ORIGINAL ARTICLE

A pilot study of the feasibility of a vaginal washing cessation intervention among Kenyan female sex workers

Linnet Masese,[1] R Scott McClelland,[1,2,3,4] Ruth Gitau,[4] George Wanje,[4] Juma Shafi,[4] Francis Kashonga,[4] Jeckoniah O Ndinya-Achola,[4†] Richard Lester,[5] Barbra A Richardson,[3,6,7] Ann Kurth[3,8]

[1]Department of Epidemiology, University of Washington, Seattle, Washington, USA
[2]Department of Medicine, University of Washington, Seattle, Washington, USA
[3]Department of Global Health, University of Washington, Seattle, Washington, USA
[4]Department of Medical Microbiology, University of Nairobi, Nairobi, Kenya
[5]Department of Medicine, University of British Columbia, Vancouver, Canada
[6]Department of Biostatistics, University of Washington, Seattle, Washington, USA
[7]Fred Hutchinson Cancer Research Center, Seattle, Washington, USA
[8]College of Nursing, New York University, New York, New York, USA

Correspondence to
Dr Linnet Masese, University of Washington, HMC Box 359909, 325 9th Avenue, Seattle, WA 98104-2499, USA; linnet@uw.edu

† Deceased.

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ABSTRACT

Background Intravaginal practices including vaginal washing have been associated with HIV-1 acquisition. This association may be mediated by mucosal disruption, changes in vaginal flora or genital tract inflammatory responses. Reducing vaginal washing could lower women's risk of HIV-1 acquisition.

Methods 23 HIV-1 seronegative women who reported current vaginal washing were recruited from a prospective cohort study of high-risk women in Mombasa, Kenya. A theoretical framework including information–motivation–behavioural skills and harm reduction was implemented to encourage participants to reduce or eliminate vaginal washing. At baseline and after 1 month, we evaluated vaginal epithelial lesions by colposcopy, vaginal microbiota by Nugent's criteria and vaginal cytokine milieu using ELISA on cervicovaginal lavage specimens.

Results The most commonly reported vaginal washing substance was soap with water (N=14, 60.9%). The median frequency of vaginal washing was 7 (IQR 7–14) times per week. After 1 month, all participants reported cessation of vaginal washing (p=0.01). The probability of detecting cervicovaginal epithelial lesions was lower (OR 0.48; 95% CI 0.20 to 1.16; p=0.10) and the likelihood of detecting *Lactobacillus* by culture was higher (OR 3.71, 95% CI 0.73 to 18.76, p=0.11) compared with baseline, although these results were not statistically significant. There was no change in the prevalence of bacterial vaginosis. Most cytokine levels were reduced, but these changes were not statistically significant.

Conclusions A theory-based intervention appeared to have a positive effect in reducing vaginal washing over 1 month. Larger studies with longer follow-up are important to further characterise the effects of vaginal washing cessation on biological markers.

INTRODUCTION

Women represent ~60% of people living with HIV-1 in sub-Saharan Africa.[1] The vaginal milieu plays an important role in women's susceptibility to HIV-1, with the presence of *Lactobacillus* species being associated with a reduced risk of HIV-1 acquisition.[2] Conversely, abnormal vaginal microbiota has been associated with an increased HIV-1 risk.[2–5]

Intravaginal practices including vaginal washing and insertion of substances are common in Africa, especially among high-risk women.[6 7] These practices are associated with adverse outcomes including bacterial vaginosis (BV) and sexually transmitted infections (STIs) including HIV-1.[8–12] The effect of vaginal washing on HIV-1 susceptibility may be mediated through mucosal disruption, perturbations in the vaginal microbiota and genital tract inflammatory responses.

Intravaginal practices including vaginal washing are often deeply rooted in cultural norms and beliefs about hygiene, sexuality and health, and may be difficult to change.[13] Studies in US women have demonstrated that it is possible to modify intravaginal practices, particularly vaginal douching.[14 15]

The objective of this study was to determine whether a theory-based behavioural intervention might help women to modify or eliminate potentially harmful vaginal washing practices. We also collected pilot data to estimate the impact of vaginal washing cessation on cervicovaginal mucosal epithelial lesions, the microbiota and cytokine levels.

