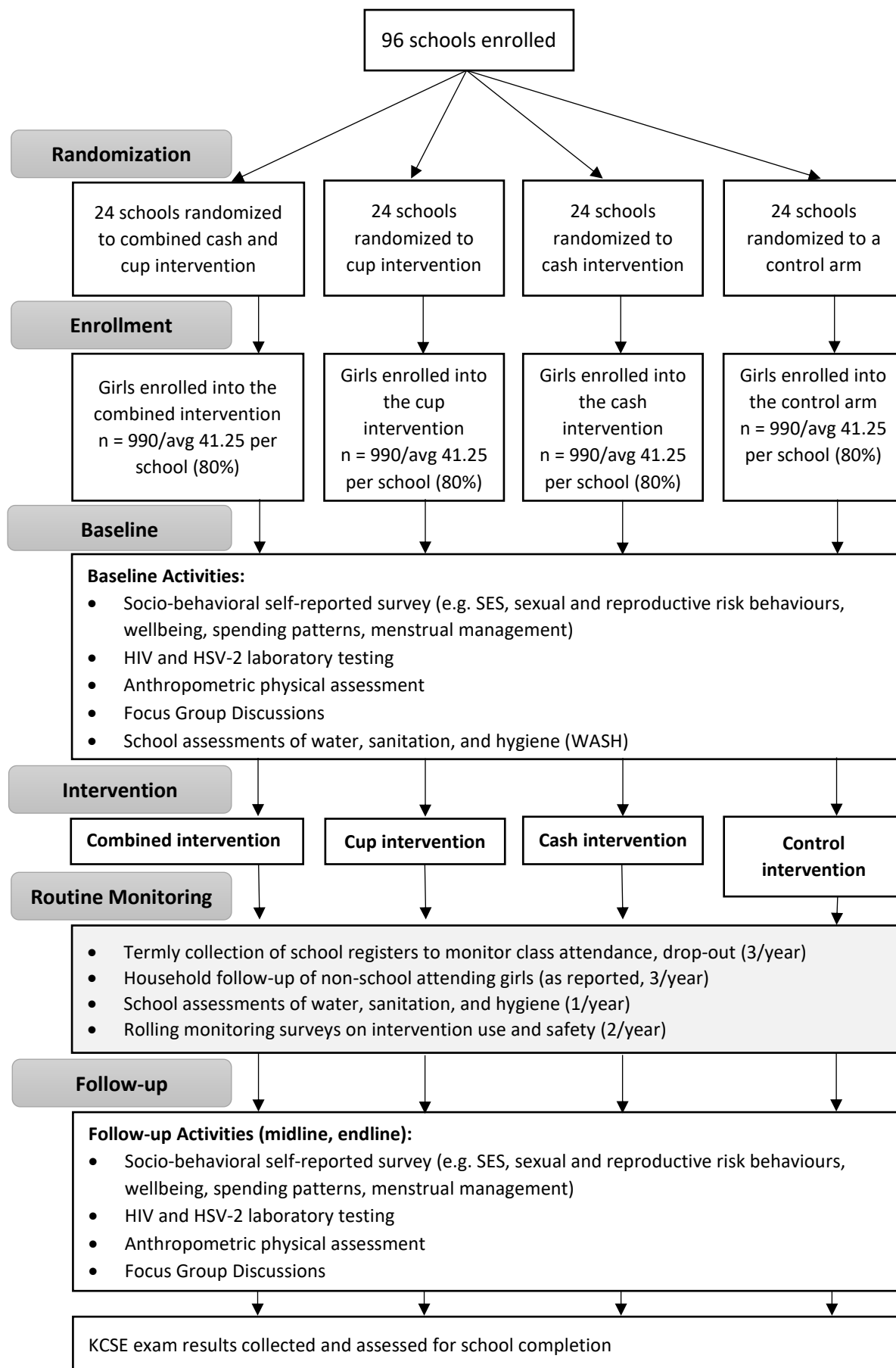
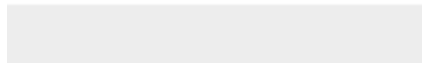


Figure 2: Flowchart of randomisation and study design. The expected number of participants randomized to each arm and the percentage of enrolled expected to contribute to outcomes indicated (estimated FU 80% n=792).



Click here to access/download
Supplementary Material
CCG SPIRIT Checklist_v8.pdf





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Supplementary Material
Appendix 2 CCG SAE Form.pdf

