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Evaluation of a novel, combined Point-of-care approach for the management of abnormal vaginal discharge in a low-resource setting- is it effectively reducing antibiotic use: a randomized controlled trial including follow-up

STATISTICAL ANALYSIS PLAN

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Abbreviations:

SAP: Statistical analysis plan

POC: Point-of-care

VD: Vaginal discharge

LLMICs: Low and lower-middle-income countries

STIs: Sexually transmitted infections

***Ct*: Chlamydia trachomatis**

***Ng*: Neisseria gonorrhea**

***Tv*: Trichomonas vaginalis**

BV: Bacterial vaginosis

AMR: Antimicrobial resistance

POCTs: Point-of-care tests

OTC: Over the counter

DV: Domestic violence

AD: Anxiety and depression

HSCL: Hopkins Symptom Checklist

ORCs: Outreach centers

ITT: Intention- to- treat

CONSORT: Consolidated Standards of Reporting Trials

RD: Risk difference

CI: Confidence interval

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1. Introduction:

This document entails the details of the statistical analysis plan (SAP) for the "Evaluation of a novel, combined Point-of-care (POC) approach for the management of abnormal vaginal discharge (VD) in a low-resource setting- is it effectively reducing antibiotic use: a randomized controlled trial (RCT) including follow-up" study. The purpose of developing the SAP is to provide a clear picture of how each outcome variable is defined, and the outcomes of the study objectives will be addressed following the analysis plan set out in this guideline. However, the guidelines do not cover the analysis for the additional exploratory study.

Justification at the end of the report shall be provided in case of any deviation from the planned statistical analysis.

2. Background and rationale:

Vaginal discharge (VD) is a common health concern among reproductive-age women worldwide (1). In low- and lower-middle-income countries (LLMICs), one-fourth of women experience VD, and among these, about one-third is caused by one of three curable sexually transmitted infections (STIs): *Chlamydia trachomatis (Ct), Neisseria gonorrhea (Ng)*, *Trichomonas vaginalis (Tv)*, or bacterial vaginosis (BV) (2–5). Syndromic management, the standard approach in LLMICs, relies on empirical antibiotic treatment, leading to overtreatment with antibiotics, contributing to antimicrobial resistance (AMR) (6). Affordable, accurate, and rapid diagnostic tests, such as point-of-care tests (POCTs), are needed in such a context to reduce unnecessary antibiotic use (6). Additionally, to reduce antibiotic use in a culture used to the over-the-counter (OTC) acquisition of antibiotics and possibly somatization of psychosocial problems, education on VD and antibiotics, as well as recognition of mental health or domestic violence (DV) issues, may be necessary (2,7,8).

Therefore, this study aims to evaluate the effectiveness of implementing POCTs in clinical settings in optimizing antibiotic use and explore the impact of integrating reproductive health education and psychosocial support into VD management.

3. Trial Objectives and Outcomes:

3.1 Trial objectives:

3.1.1. Primary Objectives:

- To demonstrate the effectiveness of POCTs in reducing overtreatment of abnormal VD with antibiotics in an LLMIC setting.

3.1.2. Secondary Objectives:

- To determine the impact of the addition of educational and psychosocial support on adherence to the treatment recommendations, health-seeking behavior, symptom development, and patient satisfaction.
- To assess the diagnostic accuracy of a combination of POCTs for *Tv* and BV, both combined and individually.

3.2 Outcomes:

3.2.1 Primary Outcomes:

1a) The proportion of participants over-treated (overall) with antibiotics at the primary consultation with a health practitioner, comparing treatment as usual with POCT-based treatment (Arm 1 vs Arm 2+3).

