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14. ABSTRACT

Purpose: We evaluated the type and intensity of training that is required for military women to make accurate self-diagnosis and self-treatment decisions with the WMSD Kit©. Design: A randomized, two-factor, controlled trial design was used to compare womens accuracy rates among six levels of training, ranging from simplest (videotape) to most intensive (videotape + psychomotor skill training + cognitive rehearsal training). Methods: The Kit included commercial, point-of-care diagnostic devices and the WMSD Decision-Making Guide©. To determine their self-diagnoses and self-treatment decisions, women analyzed standardized non-infectious specimens that yielded positive and negative diagnostic results. Sample: The volunteer participants included Army, Navy, Air Force, and Marine women (N=265) from three military installations, ages 18-58 years. Analysis: Comparison of accuracy rates among the six types of training sessions were determined by a 2-factor analysis of variance at alpha=0.05. Self-treatment accuracy, commission error, and omission error rates for each of the 7 potential self-diagnosis and self-treatment decisions were calculated from 2x2 contingency tables. Findings: Womens overall self-diagnosis and self-treatment accuracy was 80.7%, which exceeds the minimum accuracy criterion of ≥75%.Overall treatment commission errors were 10%, and omission errors were 9.9%, which meet the maximum error criteria of ≤10% and ≤15% respectively. Six of the 7 potential diagnosis and treatment options met these criteria. Vaginal yeast diagnoses were least accurate (67.4%), in part, due to faulty test indicators on the diagnostic devices. Implications for Military Nursing: The WMSD Kit shows great promise for improving military womens health during deployment. This study shows that pre-deployment training for accurate use of the Kit requires only a 23-minute videotape.

15. SUBJECT TERMS

military womens health, genitourinary symptoms, accurate self-diagnosis and self-treatment decisions

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Table of Contents

Abstract

During deployment, most women are hesitant to attend sick call for genitourinary symptoms, and 25% of the women would not seek care at all. A potential solution is to issue accurate, field-expedient Women in the Military Self-Diagnosis (WMSD) Kits©.

Purpose: We evaluated the type and intensity of training that is required for military women to make accurate self-diagnosis and self-treatment decisions with the WMSD Kit©.

Design: A randomized, two-factor, controlled trial design was used to compare women's accuracy rates among six levels of training, ranging from simplest (videotape) to most intensive (videotape + psychomotor skill training + cognitive rehearsal training).

Methods: The Kit included commercial, point-of-care diagnostic devices and the WMSD Decision-Making Guide©. To determine their "self-diagnoses" and "self-treatment decisions," women analyzed standardized non-infectious specimens that yielded positive and negative diagnostic results.

Sample: The volunteer participants included Army, Navy, Air Force, and Marine women (N=265) from three military installations, ages 18-58 years.

Analysis: Comparison of accuracy rates among the six types of training sessions were determined by a 2-factor analysis of variance at alpha=0.05. Self-treatment accuracy, commission error, and omission error rates for each of the 7 potential self-diagnosis and self-treatment decisions were calculated from 2x2 contingency tables.

Findings: Women's overall self-diagnosis and self-treatment accuracy was 80.7%, which exceeds the minimum accuracy criterion of ≥75%.Overall treatment commission errors were 10%, and omission errors were 9.9%, which meet the maximum error criteria of ≤10% and ≤15% respectively. Six of the 7 potential diagnosis and treatment options met these criteria. Vaginal yeast diagnoses were least accurate (67.4%), in part, due to faulty test indicators on the diagnostic devices.

