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| 13. SUPPLEMENTARY NOTES N/A | | | | | |
| 14. ABSTRACT Sexually transmitted infections (STI) are at pandemic proportions among young women, ¹ and STI rates are seven times higher in military personnel than civilians. ² To meet the need for "a fit and ready force" our research team designed the <i>Strong Women Stay Safe (SWSS) Kit</i> [®] that includes a <i>Sexual Health Self-Assessment</i> [®] and a <i>Sexual Health Information Guide</i> . [®] The Kit is an innovative, self-administered, theoretically- and empirically-based decisional support system that provides women with the information and skills they need to negotiate safer sex during sexual encounters. Specific Aims. 1) Create a web-based version of the <i>SWSS Kit</i> [®] to include a <i>SWSS Virtual Date</i> [®] game. 2) Evaluate the effectiveness and benefit of paper and web-based versions of the <i>SWSS Kit</i> [®] on military women's use of safer sex behaviors and exposure to STIs over a 6-month period. 3) Validate the theoretical consistency of the electronic <i>SWSS Kit</i> [®] through analysis of meta-data from the web-based application. Design– Aim 1. A multidisciplinary collaboration among Nursing, Fine Arts (digital animation and interactive media), and Computer Science was required to convert the <i>SWSS Kit</i> [®] to a web-based interactive platform, and develop the <i>SWSS Virtual Date</i> [®] Game. Procedure. An iterative design and evaluation process involved: 1) usability testing of the paper prototype; 2) production of a web prototype via programming, interface, and interaction design; 3) focus group testing and evaluation; and beta-testing. Results. The paper and web-based <i>SWSS Kits</i> [®] are ready for implementation, however, Aims 2 and 3 were not completed during the study time-frame. Implications. The innovative <i>SWSS Kit</i> [®] is: 1) an autonomous, decision-making process tailored to women's individual sexual health goals and values; 2) delivered in an interactive, virtual and private format preferred by young women; 3) not dependent upon practitioners or trained facilitators; 4) women are able to "dose" themselves with specific information as needed. | | | | | |

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TriService Nursing Research Program Final Report Cover Page

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| USU Project Number | N11-P10 |
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Signatures

PI Signature

Nancy A. Ryan-Wenger Date 22 July 2016

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Abstract

Sexually transmitted infections (STI) are at pandemic proportions among young women,¹ and STI rates are seven times higher in military personnel than civilians.² To meet the need for “a fit and ready force” our research team designed the *Strong Women Stay Safe (SWSS) Kit*[®] that includes a *Sexual Health Self-Assessment*[®] and a *Sexual Health Information Guide*.[®] The Kit is an innovative, self-administered, theoretically- and empirically-based decisional support system that provides women with the information and skills they need to negotiate safer sex during sexual encounters.

Specific Aims.

- 1) Create a web-based version of the *SWSS Kit*[®] to include a *SWSS Virtual Date*[®] game.
- 2) Evaluate the effectiveness and benefit of paper and web-based versions of the *SWSS Kit*[®] on military women’s use of safer sex behaviors and exposure to STIs over a 6-month period.
- 3) Validate the theoretical consistency of the electronic *SWSS Kit*[®] through analysis of meta-data from the web-based application.

Design– Aim 1. A multidisciplinary collaboration among Nursing, Fine Arts (digital animation and interactive media), and Computer Science was required to convert the *SWSS Kit*[®] to a web-based interactive platform, and develop the *SWSS Virtual Date*[®] Game.

Procedure. An iterative design and evaluation process involved: 1) usability testing of the paper prototype; 2) production of a web prototype via programming, interface, and interaction design; 3) focus group testing and evaluation; and beta-testing.

Results. The paper and web-based *SWSS Kits*[®] are ready for implementation, however, Aims 2 and 3 were not completed during the study time-frame.