MATERIALS AND METHODS

Participants

We conducted a prospective study involving both behavioural and biomedical components between March and August 2009 in Mombasa, Kenya. Participants were recruited from an ongoing cohort study of HIV-1 seronegative female sex workers aged 18–45 years old. Methods for the parent cohort have been described.[16] Women in the cohort are counselled about the potential risks of vaginal washing, but the practice remains highly prevalent.

Our study focused on vaginal washing, as this is by far the most prevalent intravaginal practice in the cohort.[17] For this substudy, we recruited women who reported vaginal washing beyond the introitus within the last month. In addition, women were required to be sexually active, non-pregnant, not within the first 3 months post partum, and not on hormonal contraception or, alternatively, on stable hormonal contraception for ≥2 months.[10 18] The study was approved by ethical committees at the Kenyatta National Hospital and the University of Washington.

Clinical procedures

At the screening visit, eligible women were given information about the study. Those interested in

participating were required to provide written informed consent. The baseline (enrolment) visit was scheduled within 1 week after the screening visit.

At the baseline visit, study nurses completed a structured interview covering medical, gynaecological and sexual history. An additional questionnaire detailing vaginal washing practices including the frequency, timing and substances used was administered. A trained study physician performed a physical examination including pelvic speculum examination with collection of specimens for laboratory diagnosis of genital tract infections. The physician collected cervicovaginal lavage specimens using 2 ml phosphate buffered saline for assessment of cytokine levels. We measured both pro-inflammatory (IFN-γ, TNFα, interleukin (IL)-1, IL-2, IL-6, IL-8, MCP-1, RANTES, monokine induced by Interferon-γ, IP-10) and anti-inflammatory cytokine (IL-4, IL-10) levels. Our objective was to assess the impact of cessation of vaginal washing on these vaginal cytokines in order to understand whether there was a substantial shift in the overall vaginal inflammatory milieu with cessation of vaginal washing. Colposcopy was performed using a standardised approach to identify epithelial disruption, vascular disruption, erythema and friability.[19] Lesions were considered iatrogenic if they appeared to have been caused by speculum insertion.

During the baseline visit, women received the first part of the intervention package from the counsellor. This included a reminder of the objective of the study. The counsellor acknowledged that women engaged in vaginal washing for various reasons, some of which may be difficult to modify. Women were asked to reduce or discontinue these practices for 1 month, during which we would provide staff and peer support, including the intervention sessions. Women were reminded to be as truthful as possible about the barriers they faced in making this change. They were also reminded that there were no repercussions if they were unable to stop or reduce vaginal washing. Thereafter, participants were scheduled to attend weekly intervention sessions for 3 weeks before returning for the final week-4 visit. At the final visit, study nurses once again conducted a structured interview regarding intravaginal practices, and the participants had a physical examination that included a pelvic examination, colposcopy and collection of cervicovaginal lavage specimens. One woman with BV and symptomatic vaginal discharge received syndromic treatment with oral metronidazole and clotrimazole pessaries at baseline.

Theoretical framework

A theoretical framework including information–motivation–behavioural skills (IMB) model,[20] stages of change[21] and harm reduction was implemented to encourage participants to reduce or eliminate vaginal washing.[22] Following the IMB model, the intervention provided information on the impact of vaginal washing on women's health. We provided staff and peer support for behaviour change. The harm reduction framework aimed at reduction or elimination of vaginal washing, while acknowledging the incremental nature of behaviour change.

To assess participants' readiness to stop potentially harmful vaginal washing practices, we used the trans-theoretical model that employs five stages of behaviour change.[23] The stages include precontemplation (not ready for change), contemplation (ready to consider making a change in the near future), preparation (ready to start taking action towards behaviour change), action (initiating behaviour change) and maintenance (sustaining behaviour change over time). At each visit, we assessed women's stage of behaviour change in relation to modifying vaginal washing by asking, *"What do you think about stopping your intravaginal practices? For example, stopping all vaginal washing and insertion of substances?"* The participants were given the following options as responses to this question: *0=no need to (precontemplation), 1=Might be good, but I'm not ready to do this consistently (contemplation), 2=I'm ready to do this now (preparation), 3=I've been doing this consistently within the past 3 months (action)* and *4=I've been doing this consistently for more than 3 months (maintenance)*. These responses were based on the validated approach to the trans-theoretical model.[21] By design, we did not expect anyone to reach the maintenance stage during this 1-month intervention.