Outcome variable: Over- treatment: binary Yes/No

Definition: Correct antibiotic prescription. It is defined as receiving the following medication in accordance with the national guideline on case management of sexually transmitted infections in Nepal (9). "

Ng positive: cephalosporin (cefixime or Ceftriaxone) and macrolide (azithromycin)

Ct: Tetracycline or macrolide or fluoroquinolones (Doxycycline or azithromycin or erythromycin or ofloxacin)

Tv: Nitroimidazole (metronidazole or secnidazole or tinidazole)

BV: Metronidazole or clindamycin

Over-treatment with antibiotics is defined as receiving one of these antibiotics (as recommended under the Nepal STI case management guidelines) when the respective gold standard tests are negative (9).

1(b) The proportion of participants prescribed AMR-driving antibiotics at the primary consultation, comparing treatment as usual (Arm 1) with POCT-based treatment (Arm 2 and Arm 3).

Outcome variable: AMR- driving antibiotics: binary Yes/No
Definition: AMR-driving antibiotics are defined as receiving macrolides, cephalosporins, or fluoroquinolones at primary consultation with the health practitioner.

(1c) The proportion of participants adhering to the treatment recommendations at 4 weeks follow-up.
Outcome variable: Treatment adherence: binary Yes/No
Definition: Adherence is assessed during telephonic follow-up at 4 weeks and is defined as follows. a) Participants reported that they took the prescribed medication, and b) no additional purchase of antibiotics, and c) no purchase of other medication for VD.

Treatment adherence	**Questions at 4 weeks of follow-up**	**Adherence**
1) Participant reporting that they took prescribed medication	Did you take the medication given? 0: No 1: Yes, the way I was told 2: Yes, but not quite the way I was told 3: Not given any medication	Taking medication, the way participant was told AND No additional purchase of antibiotics OR Yes, antibiotics Yes, but not antibiotics

2) No additional purchase of antibiotics 3) No purchase of other medication for VD	Have you taken some other medication in the meantime? 0: No 1: Yes, antibiotics 2: Yes, but not antibiotics 3: Yes, don't know type If taken medication, for which problem? 0: For another problem than VD 1: For VD 2: For lower abdominal pain	Yes, don't know type AND for another problem than VD

3.2.2 Secondary Outcomes:

1. Proportion of participants prescribed antibiotics.
   Outcome variables: prescribed antibiotics: binary Yes/No
2. Proportion of participants overtreated with antibiotics despite negative gold standard test for individual pathogens (*Ct, Ng, T v*), or BV.
   Outcome variables: Overtreatment: binary Yes/No
3. Proportion of participants undertreated for *Ct, Ng, Tv,* or BV.
   Outcome variables: Undertreatment: binary Yes/No
   Undertreatment is defined as not receiving antibiotics as specified by Nepali STI management for a positive gold-standard test for any of these pathogens: *Ct, Ng, Tv*, or BV.
4. The proportion of participants adhering to the treatment recommendation compared across separate intervention arms with the standard treatment at 4 weeks and 4 months.

Treatment adherence	**At 4 weeks and 4 months of follow-up**	**Adherence**
1) Participant reporting that they took prescribed medication	Did you take the medication given? 0: No 1: Yes, the way I was told 2: Yes, but not quite the way I was told 3: Not given any medication	Taking medication, the way participant was told AND No additional purchase of antibiotics OR Yes, antibiotics Yes, but not antibiotics Yes, don't know type AND for another problem than VD
2) No additional purchase of antibiotics	Have you taken some other medication in the meantime? 0: No 1: Yes, antibiotics 2: Yes, but not antibiotics 3: Yes, don't know type	
3) Other medication for VD	If taken medication, for which problem? 0: For another problem than VD 1: For VD 2: For lower abdominal pain	

5. Change in VD symptoms will be assessed at 4 weeks and 4 months among women and compared between separate intervention arms with the standard treatment, depending on the educational intervention received. Changes in VD symptoms will be recoded from five into three groups.

i. Better, no problem anymore will be recoded to better

ii. Same, better first but came back will be recoded to unchanged

iii. Worse will be recoded to worsened

6. Proportion of women screening positive for anxiety and depression (AD) at baseline and 4 months.

7. Patient satisfaction will be compared between the separate intervention and standard treatment.

4. Diagnostic Variables:

i. **Point-of-care tests**: Results are presented to Health practitioners (Arm 2 and 3).