Implications. The innovative *SWSS Kit*[®] is: 1) an autonomous, decision-making process tailored to women’s individual sexual health goals and values; 2) delivered in an interactive, virtual and private format preferred by young women; 3) not dependent upon practitioners or trained facilitators; 4) women are able to “dose” themselves with specific information as needed.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

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

Secondary Priority

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

Progress Towards Achievement of Specific Aims of the Study or Project

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

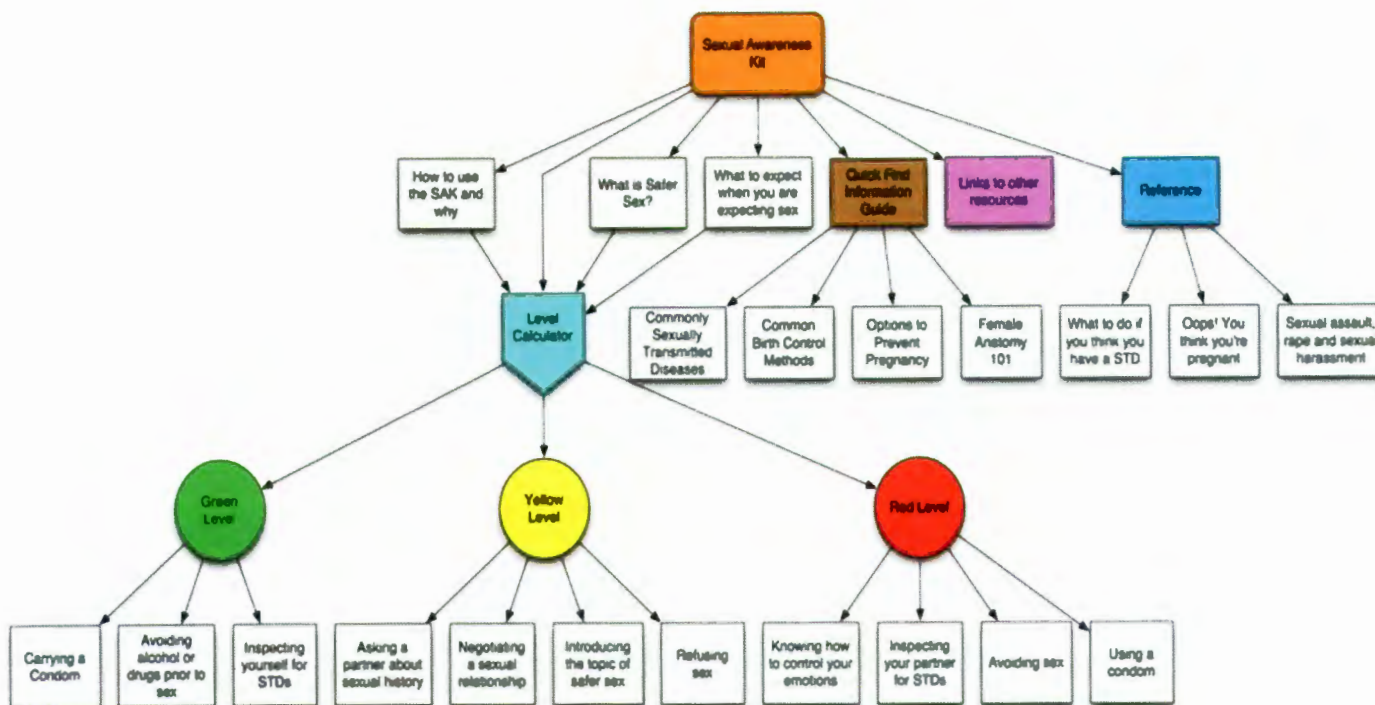
SPECIFIC AIM 1. Create a web-based version of the *SWSS Kit*[®] to include a *SWSS Virtual Date*[®] game.

Refinement of the Paper Version. The paper version of the *Strong Women Stay Safe (SWSS) Kit*[®] in the form of a 73-page 7x4 inch spiral-bound notebook, was refined and improved during the creation of the web-based version. This Kit begins with a *Sexual Health Self-Assessment*[®] to identify personal sexual risk patterns and sexual health goals and values followed by the *Sexual Health Information Guide*[®], which consists of detailed, easy-to-read information and color photographs describing safer sex, STIs, birth control, and color-coded risk-level *prescriptions* for protecting oneself in sexual encounters of varying intensity and risk. The prescriptions include suggested language for negotiating condom use or sexual refusal in high-risk situations.

