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14. ABSTRACT
Health damaging behaviors of young military personnel are reflections of health problems facing all young people in the United States. Military life presents opportunities and challenges that may both protect and place young troops at risk for health damaging behaviors. Challenges for maintaining a healthy armed force include high rates of sexually transmitted infections (STIs), unintended pregnancies (UIPs), misuse of alcohol/substances, and personal sexual violence defined as violence within one's personal (dating or marital) relationships. The common thread through these negative health outcomes is volitional behavior. Such behaviors do not only result in illness or injury, but also negatively impact performance of military duties and threaten military readiness. Despite military leadership in setting standards and policies regarding professional behavior and universal health care for preventing and eliminating such negative health outcomes, many health problems remain. Building on our previous military research, we developed and implemented a cognitive-behavioral, skills-building intervention to prevent and reduce young troops' risk for STIs, UIPs, alcohol/substance misuse, and personal sexual violence. This research also aimed to establish the best training practices for educating young troops about health issues that impact military performance and readiness. Finally, this research has direct implications for health promotion and disease prevention education strategies designed to reach military men and women early in their careers.

15. SUBJECT TERMS
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INTRODUCTION

This research was conducted among soldiers enrolled in Advanced Individual Training at Fort Jackson SC. It utilizes a group, randomized controlled intervention trial study design to evaluate the effectiveness of a cognitive-behavioral intervention to: (1) prevent sexually transmitted infections (STIs), unintended pregnancies (UIPs), alcohol and other substance misuse, and exposure to or involvement with personal sexual violence; (2) reduce participants' risk for STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with personal sexual violence by (a) decreasing gaps in knowledge and misperceptions about risk and prevention, (b) increasing motivation to change risk behaviors, (c) building effective skills to engage in health promoting behaviors, (d) decreasing sexual risk behavior; and (3) determine the best strategy for educating participants about the sensitive health matters such as STIs, UIPs, alcohol and other substance misuse, and exposure to or involvement with personal sexual violence. Additionally, all participants completed self-administered questionnaires and were screened for STIs (*C. trachomatis* and *N. gonorrhoeae*) at baseline. As of July 31, 2013, 933 AIT soldiers undergoing training within the 187th Ordnance Battalion at Fort Jackson, SC were enrolled in this randomized controlled intervention research trial. Of these research participants, to date, 149 have completed a web-based, self-administered questionnaire ranging between 6 and 12 months post-intervention. Since our funding was halted during the evaluation process, we have not been able to complete remaining follow-up questionnaires since a number of the participants are still pending in the follow-up window. If we are able to secure new research funds, we will continue efforts to follow the remaining soldiers per our research protocol. The completion of these follow-up questionnaires is essential for the evaluation of the effectiveness of the experimental intervention.

BODY

Statement of Work

The following include the Statement of Work (SOW) activities for this research project as well as a brief description of the activities that were undertaken to accomplish each SOW.

Brief commanding officers at each participating site and enlist the support of the preventive medicine and medical community at each of the participating commands.

The following briefs were completed in 2004:

1. **Fort Bragg, NC:** MAJ Lolita Burrell (then CPT (P), Richard Carr, and Crystal Ross were briefed. MAJ Burrell was tasked with assisting with the operational and scientific aspects of the study. We had monthly conference calls with her to discuss all aspects of the study until she change posts and was no longer named our Government Officer of Record.

2. **Fort Monroe, VA:** COL James Jolissaint, Command Surgeon, US Army TRADOC, and Dr. Carole van Aalten, Risk Reduction Manager were briefed. We had three conference calls with Col Jolissaint and Dr. van Aalten. COL Jolissaint played a key role in assisting us in identifying Fort Sam Houston as a participating performance site.

3. **Fort Sam Houston, TX:** Briefs were conducted with Col Maureen Coleman, AMEDDCS, the Commanding Officer of the 32nd Medical Battalion, MAJ Beverly Jefferson, MAJ Chad Nelson, CPT David Glen, CPT Jennifer Jablin, and LTC Caron Wilbur. COL Coleman retired and LTC Wilbur became our point of contact. She was subsequently named a site investigator by the BAMC IRB. LTC Wilbur was going to assist us with setting up focus group discussions and all operational and scientific aspects of the study that pertains to Fort Sam Houston, but due to months of delay with the BAMC IRB's review of our protocol to conduct focus groups we withdrew our application to conduct research at Fort Sam Houston. At that point in time we had no leads (contacts) on suitable Army posts to conduct the proposed research.