Implications for Military Nursing: The WMSD Kit shows great promise for improving military women's health during deployment. This study shows that pre-deployment training for accurate use of the Kit requires only a 23-minute videotape.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☒ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

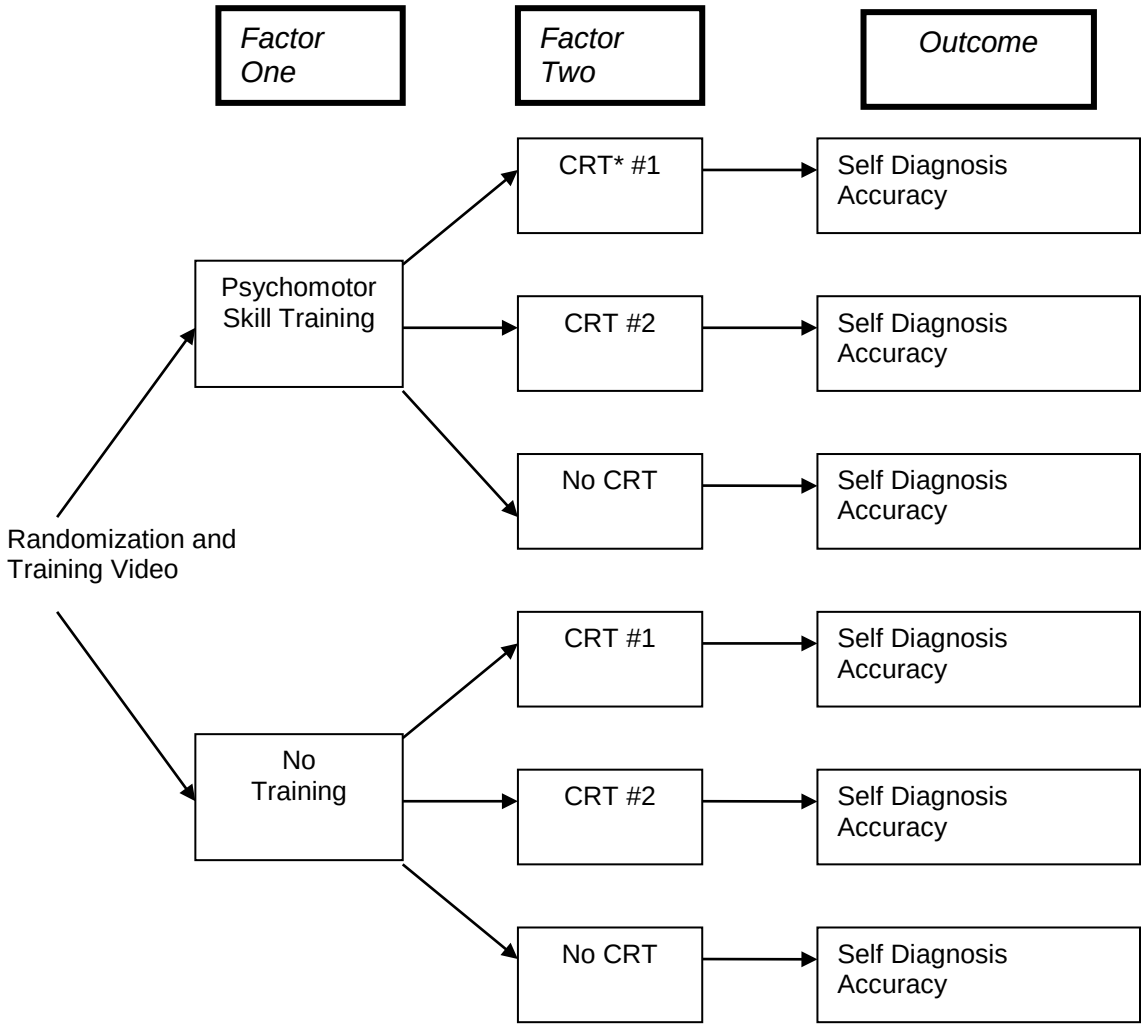
Progress Toward Achievement of Specific Aims of the Study or Project

Findings related to each specific aim, research or study questions, and/or hypothesis:

A. Brief Description of Research Design

We conducted a randomized, two-factor, controlled trial to meet the specific aims of the study. Each training session began with a standardized, pre-recorded 23-minute training video on use of the WMSD-2 Kit, including the materials comprising the Kit and the self-diagnosis process. The sessions continued according to randomly assigned levels of training intensity. Women simulated the process of self-diagnosis using the WMSD Decision-Making Guide, standardized point-of-care diagnostic tests, and non-infectious, non-hazardous reagents with pre-determined positive and/or negative results. Accuracy was determined by the women's ability to select the correct self-treatment method from the Decision-Making Guide based on their self-diagnoses. Training intensity was manipulated by combinations of two levels of Psychomotor Skill Training (PST) and Cognitive Rehearsal Training (CRT). Two PST levels included practice with the diagnostic test materials or no practice. Three CRT levels included No CRT, case studies with test results provided (CRT #1), or case studies with test results directly on the diagnostic devices (CRT #2). The combinations ranged in intensity from no training other than the video, to the video, plus PST, plus CRT #2 (Figure 1).

Figure 1. Levels of Training



*CRT = Cognitive Rehearsal Training

B. Specific Aim #1: Evaluate the accuracy of military women's simulated self-diagnoses with the WMSD Kit,© depending upon the training methods employed.

Based on their self-diagnosis test results and use of the WMSD Decision-Making Guide©, the overall accuracy of the women's self-treatment decisions was 80.7%. There were no significant differences in the military women's accuracy in conducting diagnostic tests with the WMSD Kit across the six combinations of videotape, psychomotor training and/or cognitive rehearsal training ($F=0.900$, $p=0.344$). These findings will be very useful to the military if the WMSD Kit becomes standard gear for deployed military women, because the minimal amount of training will be sufficient to ensure that the women will be able to conduct the self-diagnosis tests accurately. The minimal amount of training required was the 23-minute videotape.

C. Specific Aim #2: Refine the WMSD Kit© and algorithms to achieve a diagnostic accuracy of ≥ 75% and projected self-treatment commission errors of ≤10% and omission errors of ≤15%

for each possible diagnosis by evaluating the relative contributions of the various components of the WMSD-2 algorithms for bacterial and yeast vaginitis and urinary tract infection against standardized reagents and specimens.

The women's overall diagnostic and self-treatment accuracy averaged 80.7%, which exceeds the criterion of ≥75%. Their projected self-treatment commission errors averaged 10%, which meets the criterion of ≤10%, and average omission errors were 9.9%, which is less than the criterion of ≤15%. Table 1 shows the accuracy and error rates for the seven potential diagnosis and treatment decisions. All but one of the self-diagnosis and self-treatment options met our criteria for accuracy. The accuracy rates for self-diagnosis and treatment of vaginal yeast infections were inadequate. The SavvyCheck™ device that we used to test for presence or absence of yeast organisms was the primary cause for error. When a yeast-laden swab mixed with the reagent in the device, two purple lines indicated a positive test. The lines were often quite faint, and it was difficult to decide if there were one or two lines visible. This is the only point of care device on the market that is specific for identification of vaginal yeast at this time. We continue to look for better diagnostic devices for vaginal infections and urinary tract infections.

Table 1. Accuracy, commission, and omission error rates associated with each potential self-diagnosis and self-treatment decision on the WMSD Decision-Making Guide©.

Self-Diagnosis and Treatment Decision	Accuracy Rate	Commission Error Rate	Omission Error Rate
Criterion	≥75%	≤10%	≤15%
Vaginal yeast infection	67.4	12.5	20.1
Bacterial vaginal infection	81.4	8.7	9.8
Urinary tract infection	81.4	9.8	8.7
No medication required	84.8	4.9	10.2
Re-test tomorrow	79.9	8.7	11.4
See health care provider	80.2	13.3	6.5
Normal	84.8	12.5	2.7
Average rate	80.7	10.0	9.9

Relationship of Current Findings to Previous Findings

Dr. Nancy Ryan-Wenger and Dr. Nancy Lowe have conducted a 13-year program of research to develop an accurate, reliable, and field-expedient self-diagnosis and self-treatment kit for vaginal and urinary symptoms, thereby avoiding the need for a healthcare visit, or a gynecologic examination during deployment.[1-8] The Women in the Military Self-Diagnosis (WMSD) Kit© includes diagnostic test devices and the WMSD Decision-Making Guide© that allow women to make accurate self-diagnoses and self-treatment decisions comparable to diagnostic gold standards, health care provider diagnoses, and/or standardized specimens.