Development of the Electronic Version. An iterative process was used to develop the electronic version of the *SWSS Kit*[®] and *SWSS Virtual Date*[®] game.

Step 1. Usability testing of the paper prototype. Usability testing is an efficient means of finding out whether the system meets its intended purpose. Paper prototyping is an established design research tool established in the 1990s by the engineering field. A focus group of 8 women were presented with a paper version of the interface that is manipulated by a person "playing the role of the computer," who does not explain how the interface is intended to work. The initial prototype is a mocked-up rough representation of the idea. The rougher the design, the more willing people are to challenge its most basic assumptions. This prototype helped to represent screen layout, interface widgets, content, and unexpected user actions. Neilson estimated that productivity is increased 100-fold when changes are identified before coding begins.¹¹⁴ Outcomes from these sessions were documented and distilled for inclusion in the implementation and refinement of the logic diagram, which became the map for the interactive web prototype. The logic diagram is illustrated in Figure 1 below.

Step 2. Production of a web prototype with interactive modules (programming, interface and interaction design). The Design Model was based on user activity and employed the user's language and context. The model fits the user's mental model, as established in the paper prototyping phase. The content was delivered via a typical web browser. Developed in concert with the interface architecture is the Interaction Design, which is distinct from technical design. The scope of the design is "everything but code" and includes: look and feel, language, screen objects and layout, navigation, and user assistance. The initial interface included the *SWSS Sexual Health Assessment*[®], *Sexual Health Information Guide*[®], *Virtual Date Game*[®], with a *Quick Find Information Guide*.

Figure 1: SWSS Kit,[®] Content and Interactive Flow Chart for Paper and Electronic Versions

Step 3. Focus group testing and evaluation of the SWSS[®] online interactive modules. The SWSS[®] prototype was evaluated by two separate focus groups. Participants were asked to provide feedback on several proposed female avatars, and on the system's interface, usability and the flow and content of the software in general and the sexual encounter scenarios, specifically. Usability testing is the principle means of finding out whether the system meets its intended purpose. The focus group was tested for retention, engagement, and understanding in the following order:

1 – Unobtrusive observation to measure the intuitiveness of the interface (20-30 minutes): Initially the focus group was briefly introduced to the program and then surveyed to determine their expectations for programs that would cover safe sex subject matter. Next, the women were asked to start the interaction and move through the levels to the best of their ability. We did not provide intervention or instruction, but observed and recorded the participants' progress.

2 – Interactive Observation (20-30 minutes): The design team interrupted individual participants during the interaction by posing questions regarding observed cues that implied success or delay in program use. Participants were encouraged to verbalize their criticisms of the *Virtual Date*[®] interactive game. Since discussion was based on evolving patterns of interaction, we did not use pre-prescribed questions.

3 – Survey (10-15 minutes): Participants were asked to reflect on their experience with the game, its interface and contents and indicate, in writing, their opinions on the strengths and weakness of these areas. This is a cerebral process that encourages the construction of experience ratings and summaries, and also benefits participants who best express themselves

non-verbally. In addition, the panel of experts evaluated the *SWSS Kit*[®]. These evaluations were used to establish criteria for refining the content and interaction for the final stage of development.

Step 4. Beta-testing of the web-based *SWSS Kit*[®]. Five young women, three study investigators, and the study project director evaluated the flow of the interactive, tailored information presented in the *Sexual Health Self-Assessment*[®] and *Virtual Date*[®] game. This was another iterative process to identify and correct glitches in the software.

Results.

The paper and web-based versions of the *SWSS Sexual Health Self-Assessment*[®] are innovative decision aids that take women through an autonomous, decision-making process tailored to their individual sexual health goals, values, and potential sexual encounters. As women's circumstances and experiences change, this self-assessment can be used multiple times to achieve a knowledge and skills "dose" effect. The companion *Sexual Health Information Guide*[®] consists of detailed, easy-to-read information and color photographs describing safer sex, STIs, birth control, and color-coded risk-level *prescriptions* for protecting oneself in sexual encounters of varying intensity and risk. The prescriptions include suggested language for negotiating condom use or sexual refusal in high-risk situations. The web-based version of the Kit includes a *Virtual Date*[®] game in which women's responses lead them directly to specific sections of the Information Guide.