4. **Marine Corps Recruiting Depot (MCRD), Parris Island, SC:** Given our prior experience at Fort Sam Houston, COL Brian Luke from USAMRMC, our then government officer of record (GOR), provided us permission to pursue our research project solely within the U.S. Marine Corps. With this permission we contacted and briefed the Training Command at the MCRD in Parris Island, SC. The MCRD was the site of our prior research with Marine Corps female recruits (see Boyer CB et al., Evaluation of a cognitive-behavioral, group, randomized controlled intervention trial to prevent sexually transmitted infections and unintended pregnancies in young women. *Preventive Medicine*, 40(2005): 420-431, 2005). COL Biszak, the Commanding Officer and LTC Elzie, the Executive Officer, along with MAJ Neal Pugliese, MAJ John Holbrook, MAJ Diana Staneszewski, MAJ Eric Junger, COL Johnson (Commanding Officer of 4th Battalion), and MAJ Carolyn Bird (Executive Officer of the 4th Battalion) were briefed on the proposed research. With agreement to move forward MAJ Pugliese and MAJ Carolyn Bird were our points of contact.

5. **Naval Hospital, Beaufort, SC:** CAPT James Hoffower (Commanding Officer) and CAPT H. John Gerhard (Executive Officer) were briefed regarding the purpose and goals of the proposed research since they were the medical commanders in charge of the MCRD.

The following briefs were conducted in 2005:

6. **Marine Corps Recruit Depot (MCRD), Parris Island, SC and the Beaufort Naval Hospital, Beaufort SC**: The command leaders included Mr. Eric Junger GS11, LTC Neal Pugliese, CAPT Rodney Towery, MAJ William Clark, MAJ Douglas Alexander, and CDR Arthur Giguere. After receiving approval to conduct focus groups at the MCRD it was withdrawn by the Executive Officer of the Training Command. The reason cited for declining participation in the study was due to significant training demands.

7. **Headquarter Marine Corps, Preventive Medicine Office, Quantico, VA**: We subsequently contacted the First Marine Expeditionary Force (I MEF) at Camp Pendleton, CA, (September 2005). Our contact was CDR David McMillan. After months of interactions we were then referred to LCDR Janet Spira from the First Marine Expeditionary Force (I MEF), Camp Pendleton, CA. After numerous interactions and tremendous interest and in the potential health benefits of our proposed research, at the request of LCDR Spira we sent a written brief to the Commanding General of I MEF. Despite tremendous interest and months of electronic and telephone communication, LCDR Spira informed us that her Surgeon

General declined participation in our study due to the I MEF's significant preparations for deployment and the large number of troops who were deployed, despite their initial interest in participating in the health research intervention. Thus, all our efforts from the prior year were lost with this decision.

The following briefs were conducted in 2006:

8. Since we no longer had an opportunity to conduct our proposed research with Marine Corps personnel from the I MEF, we were then provided the opportunity to speak with LTC Michael Reiss, USAMEDD, USJFCOM, Science and Technology Division, Capabilities Development Directorate, HQ TRADOC (July 2006). Subsequently, LTC Reiss arranged a conference call with LTC Sonya Corum, TRADOC Research and Analysis Dietitian, is the Directorate of BCT, Fort Jackson, SC (July 2006). As a result of several conference calls with LTC Corum, Drs. Boyer and Shafer and MAJ Lolita Burrell, WAMC-Ft Bragg, we were invited to Fort Jackson to brief COL Thomas Hayden, Deputy Commanding Officer, Headquarters, U.S. Army Training Center and Fort Jackson Office of the Commanding General, Fort Jackson (August 2006). Our brief with Col Hayden led to a subsequent brief with COL James Mundy, Commander, Moncrief Army Community Hospital, Fort Jackson, and members of his staff, COL Kathleen Dunemn, and LTC Larry Andreo (October 2006). Additionally, at the request of COL Mundy, we submitted an electronic brief (a Microsoft PowerPoint slide set that described the proposed research plan) to MAJ GEN Eric Schoomaker, Medical Corps, Commanding General, U.S. Army Medical Research and Materiel Command, Fort Detrick (December 2006).

   Deliverable for SOW 1: In November 2006 we were granted permission by COL Hayden to initiate the first phase of the proposed study, which is SOW 2. Thus, the remaining SOW's are carried out at Fort Jackson, SC with Advance Individual Training (AIT) soldiers.