a. For *Ct* and *Ng Cepheid GeneXpert®*

b. For BV and *Tv:* PH and whiff test

c. For *Tv* OSOM if PH>4.5 and whiff negative after first half of participants

ii. **Gold standard tests:**

a. For *Ct, Ng,* and *Tv Cepheid GeneXpert®*

b. For BV: Nugent scoring.

iii. **STI status:** Participants testing positive for at least one of the STIs *(Ct, Ng, or Tv)* by *Cepheid GeneXpert®* are classified as STI positive. STI negative is defined as negative if all three tests are negative. BV status (Nugent score>6) will be reported separately. All the invalid and missing cases will be excluded from the analysis.

iv. **Anxiety and Depression (AD):** A positive screening for either anxiety or depression was defined as a Hopkins symptoms checklist (HSCL) score greater than 1.75 (10).

v. **Domestic violence (DV):** DV was defined as participants' self-reported experience of emotional, physical, or sexual violence perpetrated by an intimate partner or any family member (11). The participants will be classified as having experienced DV if they answer yes to any of the following questions and no if they answer no to all the following questions:

- Since you've been married or living with a partner, have you been emotionally abused by someone in the family?
- Since you've been married or living with a partner, have you been physically abused by someone in the family?

- Within the last year, have you been hit, slapped, kicked, had your hair pulled, spat on, struck with an object, or otherwise physically hurt by someone in the family?
- Within the last year, has anyone in the family forced you to have sexual activities without your consent?

5. Methods/Design:

5.1 Trial design:

This study is a randomized, double-blind, superiority trial. The trial participants are randomly allocated to one of the three RCT arms with the allocation ratio of 1:1:1. Participants in arm 1 receive treatment based on a syndromic approach; those in arms 2 and 3 receive prescriptions based on POCT results. In addition to that, the participants in arm 3 receive counseling if they screen positive for A and/or D and want a referral if they have experienced any form of DV. Also, participants in this group receive education about VD and antibiotics.

5.2 Trial setting:

The study is conducted in Dhulikhel Hospital and seven of its 18 outreach centers (ORCs). The ORCs were selected using convenient sampling in accordance with facility-based observation checklists.

5.3 Eligibility criteria:

5.3.1. Inclusion criteria:

a) Women 18 years or above with the main complaint of VD visiting the gynecology outpatient department at Dhulikhel Hospital or one of the selected ORCs. (Pregnancy is not an exclusion criterion.)

5.3.2. Exclusion criteria:

a) Current vaginal bleeding.

b) Known or suspected gynecological malignancy

c) Prior participation in the same study

d) Not contactable by mobile telephone

5.4 Trial arms and Interventions

The participants are randomized to one of the three trial arms:

- Arm 1: Standard treatment where POCT results are not made available to the health practitioners. The treatment for the participants is given according to syndromic management following the STI management of the national guidelines of Nepal.
- Arm2: POCT results are made available to health practitioners, and these results are used as a guide to make treatment decisions for the participants.
- Arm3: POCT results are made available to the health practitioner. In addition to this, psychosocial and educational interventions are also provided to the participants.

5.5 Randomization and Blinding: Participants are assigned to a randomization group using a computer-generated sequence made using a research randomizer through a simple randomization method. All the participants are recruited consecutively, with a sealed envelope with a unique identification number opened to one of the three trial arms. Allocation is based on pseudorandom numbers uniformly distributed between 0 and 1, ensuring an equal probability of assignment to each arm.