Relationship of current findings to previous findings:

The most effective STI prevention interventions are based upon a behavioral change theory and are targeted toward characteristics of the learner³. However, the behavioral effects of these interventions often fade within a year. Electronic interventions tailored to the population of interest offer a solution to this. Computer-based, electronic interventions have an advantage in that they are more cost-effective, have greater intervention fidelity, greater flexibility in dissemination, and can be dosed longitudinally⁴⁻⁵. As with human-facilitated interventions, computerized interventions that were targeted to demographic characteristics of the learner were significantly more efficacious⁶. A non-significant trend was that studies with longer follow-up had smaller effects, suggesting that effects may wane after a year. This may be due to limited dosing, lack of skills training, and non-tailoring of the intervention. So although electronic interventions are efficacious in promoting condom use in the short term, there are gaps in the method of delivery that can be improved upon to promote safer sex and positive sexual health outcomes.

The *SWSS Kit*, tailored to women's current sexual risk, knowledge, and skills to practice safer sex improves upon current and past methods designed to prevent STIs and promote safer sex. This Kit has strong potential for successful use by military women in garrison and during deployments.

Effect of problems or obstacles on the results:

A series of events occurred that significantly delayed our study, beginning with a late start date of 14 DEC 2011 due to the process of obtaining IRB approvals from The Ohio State University (OSU) and USUHS. We had planned for one year to develop, beta test, and launch the booklet and electronic versions of the *SWSS* interventions in collaboration with faculty from the departments of Fine Arts and Computer Science at OSU. This process actually required 2 years (JAN 2012-JAN 2014) because of the complexity of the application and time constraints

experienced by our faculty collaborators. Beta testing of the intervention was not completed because our collaborator from Computer Science left the university for another position. He did not inform us of this move, nor did he leave instructions on how to access the electronic application. Ultimately, we transferred the web-based product to Nationwide Children's Hospital where the Information Services Department technicians assisted with beta-testing and final revisions of the SWSS Kit. This process required an additional 6 months. However, the final products meet all requirements for functional use of the paper and web-based sexual health decision-making guides and the *SWSS Virtual Date*® game.

Limitations: none

Conclusion: The paper and web-based SWSS Kit interventions are innovative, self-administered, theoretically- and empirically-based decisional support systems that provide women with the information and skills they need to negotiate safer sex during sexual encounters and minimize exposures to STIs.

SPECIFIC AIMS 2 & 3.

- 2) Evaluate the effectiveness and benefit of paper and web-based versions of the *SWSS Kit*® on military women's use of safer sex behaviors and exposure to STIs over a 6-month period.
- 3) Validate the theoretical consistency of the electronic *SWSS Kit*® through analysis of meta-data from the web-based application.

Relationship of current findings to previous findings:

Due to a series of events, data were not collected, thus, there are no findings to report.

Effect of problems or obstacles on the results:

1. We received a no cost extension from TSNRP for one year, ending 31 MAR 2015.
2. After about 6 months of negotiations with OSU, in JUN 2014, we transferred the electronic SWSS program to the PI's current workplace, Nationwide Children's Hospital (NCH) in Columbus, OH. We hired staff from the NCH Research Institute Information Services Core to re-format the application, beta test, and launch it on a secure server. This process required another 6 months. By MAR 2014, the *SWSS Kits*® were ready to launch.
3. In the meantime, we were verifying our proposed data collection sites at Fort Sam Houston, TX, and completing an IRB application to Beaumont Army Medical Center (BAMC). In MAR 2014, we negotiated with COL Denise Hopkins-Chadwick, AN, USA, Dean of the AMEDD Center & Schools, to recruit military women for the study. She was then assigned to another position, and the new Dean agreed to serve as the Administrative PI for our IRB application to BAMC. This person was then assigned to another position, therefore, after more than a year, our IRB application was not submitted to BAMC.
4. We received another 1-year no cost extension from TSNRP, ending 31 MAR 2016.