Urinary Tract Infection (UTI) Self-Diagnosis

In our first study, a paper-and-pencil version of the WMSD Decision-Making Guide included the classic triad of UTI symptoms as indicators of UTI.[3] It is common practice, but still

controversial, for providers to diagnose UTI and prescribe antibiotics by telephone from women's reports of symptoms - without a urine culture. The 86 female civilian participants' self-diagnoses were 100% in agreement with the providers' clinical diagnoses of UTI. A limitation of that study was that we did not validate the diagnoses against urine culture results. In our second study, uncomplicated UTI was defined as the presence of two or more classic UTI symptoms and a body temperature of *<100.4 F* indicated on a slide-rule version of the WMSD Decision-Making Guide. Both the women's (N=715) and the providers' (N=5) UTI diagnoses were compared with the gold standard of urine culture. Accuracy rates were only 65.7% for providers and 60.1% for the women.[8] *In the current study, UTI was defined as the indication of nitrites on a urine dipstick, and a body temperature of <100.4 F. Women's (N=265) self-diagnoses of UTI were compared to the known solutions that we used to mimic the presence or absence of nitrites and leukocytes. The women's accuracy rate was 81.4%.*

Self-Diagnosis of Vaginitis

In our first study, we used the color and consistency of vaginal discharge, vaginal pH, and whiff tests as indicators for self-diagnosis of bacterial and yeast vaginitis.[3] The 86 female civilian participants' self-diagnoses were 89.6% accurate when compared to the providers' clinical diagnoses. Again, we did not validate the providers' diagnostic accuracy. In the second study, the WMSD Kit included a commercial testing device for presence of vaginal pH and amines, in combination with the presence or absence of vaginal itching, to differentiate between bacterial/*Trichomonas*, and yeast vaginitis.[7] The research plan was to compare women's (N=715) self-diagnoses and providers' (N=5) clinical diagnoses to DNA-probe analysis for evidence of *Gardnerella* species, *Trichomonas* vaginalis, and *Candida* species in vaginal fluids. Unfortunately, an unknown number of the commercial testing devices for pH and amines were flawed, yielding unreliable results, thus self-diagnostic accuracy rates could not be determined with certainty. Providers used clinical examination, history, microscopy, pH and experience to make a clinical diagnosis. Compared to DNA, providers' diagnostic accuracy rates ranged from 46% to 73.6%.[7] In the current study, the WMSD Kit included point-of-care testing devices for determining bacterial vaginitis (pH), a yeast infection (SavvyTest™ for *Candida* species), and a revised slide-rule version of the WMSD Decision-Making Guide. We used standardized specimens that mimic positive and negative test results to evaluate the women's self-diagnosis accuracy. *In this study, the women's (N=265) self-diagnostic and self-treatment accuracy for bacterial vaginitis was 81.4%, and for yeast vaginitis was 67.4%.*

Effect of Problems or Obstacles on the Results

A primary obstacle that could not be overcome in this study was the women's difficulty in interpreting faint purple lines as positive or negative indicators of vaginal yeast infection on some of the SavvyCheck™ devices. This was an isolated problem, and had no effect on women's ability to conduct and interpret the other diagnostic tests, or on their self-treatment decision-making for other potential diagnoses.

Strengths and Limitations of the Study

A strength of the study was the randomized, controlled design used to evaluate military women's diagnostic and self-treatment accuracy, given six different levels of training intensity. A limitation was random assignment of women by groups rather than individually. However, the reality is that pre-deployment training is conducted with groups of service members, not by individual. It is not feasible to train women individually to use the WMSD Kit in any setting.