1. **Conduct elicitation research (focus groups and interviews) to develop: (1) separate gender- and branch-specific interventions to reduce health damaging behaviors associated with STIs, unplanned pregnancies, alcohol and other substance misuse, and sexual violence; and (2) pre- and post-intervention self-administered, questionnaires to assess knowledge, attitudes, beliefs, and behaviors of the target groups.**

   The primary purpose of the focus groups (anonymous small-group discussions) was to determine the best intervention strategy to affect behavioral change among soldiers who were undergoing AIT at Fort Jackson. Another purpose of the focus group discussions was to better understand AIT soldiers' knowledge, attitudes, beliefs, and behaviors related to risk and prevention of sexually transmitted infections (STIs), unintended pregnancies (UIPs), and alcohol and substance misuse. In addition, the information gathered from the focus group discussions was to better understand the Army-specific context in which health promoting and health risk behaviors occur. For example, we were interested in learning how a recent or impending deployment may influence risk for STIs, UIPs, and alcohol and substance misuse.

   Prior to conducting focus group discussions we had to obtain Institutional Review Board (IRB) approval, first from the Committee on Human Research (CHR) at the University of

California, San Francisco (UCSF). We received UCSF CHR approval on January 28, 2004 (Approval number: H7183-2417-01B). We subsequently applied for and were granted IRB approval to conduct focus group discussions from the U.S. Army Medical Research and Materiel Command (USAMRMC) Human Subjects Research Review Board (HSRRB) in May 2007 (Approval Number A-12373.1a).

Deliverable for SOW 2: Six separate male and female focus group discussions were conducted at Fort Jackson in Columbia, SC on September 28-29, 2007. Four groups were among soldiers in AIT (two male and two female groups) and two groups among junior enlisted personnel (one male and one female group). Results of the focus group discussions indicate a clear need for Army-specific interventions to prevent the risk of behaviors related to the acquisition and transmission of STIs and UIPs by increasing accurate knowledge, improving protective attitudes, enhancing motivation to enact behavior change, increasing communication, problem-solving, and decision-making skills to reduce STI- and UIP-related skills. Moreover, we learned that gender-specific (separate) interventions would not work in the AIT context since male and female soldiers trained and socialized together and the male-to-female ratio is seven to three, thus making delivery of separate groups unfeasible. Additionally, three major areas of potential risk were identified:

1. In male-female soldiers social interactions during periods of leave:
   a. During weekend leaves male and female AIT soldiers socialize at clubs, malls, and other places. While they all do not engage in activities that may increase their risk for STIs and UIPs, some do drink and engage in unprotected sexual behavior.
   b. Although some soldiers indicated knowledge regarding methods of reducing risk, including abstinence from drinking or drinking in moderation and/or abstinence from sexual activity or using barrier methods to reduce risk during sexual behavior, some soldiers reported limited or incorrect knowledge, negative attitudes, a lack of motivation and skills to reduce their risk while engaging in these behaviors.
   c. Both male and female soldiers indicated that STIs and UIPs were of concern for them and some heard of instances where these negative health outcomes have occurred.
   d. Some soldiers reported that going to the Troop Medical Clinic is a great place to go for reproductive health concerns such as STIs or pregnancy, some indicated concern that their health information would not be kept private, which may prevent them from seeking healthcare in a timely manner or for prevention purposes.

2. When transitioning from AIT training to their first duty station, junior enlisted soldiers, especially female soldiers, reported knowledge of instances when soldiers first arrive to a new duty station, they receive a great deal of attention from male soldiers:
   a. It was reported that some soldiers are motivated by genuinely helping the "newbie" and some are motivated by possible opportunities for selfish reasons such as garnering attention or even dates.
   b. Some soldiers perceived this to be a particularly vulnerable time for female soldiers, especially those who are naïve or unsuspecting of the other the person's motives.
   c. Some soldiers (especially female soldiers) indicated that there is a need for training to give young male and female soldiers skills about how to handle social transitions to a new post.

3. When learning about their initial deployment abroad (e.g., Iraq):
    a. Both male and female soldiers reported feelings of being prepared for deployment in terms of their technical skills, but reported apprehension about the unknown and unexpected things to come; concern that family members and other love ones will worry about them; and unease about not having opportunities for rest and relaxation during long periods of deployment.
    b. As a result of these concerns, some soldiers reported an accelerated rate of engaging in some behaviors including drinking more and/or engaging in sexual activity. Along these lines some reported (mostly males) wanting to make sure they leave a legacy (child) behind if the event that they do not return from deployment, thus prompting opportunities for engaging in unprotected sexual intercourse.