Weekly intervention sessions

Structured group sessions were held weekly for 3 weeks. The quantitative questionnaire on vaginal washing practices was administered to each participant before the start of every meeting by a study nurse who was not involved in the intervention sessions. No physical examination was conducted during these visits. The intervention sessions were facilitated by a trained counsellor who was blinded to the participants' responses to the nurse-administered questionnaires. Qualitative data (note-taker notes/report) were collected during the intervention sessions. Relevant topics regarding vaginal health and intravaginal practices were discussed. At the end of each session, facilitators answered questions and provided a summary. Women were encouraged to attend all sessions, participate in discussions and share their behavioural strategies. Transportation costs were reimbursed.

Since vaginal washing practices were self-reported, we used several approaches to minimise reporting bias. At each interview, study nurses acknowledged that changing behaviour was not easy, and reassured participants that reimbursement and clinical care would not be compromised if they were unable to reduce or eliminate vaginal washing. The nurses reminded participants that we needed them to report their practices accurately to allow us to learn how to help women reduce these practices in the future. Interviews were conducted in a private setting. We used separation of duties, such that the counsellor involved in the intervention did not conduct the interviews, and information about the women's responses was not reported back to the counsellor. Likewise, information from intervention sessions was not reported back to the interviewers.

In summary, this was a 3-week intervention with concurrent assessments at each week and one final assessment at week 4. A poststudy assessment of vaginal washing was conducted in a subset of women who returned for visits in the parent cohort 6–12 months later. Detailed information on the intervention is available from the authors upon request.

Laboratory methods

HIV-1 serostatus was determined by ELISA (Detect HIV1/2, BioChem Immunosystems, Montreal, Canada). Positive tests were confirmed using a second ELISA (Recombigen, Cambridge Biotech, Worcester, Massachusetts, USA or Vironostika HIV-1 Uniform IIAG/AB, bioMerieux, Marcy l'Etoile, France). Vaginal Gram-stained slides were evaluated for BV using Nugent's criteria.[24] We also used Amsel's criteria for BV diagnosis.[25] Vaginal secretions were inoculated onto Rogosa agar for isolation of *Lactobacillus* species.[26] Vaginal cytokine levels were tested using ELISA (BioSource Diagnostics, Nivelles, Belgium).

Statistical analysis

We used data from our quantitative questionnaire from the baseline visit and each of the four follow-up visits to assess changes in vaginal washing behaviour across the five visits using the Friedman test. For comparisons in the vaginal microbiota, mucosal epithelial lesions and cytokines, we compared the baseline visit with the week-4 visit. Since relatively few (0–2) lesions were observed in any category (epithelial disruption, vascular disruption, erythema and friability), we combined the categories into one variable indicating the presence of any non-iatrogenic lesions. We used generalised estimating equation models with a logit link and an exchangeable correlation structure to compare the presence of lesions and presence of BV between the baseline and week-4 visit. Generalised estimating equation models with a Gaussian link and an exchangeable correlation structure were used to compare changes in cytokines between the baseline and week-4 visits. Cytokine data were $\log_{10}$-transformed to better approximate a normal distribution.

In our analyses of changes with cessation of vaginal washing, we considered several potential confounding factors including age, hormonal contraceptive use, sexual risk behaviour, presence of STIs and week of the menstrual cycle. We assessed the effect of potential confounding factors one at a time for each outcome. If a variable resulted in a meaningful change in the OR for the predictor of interest, it would be retained in the final model. However, no potential confounding factors met these criteria. Therefore, only unadjusted results are presented. Analyses were performed using PASW V.18.0 (PASW Inc., Chicago, Illinois, USA) and STATA V.11 (StataCorp, College Station, Texas, USA).

RESULTS

Between March 2009 and July 2009, 36 women agreed to participate in the study of whom 23 reported current vaginal washing at the time of their baseline visit. The characteristics of these 23 women are shown in table 1. Briefly, their median age was 37 years (IQR 31–39). The median age at which they initiated vaginal washing was 18 years (IQR 15–22). Nine women (39.1%) reported that vaginal washing was self-taught, while 6 (26.1%) were introduced to these practices by friends or colleagues. The women reported various reasons for performing vaginal washing including to remove vaginal discharge (N=22, 95.7%) and to remove vaginal odour (N=21, 91.3%). The median frequency of vaginal washing was 7 (IQR 7–14) times per week, and the most commonly reported vaginal washing substance was soap with water (N=14, 60.9%).