5.6 Sample size and power calculations: PASS sample size software was used for calculating the sample size based on the study objective, feasibility of the recruitment, and desired precision of the estimate (two-sided 95% confidence interval). It is assumed that 85% of women with VD unnecessarily receive antibiotics and approximately one out of two women receive AMR-driving antibiotics. Further, close to 40% are assumed to purchase OTC antibiotics after consultation. Therefore, as primary outcomes, overtreatment with antibiotics and the use of AMR-driving antibiotics will be assessed post-intervention and compared between Arm 1 and Arm 2+3 (n=1500), and treatment adherence will be assessed at 4 weeks and compared between Arm 2 and 3 (n=1000). With an equal allocation ratio of 1:1:1 across three randomized groups, among a total of 1500 participants, a 10-12 percentage point difference in the expected intervention effect will still produce a narrow two-sided CI with a width of 8-12%, with at least 90% power for each of the three primary outcome comparisons at a significance level of 0.017. A CI width of approximately 15% is anticipated for the assessment of OTC use of antibiotics even with a 40% loss to follow-up. For secondary outcomes, the proportion of prescribed antibiotics will be assessed post- intervention between Arm 1 and Arm 2+3 (N=1500). Adherence to treatment recommendations will be assessed in 4 weeks and 4 months of follow-up.

6. Analysis:

6.1 Intention-to-treat (ITT) population:

Regardless of treatment received or protocol deviation, the intention-to-treat approach will be used to analyze the primary and secondary outcomes by randomization group. Complete-case analysis will be performed for the primary and secondary outcomes as long as missingness is less than 10%. Multiple imputation and sensitivity analysis will be performed if the missingness exceeds 10%.

6.2 Per protocol population: Per protocol analysis will be conducted as a supplementary analysis, comparing group 1with 2+3. Participants with a negative STI result will be considered adherent to the protocol for Arm 2 /Arm 3 if the specific antibiotic for the particular STI is not given, as it is not indicated for a negative STI result.

7. Considerations for Data Analysis:

7.1 Reporting guidelines: Consolidated Standards of Reporting Trials (CONSORT) 2025 statement will be followed for reporting the results of the clinical trial (12).

7.2 Participant flow chart

The total number of participants approached and assessed for eligibility will be reported along with the number who met the inclusion criteria. The number of participants included in the study, as well as those excluded, will be documented, and the reason for non-inclusion in the study will be presented. The number of participants lost to follow-up will also be reported. A participant flow chart will be used to illustrate the process of recruitment, allocation, inclusion, and follow-up.

7.3 Endpoints

Endpoints	Arms	Time point measured at
Primary Outcomes		
1. Proportion of participants overtreated (overall) with antibiotics (receiving specified antibiotics with a negative gold standard test).	Arm 1 Vs Arm 2+3	Post-intervention (Day 0-7)
2. Proportion of participants prescribed AMR-driving antibiotics.	Arm 1 Vs Arms 2+3	Post-intervention (Day 0-7)
3. Proportion of participants adhering to treatment recommendations (taking prescribed medication, no OTC acquisition of antibiotics or other medication)	Arm 2 Vs Arm 3	Follow-up at week 4±1
Secondary Outcomes		
1. Proportion of participants prescribed antibiotics.	Arm 1 Vs Arm 2+3	Post-intervention (Day 0-7)
2. Proportion of participants overtreated with antibiotics despite a negative gold standard test for individual pathogens (*Ct, Ng, Tv)* or BV	Arm 1 Vs Arm 2+3	Post-intervention (Day 0-7)
3. Proportion of participants undertreated for *Ct, Ng, Tv* or BV.	Arm 1 Vs Arm 2+3	Post-intervention (Day 0-7)
4. Proportion of participants adhering to treatment recommendations (taking prescribed medication, no OTC	Arms 1,2 and 3	Follow-up at 4week±1 Follow-up 4month±1

acquisition of antibiotics, or other medication)		
5. Change in VD symptoms at 4 weeks and 4 months among women, depending on receiving educational material.	Arms 1,2 and 3	Follow-up at 4week±1 Follow-up 4month±1
6. Proportion of women screening positive for AD at baseline and 4 months	Arms 1,2 and 3	Follow-up 4month±1
7. Patient satisfaction (Likert scale)	Arms 1,2 and 3	Follow-up at 4week±1 Follow-up 4month±1

7.4 Statistical analysis:

Descriptive statistical tools like frequency, percentage, mean, standard deviation, median, and interquartile range will be used to express the results for continuous variables. Normal assumptions will be checked by visual inspection of histograms and normality plots.

