Self-testing for *Trichomonas vaginalis* at home using a point-of-care test by women who request kits via the Internet

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Abstract

We offered a point-of-care test for *Trichomonas vaginalis* to women via the Internet to determine if it was acceptable to women to perform the test at home. Most of the 102 participants felt that it was easy to collect the specimen, follow the instructions, and read and interpret the results for the trichomonas self-testing assay.

Keywords

home testing

Women were invited to participate in a research study via Internet recruitment to order and perform an investigational-use only version of a Food and Drug Administration-approved, Clinical Laboratory Improvement Amendments-waived point-of-care (POC) test for *Trichomonas vaginalis* at home.^{1,2} Women who ordered a routine standard-of-care (SOC) vaginal test kit for nucleic acid amplification testing (NAAT) from the [iwanthekit](http://iwanthekit.org) website (iwanthekit.org) and gave consent to be included in the study were sent a test kit to perform the test at home and invited to interpret and report their findings on the website, and answer a questionnaire. Instructions for collecting the sample and performing the home test, with visual aids, were included with the kit. The objective was to evaluate the acceptability and feasibility for women to test themselves at home with a simple POC test for trichomonas using self-collected vaginal swabs after ordering a test kit via the Internet and to see if they could interpret the result correctly.

Overall, 608 women accessed the [iwanthekit](http://iwanthekit.org) rapid trichomonas testing website page. Of them, 210 expressed their interest in self-testing for trichomonas and 199 met the inclusion criteria. Of these 199 women, 145 agreed to participate in the study after the study coordinator contacted them by phone for informed consent and 102 of them (70.3%) completed the trichomonas self-testing. Ninety-four (92.2%, 95% confidence interval (CI):

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86.9–97.4) also mailed self-collected specimens to the laboratory for trichomonas testing. The participating women were mostly between 18 and 30 years of age (63.7%, 95% CI: 54.4–73.1; Table 1). Results of a risk quiz on the website indicating probability for having an STI^{3,4} demonstrated that the majority (71.6%, 95% CI: 62.8–80.3) had a risk score in the intermediate risk category (5–7) and high risk category (8–10), based on a point system of 0–10 (Table 1).

Among the 102 participants who reported rapid trichomonas self-testing results, three (2.9%, 95% CI: 0.0–8.4) reported that the image indicating their test results were strong positive, five (4.9%, 95% CI: 1.6– 11.1) reported weak positive, 78 (76.5%, 95% CI: 68.2– 84.7) reported negative, and 16 (15.7%, 95% CI: 8.6–22.7) did not report. Three women reported their test as positive and 93 reported as their test as negative; two reported the result as invalid; and four reported that they were not sure. Two samples that had been interpreted as positive by participants were both found positive from the swab mailed in for NAAT testing. The other sample reported as a positive by the participant was not returned for the SOC NAAT test. There were 87/102 (85.3%, 95% CI: 78.4–92.2) results reported as negative by both assays. There were five women who reported that the image looked like a weak positive, three interpreted the report as negative and two reported the result as 'don't know'. For the remaining five samples, the SOC NAAT test was negative.

The participating women indicated that for the rapid trichomonas self-testing it was 'easy to collect the specimen' (95.1%, 95% CI: 90.9–99.3), 'follow the instructions' (84.3%, 95% CI: 77.3–91.4), and 'read and interpret the results' (90.2%, 95% CI: 82.7–95.2; Table 1). Most participants also reported that the results were definitely or probably correct and reliable. Forty-six participants (45.1%, 95% CI: 35.4–54.8) would pay a maximum of \$10 if the test were available over the counter, 41 (40.2%, 95% CI: 30.7–49.7) would pay \$20, and the remaining 15 (14.7%, 95% CI: 7.8–21.6) participants would pay up to \$30. No one would pay \$40 or \$50.

Self-testing at home for trichomonas using a POC test appeared to be feasible and acceptable to women who volunteered to participate and completed the study. However, of 199 women who were eligible and expressed interest in hearing more about the study, only 145 (72.9%, 95% CI: 66.7–79.0) signed the online consent form and 102/145 (64.8%, 95% CI: 62.9, 77.8) completed the study in its entirety. Since several online steps were required to complete the study, including a phone conversation to explain the study, we believe that this may have contributed to the low completion rate.