Across the five visits, there was a change in behaviour towards reducing or eliminating vaginal washing (figure 1). In all, 13 women attended all three intervention sessions, while 10 attended two intervention sessions. At the baseline visit, most participants reported being within the first three stages of behaviour change (precontemplation N=5, 22%, contemplation N=6, 26% and preparation N=11, 52%). All 22 (96%) of the women who completed the study reported being in the action stage, suggesting that they had ceased vaginal washing during the 1-month intervention (Friedman test p=0.01).

In accordance with the harm reduction approach, we asked women to make an effort to reduce (eg, reduce frequency), modify (eg, change from using soap and water to using water alone) and eliminate vaginal practices. Since cessation was the most frequent outcome, we only presented data from the elimination question.

Table 1 Baseline characteristics of the 23 participants

Characteristic	Median (IQR) or number (percent)
Demographics	
Age (years)	37 (31–39)
Education (years)	8 (8–12)
Marital status	
Never married	5 (21.7)
Currently married	2 (8.7)
Widowed or divorced	16 (69.6)
Hormonal contraceptive method	
OCP	2 (8.7)
DMPA	6 (26.1)
Sexual risk behaviour in the past week	
Abstinent	6 (26.1)
Unprotected intercourse*	3 (17.6)
100% condom use*	12 (70.6)
>1 sex partner*	6 (35.3)
>1 sex encounter*	11 (64.7)
Vaginal washing practices	
Age at start	18 (15–22)
Reason for vaginal washing†	
To remove vaginal discharge	22 (95.7)
To remove vaginal odour	21 (91.3)
To remove menstrual blood	18 (78.3)
Disease prevention	8 (34.8)
Disease treatment	0
Other reason‡	3 (13.0)
From whom they learnt†	
Taught myself	9 (39.1)
Grandmother	1 (4.4)
Mother	2 (8.7)
Sister	1 (4.4)
Friend/colleague	6 (26.1)
Others§	5 (21.7)
Vaginal washing frequency	7 (7–14)
Substance used	
Water only	8 (34.8)
Soap and Water	14 (60.9)
Antiseptic	1 (4.4)
Method	
Finger	16 (69.6)
Cloth	7 (30.4)
Timing of vaginal washing†	
Before sex	14 (60.9)
After sex	22 (95.7)
During bathing	23 (100)
After using the toilet	12 (52.2)
During menses	18 (78.3)
After menses	22 (95.7)
Use of vaginal lubrication	
Petroleum jelly	0
Saliva	1 (4.4)
Other¶	1 (4.4)

*Among 17 women who reported sexual intercourse in the last week.
†Percentages add up to >100% because some women reported more than one reason for vaginal washing, more than one person from whom they learnt to perform vaginal washing and vaginal washing at more than one time.
‡Three women reported cleanliness as the reason for performing intravaginal practices.
§Five women reported that they learnt intravaginal practices from their teachers (three), godmother (one) and neighbour (one).
¶One woman reported using a commercial lubricant (KY Jelly).
DMPA, depot medroxyprogesterone acetate; OCP, oral contraceptive pills.

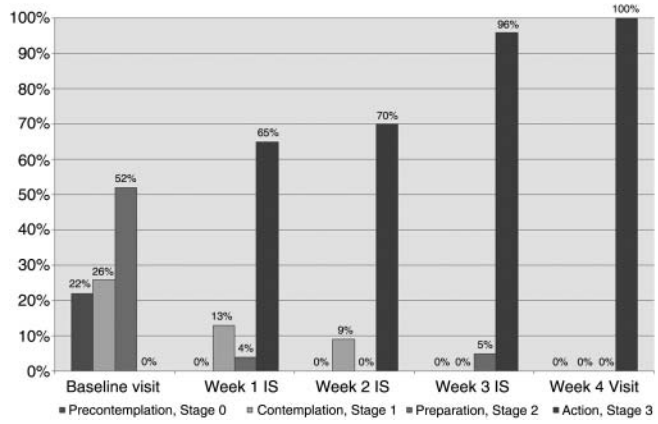

Figure 1 Stages of behaviour change for ceasing vaginal washing across five study visits.* Friedman test: p=0.01. *19, 18, 20 And 22 women attended week 1 IS, week 2 IS, week 3 IS and week-4 visit, respectively. There were no women in maintenance, stage 4.
IS, intervention session.