5. We began negotiations again with COL Hopkins-Chadwick, now Vice President, Directorate of Training and Academic Affairs, Army Medical Department Center and School Health Readiness Center of Excellence, to assist us with access to military women for our study. She joined our study as a Co-Investigator in JUN 2015. With her assistance, we were able to complete and file an IRB application to BAMC. It was finally approved on 18 MAR 2016 after three revisions.
6. On 25 MAR 2016, I requested a 60-day extension during which I planned to pre-pay all travel expenses for a series of trips to San Antonio for subject recruitment and data collection. My intent was to commit all of the funds by 31 MAR 2016, and complete all data collection by 8 DEC 2016. Any additional expenses were to be paid by the investigators. The 60-day extension was denied, and we were out of time and funds to test the intervention.

Significance of Study or Project Results to Military Nursing

Sexually transmitted infections (STI) are at pandemic proportions among young women¹, and STI rates are up to 7 times higher in military personnel². Currently the best method to prevent sexually transmitted infections is either through abstinence or the use of a condom. Most young women have had limited exposure to information about STIs and ways to prevent them. Interventions that are theoretically-based and tailored to the targeted population have demonstrated success in clinical trials; however, the effects of these interventions wane after time, most likely because they require a practitioner or trained facilitator to deliver the intervention, and there is no follow-up or coaching after the intervention is complete³⁻⁵. The *Strong Women Stay Safe Kit*[®] has the potential to effect long-term sexual health decision-making because it is a self-administered intervention that does not rely on a practitioner or facilitator to deliver it; and it provides a mechanism for women to “dose” themselves, as needed, with practical information and decision-making skills on an on-going basis. This innovative Kit is designed to meet the needs of women in garrison or deployment settings. Military nurses who care for women can recommend the *SWSS Kit*[®] to military women, keep paper versions of the Kit in their offices, and add the electronic web-based version of the Kit to computers that may be available to women in waiting rooms and examination rooms.

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

None

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Summary of Dissemination

| Type of Dissemination | Citation | Date and Source of Approval for Public Release |
|------------------------------|-----------------|---|
| Publications | None | |
| Publications in Press | None | |
| Published Abstracts | None | |
| Podium Presentations | None | |
| Poster Presentations | None | |
| Media Reports | None | |
| Other | | |

Principal Investigator (Ryan-Wenger, Nancy A.)

USU Project Number: HU0001-11-T505

Reportable Outcomes

| Reportable Outcome | Detailed Description |
|--|-----------------------------|
| 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 | 120 |
| Subjects Available | N/A |
| Subjects Contacted or Reached by Approved Recruitment Method | N/A |
| Subjects Screened | N/A |
| Subjects Ineligible | N/A |
| Subjects Refused | N/A |
| Human Subjects Consented | N/A |
| Subjects Who Withdrew | N/A |
| Subjects Who Completed Study | N/A |
| Subjects With Complete Data | N/A |
| Subjects with Incomplete Data | N/A |

Demographic Characteristics of the Sample

| Characteristic | <i>Not Applicable</i> |
|--|---------------------------|
| Age (yrs) | ± |
| Women, n (%) | () |
| Race | |
| White, n (%) | () |
| Black, n (%) | () |
| Hispanic or Latino, n (%) | () |
| Native Hawaiian or other Pacific Islander, n (%) | () |
| Asian, n (%) | () |
| Other, n (%) | () |
| Military Service or Civilian | |
| Air Force, n (%) | () |
| Army, n (%) | () |
| Marine, n (%) | () |
| Navy, n (%) | () |
| Civilian, n (%) | () |
| Service Component | |
| Active Duty, n (%) | () |
| Reserve, n (%) | () |
| National Guard, n (%) | () |
| Retired Military, n (%) | () |
| Prior Military but not Retired, n (%) | () |
| Military Dependent, n (%) | () |
| Civilian, n (%) | () |

Principal Investigator (Ryan-Wenger, Nancy A.)

USU Project Number: HU0001-11-T505

Final Budget Report

Rationale for Remaining Funds

7. Therefore, we are returning the remaining funds that were awarded.