The number of subjects (N=265) was adequate to meet the aims of the study. We determined the appropriate sample size via a power analysis for a factorial analysis of variance with alpha = 0.05, power = 0.80, and a medium effect size of 0.25. A total of 211 participants and approximately 35 per group were required.[9] We recruited a total of 272 military women. Of these, 7 had incomplete data for analysis of the dependent variable. Therefore, the final sample included 265 military women distributed into the six experimental groups with 37 to 52 participants each.

Generalizeability of the results was strengthened by the similarity in demographic characteristics between the sample and the general population of military women (Table 2). The active duty, reserve, and guard volunteer participants were drawn from Army, Navy, and Air Force installations in San Antonio, TX and San Diego, CA.

An overwhelming number of the military women in this and other studies we have conducted[2,4,7] report that they believe this kit would be very beneficial to other military women (94.7%) and beneficial to themselves (90.6%), and 93.7% of the women stated that they felt very or somewhat confident in the use of the Kit.

Table 2. Demographic characteristics of participants (N=265)

Characteristic	n	%
Branch of service		
Army	95	35.9
Navy	55	20.8
Air Force	106	40.0
Marine	9	3.4
Rank		
Enlisted (E1-E3)	99	37.4
NCO (E4-E9)	148	55.8
Junior officer (O1-O3)	12	4.2
Senior officer (O4-O6)	6	2.3
Race		
White	112	42.3
Black	84	31.7
Other	56	21.1
Hispanic origin	53	19.5
Highest education level completed		
High school or GED	52	19.6
Some college or associate degree	157	59.2
College graduate	53	20.0
Marital status		
Single, divorced, separated	138	39.3
Married, living with significant other	100	37.7
Other	18	6.8
Deployed for 2 weeks or more	115	57.0

Conclusion

Women's overall self-diagnosis and self-treatment accuracy was 80.7%, which exceeds the minimum accuracy criterion of ≥75%. Overall treatment commission errors were 10%, and omission errors were 9.9%, which meet the maximum error criteria of ≤10% and ≤15% respectively. Six of the seven potential diagnosis and treatment options met these criteria. Vaginal yeast diagnoses were least accurate (67.4%), in part, due to faulty test indicators on the diagnostic devices. The WMSD Kit© shows great promise for improving military women's health during deployment. This study shows that pre-deployment training for accurate use of the Kit requires only a 23-minute videotape.

Significance of Study or Project Results to Military Nursing

Research and focus groups with military women during and after deployment indicate that most women are hesitant to attend sick call for genitourinary symptoms, and 25% of the women would not seek care at all. Barriers to seeking care for these symptoms include lack of confidence in the provider, embarrassment, lack of confidentiality, prefer a female provider – most are male, do not like seeing a co-worker for care, poor facilities, lack of privacy, inconvenience, and sick call stigma.[2] A potential solution is to issue field-expedient Women in the Military Self-Diagnosis (WMSD) Kits© before and during deployments.

This study extends previous knowledge about women's ability to self-diagnose and provide self-care for vaginal and urinary symptoms. The latest version of the WMSD Kit© provides military women with the point-of-care diagnostic devices and a WMSD Decision-Making Guide to make accurate self-diagnoses and self-treatment decisions without seeing a health care provider. A minimal amount of training is required to use the Kits safely and accurately. This study showed that a 23-minute videotape was equally effective as other training methods that included the videotape and 5 different combinations of psychomotor skills training and cognitive rehearsal training. Thus, inclusion of the WMSD Kit© during pre-deployment training would be quite feasible.

An overwhelming number of the military women in this and other studies we have conducted report that they believe this kit would be very beneficial to other military women (94.7%) and beneficial to themselves (90.6%), and 93.7% of the women stated that they felt very or somewhat confident in the use of the Kit.