Our quantitative findings show a reduction in reported vaginal washing parallel reports from qualitative data collected during the intervention sessions. At study initiation, most women were pessimistic about their ability to cease vaginal washing. However, by the end of the month, most felt that they could satisfy their personal preferences and sex partner expectations without vaginal washing. The majority of women in the group discussions reported increased libido, and many stated that their regular partners enjoyed sex more when vaginal washing was eliminated. None of the women reported unpleasant odour or excessive discharge. Of 19 women returning to the clinic between 6 and 12 months after the week-4 visit, 10 (52%) reported that they had continued to abstain from vaginal washing.

We also compared the biological markers at baseline versus week 4 (table 2). There was a reduction in the number of women with non-iatrogenic genital lesions detected (OR 0.48, 95% CI 0.20 to 1.16), and an increase in the number of women with detection of *Lactobacillus* by culture (OR 3.71, 95% CI 0.73 to 18.76), although these changes were not statistically significant. There was no change in the prevalence of BV by Nugent's criteria (OR 1.00, 95% CI 0.42 to 2.38). Although most cytokine levels were reduced, these changes were not statistically significant.

DISCUSSION

In this study, we have demonstrated that a theory-based group counselling intervention may help women to modify vaginal washing practices. All participants reported cessation of vaginal washing following the 1-month intervention. We were somewhat surprised by the exceptionally high success rate, particularly because most women were not optimistic about changing these practices at baseline. However, the results of self-reported changes in vaginal washing are consistent with the positive participant feedback during the intervention sessions.

Other studies have also reported success with interventions to modify vaginal washing practices. A randomised controlled trial conducted in the US reported change in vaginal douching, although to a lesser magnitude than in our study.[15] In the US study, a stage-matched intervention with individualised counselling resulted in a 34% increase in the likelihood of reporting cessation of douching among participants in the intervention versus the control group. The success of our intervention in reducing vaginal washing might be related to the weekly group sessions, with participants motivating one another by sharing their experiences.

Because of the small sample size of this pilot study, we had limited statistical power to evaluate biological changes. Nonetheless, it is intriguing that although the proportion of women with positive *Lactobacillus* cultures increased during the intervention, there was little change in Nugent scores. However, the shifts in microbiota by Nugent's criteria were

Table 2 Generalised estimating equations analyses comparing week-4 visit with the baseline visit

	Baseline (n=23) N (%)	Week-4 visit (n=22) N (%)	OR (95% CI)	p Value
Lesions				
Total number >0	7 (30.4)	4 (19.1)	0.48 (0.20 to 1.16)	0.10
Vaginal flora				
BV (Nugent)	10 (43.5)	10 (45.4)	1.00 (0.42 to 2.38)	1.00
BV (Amsel)	8 (34.8)	7 (31.8)	0.86 (0.29 to 2.51)	0.78
Lactobacilli	2 (8.7)	6 (27.3)	3.71 (0.73 to 18.76)	0.11
	Mean (SD)	Mean (SD)	Coefficient (95% CI)	
Cytokines (log10 transformed)				
Interleukin-2	0.77 (0.26)	0.74 (0.14)	−0.03 (−0.12 to 0.06)	0.50
Interleukin-4	1.05 (0.26)	0.99 (0.24)	−0.07 (−0.20 to 0.06)	0.23
Interleukin-6	1.86 (0.57)	1.81 (0.34)	−0.05 (−0.32 to 0.21)	0.60
Interleukin-8	1.82 (0.81)	1.82 (0.79)	0.01 (−0.43 to 0.45)	0.88
Interleukin-10	0.87 (0.31)	0.81 (0.26)	−0.06 (−0.21 to 0.10)	0.44
Interferon γ	1.32 (0.25)	1.26 (0.21)	−0.06 (−0.18 to 0.05)	0.29
IP-10	3.71 (0.40)	3.71 (0.57)	0.01 (−0.24 to 0.25)	0.90
MIG	2.24 (0.73)	2.32 (0.73)	0.08 (−0.28 to 0.44)	0.64
MCP-1	0.98 (0.48)	0.85 (0.28)	−.13 (−0.33 to 0.07)	0.19
Rantes	1.31 (0.84)	1.26 (0.75)	−0.06 (−0.46 to 0.33)	0.75
TNFα	0.92 (0.50)	0.83 (0.26)	−0.09 (−0.33 to 0.15)	0.44

BV, bacterial vaginosis; IP-10, interferon-inducible protein 10; MCP-1, monocyte chemotactic protein 1; MIG, monokine induced by interferon γ; Rantes, regulated on activation normal T cell expressed and secreted; TNFα, tumour necrosis factor α.

generally in the direction of improved vaginal health (less intermediate flora).