Primary and secondary outcome analysis:

For the primary objective and secondary objective assessed at the post-intervention time point, the risk difference (RD) between intervention groups (arm 2+3) and the control group (arm 1) will be estimated. The RD with corresponding 95% confidence intervals and statistical significance will be assessed using the chi-square test. For the primary objective assessed at week 4±1 follow-up, the proportion of participants adhering to treatment recommendations will be compared between arms 2 and 3. RD with corresponding 95% CI will be estimated, and the statistical significance will be assessed using the chi-square test. A Holm-Bonferroni approach will be used to handle multiple primary outcomes.

For the secondary objective, measured at 4 weeks and 4 months, including the proportion of adherence to treatment recommendations, change in VD symptoms, and patient satisfaction, will be measured within the same participants. RD with 95% CI will be measured. Arm 1 will be taken as the reference group. Pairwise comparison will be made between arm 1 Vs arm 2, and between arm 1 Vs arm 3. A

p-value less than 0.05 will be considered statistically significant for secondary outcomes.

7.5 Subgroup analysis:

The primary and secondary outcomes will be analyzed according to suburban and rural locations, as well as before and after the addition of OSOM© POCT for *Tv*. Additionally, among those screened positive for anxiety, depression, or DV, comparison will be done between arms 2 and 3 to determine the proportion of women buying OTC antibiotics following POCT- guided treatment. An intention-to-treat approach will be used to analyze both primary and secondary outcomes, regardless of treatment received or not.

7.6 Missing data:

Complete case analysis will be performed for all the primary outcomes. The third primary outcome is predicted to have more missing data, which is the follow-up recorded at 4 weeks, compared to the first two primary outcomes, which are measured post-intervention. If the missingness is more than 10%, multiple imputation methods will be applied.

7.7 Graphical displays:

Several graphical displays will be used to present the findings. Bar graphs will be used to show the comparison across the RCT arms. A forest plot will be used to see the effectiveness of the treatment.

Table 1: Sexually transmitted infection (STI) Outcomes

Outcome	Arm 1 n (%)	Arm 2 n (%)	Arm 3 n (%)	Total n (%)
Individual STI outcomes, n (%)				
Chlamydia trachomatis (Ct)				
Ct positive				
Ct negative				
Invalid results				

Total				
Neisseria gonorrhoeae (Ng)				
Ng positive				
Ng negative				
Invalid results				
Total				
Trichomonas vaginalis (Tv)				
Tv positive				
Tv negative				
Invalid results				
Total				
Bacterial Vaginosis (BV)-Nugent scoring				
No BV (<4)				
Intermediate (4-6)				
BV (>6)				
Overall STI outcome, n (%)				
STI positive				
STI negative				
Total				

BV = Bacterial vaginosis, STI prevalence: Positive: if any of the STIs, Ct, Ng, or Tv are positive. Negative: If Ct, Ng, and Tv are negative

Table 2: Effect estimates of outcomes at post-intervention (Day 0-7)

Outcome	Comparison	Arm 1	Arm 2	Arm 3	Arm (2+3)	Effect estimate (95%CI)	P-value (chi-square)
Primary Outcome measured post-intervention, n/N (%)							
Overall overtreatment with antibiotics despite negative gold-standard test*	Arm 1 Vs Arm (2+3) * n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	
Prescribed AMR-driving antibiotics*	Arm 1 Vs Arm (2+3) * n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	
Secondary Outcome measured post-intervention, n/N (%)							
Proportion of prescribed antibiotics	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	
Overtreatment with antibiotics despite negative gold standard for *Ct*	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	NA
Overtreatment with antibiotics despite a negative gold standard for *Ng*	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	NA
Overtreatment with antibiotics despite	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	NA

negative gold standard for *Tv*/BV							
Undertreatment with antibiotics for *Ct* (n/N, %)	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	
Undertreatment with antibiotics for *Ng* (n/N, %)	Arm 1 Vs Arm (2+3) n/N (%)	n/N (%)	_____	_____	n/N (%)	RD	
Undertreatment with antibiotics for *Tv*/ BV (n/N, %)	Arm 1 Vs Arm (2+3)	n/N (%)	_____	_____	n/N (%)	RD	