In general, most of the participants expressed that the results were definitely or probably correct and reliable. Taken together, these reports seemed to indicate acceptability and belief in self-testing. These results may indicate a willingness to take responsibility for one's own sexual health, but this requires further research. It was revealing that most of the participants (61.7%, 95% CI: 52.2–71.2) preferred self-testing at home, whereas only 8.8% (95% CI: 0.4, 16.1) preferred a healthcare provider to collect the specimen and have a laboratory perform the test for them ($P < 0.001$).

This research has limitations that restrict the generalisability of the findings. The study included a small number of women and therefore had limited precision around the estimates it generated as a weakness. Internet recruitment probably does not represent the general female population of sexually active women. However, results are intriguing and offer insight into the idea of self-testing for sexually transmissible infections using POC tests, which may help overcome issues of privacy and confidentiality barriers for sexually transmissible infection testing in general. In summary, self-testing at home for trichomonas using a POC test appeared to be feasible and acceptable to women.

References

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Table 1

Characteristics, attitudes and perceptions towards rapid trichomonas self-testing among 102 women who participated in rapid trichomonas self-testing study via the IWantTheKit Internet-based screening program for sexually transmissible infections

Characteristics/questions	Categories/response	n (n= 102)	% (95% CI) n = 102
Demographics			
Age (years)	18–24	25	24.5 (16.2, 32.9)
	25–29	40	39.2 (29.7, 48.7)
	30–34	25	24.5 (16.2, 32.9)
	35	12	11.8 (5.5, 18.0)
Race	White	40	39.2 (29.7, 48.7)
	African-American	47	46.1 (36.4, 55.8)
	Other	15	14.7 (7.8, 21.6)
Ethnicity	Hispanic	7	6.9 (2.8, 13.6)
Risk score	0–4	29	28.4 (19.7, 37.2)
	5–7	67	65.7 (56.5, 74.8)
	8–10	6	5.9 (2.2, 12.4)
Attitudes and perceptions			
How easy was it for you to collect the vaginal specimen correctly?	Easy	97	95.1 (90.9, 99.3)
	Somewhat easy	4	3.9 (1.1, 9.7)
	Not easy	1	1.0 (0.0, 5.3)
How easy was it for you to follow the instructions?	Easy	86	84.3 (77.3, 91.4)
	Somewhat easy	15	14.7 (7.8, 21.6)
	Not easy	1	1.0 (0.0, 5.3)
How easy was it for you to read the test strip and interpret the result?	Easy	92	90.2 (82.7, 95.2)
	Somewhat easy	6	5.9 (2.2, 12.4)
	Not easy	4	3.9 (1.1, 9.7)
Overall, how easy was it for you to perform the test?	Easy	94	92.2 (86.9, 97.4)
	Somewhat easy	6	5.9 (2.2, 12.4)
	Not easy	1	1.0 (0.0, 5.3)
	No response	1	1.0 (0.0, 5.3)
Do you believe that the rapid trichomonas test result was correct for the sample that you collected?	Definitely correct	55	53.9 (44.3, 63.6)
	Probably correct	44	43.1 (33.5, 53.3)
	Not correct	3	2.9 (0.0, 8.4)
How much do you trust the result of the rapid trichomonas test that you collected and tested?	Trust the result very much	64	62.8 (53.4, 72.1)
	Somewhat trust the result	35	34.3 (25.1, 43.5)
	Do not trust the result	3	2.9 (0.0, 8.4)
Do you think you would recommend to a friend that she test herself for trichomonas?	Definitely would recommend	79	77.4 (69.3, 85.6)
	Probably would recommend	21	20.6 (12.7, 28.4)
	Would not recommend	1	1.0 (0.0, 5.3)
	No response	1	1.0 (0.0, 5.3)
Would you test yourself at home for trichomonas if the test were available over-the-counter?	Definitely	82	80.4 (72.7, 88.1)

Characteristics/questions	Categories/response	<i>n</i> (<i>n</i> = 102)	% (95% CI) <i>n</i> = 102
	Probably	19	18.6 (11.1, 26.2)
	Would not	1	1.0 (0.0, 5.3)

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