In examining our laboratory results, it is also notable that the number of women with positive cultures for *Lactobacillus* species was low even when women did not have BV. Some women may have vaginal microbiota in which *Lactobacillus* species are not dominant. Others may be colonised primarily with *Lactobacillus* species that would not be identified through culture on Rogosa agar.[27] It is also possible that vaginal washing influences the presence of *Lactobacillus* species on Gram stain and their viability in culture.[26]

In considering the vaginal microbiota of these high-risk Kenyan women it is also important to recognise that their 'normal' vaginal microbiota may vary from that of other populations. Nonetheless, certain vaginal microbial communities have been associated with lower HIV-1 and STI risk in this population.[2] For example, women who are culture positive for *Lactobacillus* species may be at lower risk for HIV-1 acquisition, while women with BV may be at higher risk. Thus, we feel that changes in the vaginal microbiota are potentially important in mediating the effect of interventions designed to promote vaginal health as an HIV-1 and STI prevention strategy.

While eliminating vaginal washing might reduce women's risk of HIV-1 and STIs even in the absence of other interventions, recent findings that microbicides reduce HIV-1 acquisition in women further highlight the need to address practices that could interfere with microbicide effectiveness.[28] One qualitative study from South Africa has suggested that microbicides might be more acceptable where intravaginal practices are common, particularly if the microbicide gels have effects that are similar to the desired outcomes of these practices.[29] This is an important area for further research.

Despite the success of the intervention, this study had several limitations. Vaginal washing practices were self-reported and subject to social desirability bias. We tried to minimise reporting bias by reassuring the women that their reimbursement, clinical care and ongoing participation were not dependent upon their ability to cease vaginal washing. Nonetheless, we cannot rule out misreporting. Second, the sample size limited our power to detect differences in biological markers. The reason for initially conducting a small study was that we were uncertain about whether the intervention would be at all successful. Further research including a larger sample size and a control group will be useful for characterising the biological effects of vaginal washing cessation. Based on a post hoc power calculation, sample sizes of 110 and 50 would be required to provide 80% power to detect a significant ($\alpha<0.05$) difference in the prevalence of mucosal lesions and positive *Lactobacillus* cultures, respectively, taking into account the correlation between preintervention and postintervention measures in the same women. A third limitation of our study is the fact that vaginal microbiota can fluctuate rapidly.[30] Future studies should consider more frequent sampling in order to address the variability of the microbiota over time. Fourth, we cannot rule out the possibility of selection bias. We did not collect information on the number of women prescreened regarding their interest in this study. Those who enrolled may have been more willing to change behaviour than those who declined participation. Finally, we studied female sex workers whose frequency and motivations for vaginal washing may differ from other populations.

In conclusion, a theory-based group counselling intervention appeared to have a positive effect on self-reported cessation of vaginal washing by the end of 1 month in this population of women at an increased risk for HIV-1 acquisition. Such interventions might reduce women's risk of HIV-1 acquisition directly, by lowering susceptibility to infection, and indirectly, by facilitating the correct application of vaginal microbicides. Future studies with larger sample sizes and longer follow-up will be helpful in assessing the effect of vaginal washing cessation on the cervicovaginal mucosa and vaginal microbiota.

Key messages

- Intravaginal practices such as vaginal washing are a modifiable risk factor for acquisition of HIV-1 and bacterial vaginosis.
- There are few published data on interventions to reduce intravaginal practices among African women.
- In this study, women with a high baseline frequency of vaginal washing were able to reduce these practices through participation in a theory-based intervention.
- Larger studies with longer follow-up are needed to determine the durability of the intervention effect and the vaginal washing cessation impact on biological markers.

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Contributions AK and RSM conceived the question and designed the study. AK obtained funding for the study. LM, RSM, RL, GW, JS, RG and AK participated in the collection and interpretation of the data. LM and BAR conducted the data analyses. All authors participated in the preparation of the manuscript and approved the final draft for submission.

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Competing interests None.

Ethics approval Ethics approval was provided by the University of Washington IRB and Kenyatta National Hospital Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

Patient consent Obtained.

Data sharing statement Detailed information on the intervention is available from the last author (Ann Kurth) upon request at akurth@nyu.edu

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