*RD = Relative risk difference, CI = Confidence interval, P-value chi-square test of independence, *P-value below 0.017 will be regarded as statistically significant for primary outcomes, Time point = post-intervention. The group comprised of participants randomized to either treatment A (Arm 1) or treatment B (Arms 2 and 3), and these arms were combined for analysis. The control group comprised participants randomized to Arm 1.*

Table 3: Effect estimates of outcomes at follow-up

Outcome	**Comparison**	**Arm 1**	**Arm 2**	**Arm 3**	**Arm (2+3)**	**Effect estimate (95%CI)**	**P-value** (chi-square)
Primary Outcome measured follow-up, n/N (%)							
Treatment adherence at 4 weeks*	Arm 2 Vs Arm 3* n/N (%)	_____	n/N (%)	n/N (%)	_____	RD	

Secondary Outcome measured follow-up, n/N (%)							
Treatment adherence at 4 weeks	Arm 1 Vs Arm 2 Arm 1 Vs Arm 3 n/N (%)	n/N (%)	n/N (%)	n/N (%)	____	RD	
Treatment adherence at 4 months	Arm 1 Vs Arm 2 Arm 1 Vs Arm 3 n/N (%)	n/N (%)	n/N (%)	n/N (%)	____	RD	
Change in VD symptoms at 4 weeks and 4 months	Arm 1 Vs Arm 2 Arm 1 Vs Arm 3 n/N (%)	n/N (%)	n/N (%)	n/N (%)	____	RD	
Improved							
Unchanged/Worsened							
Positive HSCL screen for Anxiety at baseline **		n/N (%)	n/N (%)	n/N (%)	____		
Positive HSCL screen for Anxiety at 4 months**		n/N (%)	n/N (%)	n/N (%)	____		
Positive HSCL screen for Depression at baseline**		n/N (%)	n/N (%)	n/N (%)	____	_	
Positive HSCL screen for Depression at 4 months**		n/N (%)	n/N (%)	n/N (%)	____	_	
Patient satisfaction at 4 weeks/4 months	Arm 1 Vs Arm 2 Arm 1 Vs Arm 3 n/N (%)	n/N (%)	n/N (%)	n/N (%)	____	OR (95% CI)	

Very dissatisfied/ Dissatisfied							
Neither satisfied nor dissatisfied							
Satisfied/ Very satisfied							

*Treatment adherence is taking prescribed medication, no OTC acquisition of antibiotics or other medications. RD = Relative risk difference, CI = Confidence interval, P-value chi-square test of independence, *P-value below 0.017 will be regarded as statistically significant for primary outcomes.*

Change in VD symptoms at 4 weeks and 4 months will be analyzed using ordinal logistic regression,

***Analysis restricted to participants with both baseline and follow-up HSCL assessments.*

Patient satisfaction is measured using a Likert scale with ordinal categories. Odds ratios are measured from an ordinal logistic regression.

7.8 Supplementary:

Appendix. Draft tables

Table 1: Sociodemographic characteristics, sexual and reproductive health behavior

Variables	**Arm 1 n (%)**	**Arm 2 n (%)**	**Arm 3 n (%)**	**Total n (%)**
Sociodemographic characteristics				
Location, n (%)				
Sub-urban				
Rural				
Total				
Age, n (%)				
18-25yrs				
26-39yrs				