Future research on the use of the WMSD Kit© during deployment is essential to determine its feasibility and usefulness in these settings. The search should continue for the most accurate, yet field-expedient, diagnostic devices for inclusion in the Kit.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

Our work has captured the attention of The Surgeon General of the Army, as illustrated in the an article published on an Army website, STAND-TO![10] Excerpts from the article are shown below. Statements most relevant to this research are underlined.

The Women's Health Task Force: **What is it?**

The Women's Health Task Force (WHTF) is a team of 43 professionals focused on the gender specific health needs of women in the military. The Army's Surgeon General Lt. Gen. Patricia Horoho directed the establishment of a WHTF in December 2011. The team was born out of the Health Services Support Assessment Team (HSSA) that in 2011 spent three months in Afghanistan talking to female warriors from all of the services about their deployment health concerns. The white paper: ***The Concerns of Women Currently Serving in the Afghanistan Theater of Operations*** is a result of those discussions. The WHTF is focused on facilitating the recommendations of the HSSA as outlined in the white paper.

…Women's health experts on the team determined six themes of concern from this assessment: Women's health education, barriers to seeking care, uniform/personal protective gear fit, psychosocial effects of deployment, effects of deployment on children and families, and sexual harassment/assault response and prevention. The assessment team made recommendations to the Army about each of these themes.

…The WHTF is actively working with a variety of Army and Department of Defense agencies regarding each of the white paper findings and recommendations. One immediate priority action is initiating ways to educate women and leaders about deployment health at military training, during annual periodic health assessments, and in social media. Additionally, they are developing a self-diagnosis kit for common female conditions for use by women in the military.

See Attachment 1 for the full website article, and Attachment 2 for the White Paper[10] (especially pp. 11-13) prepared by the HSSA.[11]

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Summary of Dissemination

Media Reports	Women's Health Assessment Team: Naclerio, A., Stola, J., Trego, L., & Flaherty, E. (2011). *The Concerns of Women Currently Serving in the Afghanistan Theater of Operations*. *White Paper*. http://usarmy.vo.llnwd.net/e2/c/downloads/262501.pdf	
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Other	WRITTEN TESTIMONY OF LIEUTENANT GENERAL PATRICIA D HOROHO THE SURGEON GENERAL OF THE UNITED STATES ARMY AND COMMANDER, US ARMY MEDICAL COMMAND COMMITTEE ON APPROPRIATIONS SUBCOMMITTEE ON DEFENSE UNITED STATES SENATE SECOND SESSION, 112TH CONGRESS FY 13 DEFENSE HEALTH PROGRAM 28 MAR 2012 (see p. 20).	

Reportable Outcomes

Reportable Outcome	Detailed Description
Copyright	The Women in the Military Self-Diagnosis and Self-Treatment Decision-Making Guide is registered for copyright by The Ohio State University Department of Technology Innovation.
Applied for Patent	none
Issued a Patent	none
Developed a cell line	none
Developed a tissue or serum repository	none
Developed a data registry	none

Recruitment and Retention Table

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	211
Subjects Available	unknown
Subjects Contacted or Reached by Approved Recruitment Method	272
Subjects Screened	NA
Subjects Ineligible	NA
Subjects Refused	NA
Human Subjects Consented	272
Subjects Who Withdrew	0
Subjects Who Completed Study	272
Subjects With Complete Data	265
Subjects with Incomplete Data	7

Demographic Characteristics of the Sample

Characteristic	
Age (yrs)	27.1 ±7.6
Women, n (%)	265 (100)
Race	
White, n (%)	112 (42.3)
Black, n (%)	84 (31.7)
Hispanic or Latino, n (%)	51 (19.2)
Native Hawaiian or other Pacific Islander, n (%)	4 (1.5)
Asian, n (%)	9 (3.4)
Other, n (%)	5 (1.9)
Military Service or Civilian	
Air Force, n (%)	106 (40)
Army, n (%)	95 (35.9)
Marine, n (%)	9 (3.4)
Navy, n (%)	55 (20.8)
Civilian, n (%)	0