40-49yrs				
≥50yrs				
Total				
Marital status, n (%)				
Unmarried/engaged/boyfriend				
Married				
Divorced/Separated/Widowed				
Total				
Education, n (%)				
No education/Basic education (1-8)				
Secondary education (9-12)				
Higher than secondary				
Total				
Sexual and Reproductive Health Characteristics				
Current pregnancy status, n (%)				
No				
Yes				
Total				
Current use of contraceptives, n (%)				
No				
Yes				
Total				
Condom use by partner, n (%)				
Never use				
Use sometimes				
Always use				
Question does not apply				
Total				

Vaginal douching, n (%)				
No				
Yes				
Total				
Unprotected intercourse within 24hr, n (%)				
No				
Yes				
Don't want to answer.				
Total				
VD related to stress, n (%)				
No				
Yes				
Total				
New sexual partner within past 3 months				
No				
Yes				
Don't want to answer.				

Table 2: Self-reported clinical information by participants and health practitioners.

Variables	**Arm 1 n (%)**	**Arm 2 n (%)**	**Arm 3 n (%)**	**Total n (%)**
Reason to visit outpatient clinic*				
Itchiness around vagina, n (%)				
No				
Yes				
Total				

Urinary leakage, n (%)				
No				
Yes				
Total				
Burning micturition, n (%)				
No				
Yes				
Total				
Problem with menstruation, n (%)				
No				
Yes				
Total				
Pain in lower abdomen or back				
No				
Yes				
Total				
Pain on vulva				
No				
Yes				
Total				
Pain during intercourse				
No				
Yes				
Total				
Infertility				
No				
Yes				
Total				

Pregnancy related				
No				
Yes				
Total				
Family planning				
No				
Yes				
Total				
Follow-up				
No				
Yes				
Total				
Clinical information				
Problem with VD*				
About 1 week				
About 1 month				
About 3 months				
More than a year				
Total				
History of medication for VD within1 week back*				
No				
Yes				
Total				
Pain**				
No				
Yes				
Total				
Pathological VD**				
No				
Yes				

Total				
Pathological cervical discharge**				
No				
Yes				
Total				

**Self-reported by participants, ** Self-reported by health practitioners. VD=Vaginal discharge*

Pathological VD: profuse, smelling fishy or rotten, other color than white is defined as pathological VD.

Pathological cervical discharge: profuse, other color than white

Table 3: Trial Outcome at baseline and follow-up

Outcome	Arm1	Arm 2	Arm 3	Total n (%)
Outcome measured post-intervention, n (%)				
Overtreatment with antibiotics despite a negative gold-standard test	-			
No				
Yes				
Total				
Prescribed AMR-driving antibiotics				
No				
Yes				
Total				
Proportion of prescribed antibiotics				
No				
Yes				
Total				

Undertreatment with antibiotics (n/N, %)				
No				
Yes				
Total				
Outcome measured at follow-up				
Treatment adherence* at 4 weeks				
Treatment adherence* at 4 months				
VD symptoms at 4 weeks				
Improved				
Unhanged				
Worsened				
VD symptoms at 4 months				
Improved				
Unchanged				
Worsened				
Psychosocial variables n (%)				
Screening at baseline				
Screen positive for anxiety				
No				
Yes				
Total				
HSCL score Anxiety (mean, SD)				
Screen positive for depression				
No				
Yes				
Total				

HSCL score Depression (mean, SD)				
Domestic violence				
No				
Yes				
Don't want to answer				
Total				
Screening at 4months (telephonic)				
Screen positive for anxiety				
No				
Yes				
Total				
Screen positive for Depression				
No				
Yes				
Total				
Patient satisfaction at 4 weeks				
Very dissatisfied				
Dissatisfied				
Neither satisfied nor dissatisfied				
Satisfied				
Very satisfied				
Median (IQR)				
Patient satisfaction at 4 months				
Very dissatisfied				
Dissatisfied				
Neither satisfied nor dissatisfied				

Satisfied				
Very satisfied				
Median (IQR)				

**Treatment adherence is taking prescribed medication, no OTC acquisition of antibiotics or other medications: IQR=Interquartile range, Patient satisfaction measured by a 5-point Likert scale with ordinal categories.*

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