The findings from the focus group discussions were used to inform the development of the interventions for AIT soldiers to reduce their risk for STI, UIPs and other health-related risk factors (SOW 3).

2. Develop comparable gender-specific interventions for male and female US Marine Corps Army personnel to: (1) prevent acquisition of STIs and UIPs; and (2) reduce the risk of STI- and UIP-related behaviors including alcohol and other substance misuse, and personal sexual violence.

Deliverable for SOW 3: Based on our focus group data it was determined that separate gender-specific interventions would not be feasible or an acceptable approach for educating soldiers in the context of AIT. Training manuals that provide content and instructions for the intervention facilitation were developed and completed in December 2008. Specifically, we developed curriculum, including the training manual for the STI/UIP prevention intervention, and an Army-specific video to reinforce health promotion information. The video is entitled, ***Off Post***. The intervention is entitled, ***Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies***. See **Appendix 1** for a detailed description of the modules' objectives for each of the four sessions of the intervention's training manual. In addition, for the comparison (control) group, an intervention was developed that focused on nutrition, physical fitness, and injury prevention. This intervention is entitled, ***Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention***. See **Appendix 2** for a detailed description of the modules for this intervention. Also, it is important to note that we developed five, two-hour sessions for each intervention (10 hours of contact time for each intervention). However, due to AIT training demands and time constraints, Command leadership asked that we reduce the sessions to four sessions for actual delivery. This resulted in a total of eight hours of education contact with soldiers for each intervention. The outline of the shortened interventions are reported here since these were the versions that were implemented as part of this research.

3. Pilot-test the gender-specific interventions, self-administered questionnaires, and the biological specimen collection protocol for feasibility.

Deliverable for SOW 4: Prior to the pilot-test implementation we applied for and received IRB approval for the intervention's implementation. UCSF CHR approval was received on

January 11, 2010 (Approval number: H7183-34767-01) and USAMRMC Human Subjects Research Review Board (HSRRB) was received on March 17, 2010 (Proposal Log Number 03210001, Award Number W81XWH-04-1-0159, HRPO Log Number A-12373.2). Implementation of the pilot-test (SOW 4) was completed in October 2010. This pilot-test provided key information regarding the feasibility and acceptability of the full-scaled intervention trial.

4. Implement the gender- and branch-specific interventions at each command.

Deliverable for SOW 5: Research activities related to this and the remaining SOWs are currently being carried out at Fort Jackson, under the guidance and support of the U.S. Army Basic Combat Training Center of Excellence (USABCTCoE). Within the USABCTCoE, LTC Sonya J. Cable (formerly Corum) was our primary research military contact for the tenure of the research. She provided guidance for all research-related logistics. Although our projected spanned across several leaders within the the187th Ordnance Battalion, LTC Dennis Kerwood was the Commanding Officer during the last month of our study implementation. Over the last year of study implementation our direct points of contact recently was CPT Patrick Coffee, the officer who was tasked with providing logistical support to the project and MAJ Emmitt Osborne, the Executive Officer the for the187th Ordinance Battalion.

As of July 31, 2013 we enrolled 933 AIT soldiers as study participants into the research project; 540 were randomized to the experimental intervention group and 393 were randomized to the control intervention group. Of the total enrollment, 368 participants were enrolled since March 2013, demonstrating our high level of productivity in the last five months of our funded project period. All participants enrolled were screened for *C. trachomatis* and *N. gonorrhoeae*; 48 (5.0%) were identified with an asymptomatic STI. Each individual identified with an STI received confidential treatment and counseling at the post's Preventive Medicine clinic per the standard of care for all soldiers seeking care at the clinic. Ms. Sarah M. Gay, RN, APHN, was the clinician who provided care to the soldiers who were identified with a positive infection. Ms. Gay noted that this "project reached individuals that would have not otherwise sought help to assess or improve their health". See **Appendix 3** for a brief overview of selected descriptive characteristics of the research participants. Since we were actively in our data collection phase of the study when our project funding ended on July 31, 2013, we have not been able to conduct extensive data analyses to report thus far.

5. Conduct 12-month follow-ups of military personnel participating in the interventions.

Deliverable for SOW 6: Activities related to this SOW are still underway. Early in the implementation of the intervention it became obvious that a 12-month follow-up period of study participants would not be feasible since many of the soldiers would not be physically stationed in the continental United States (CONUS). Given this, we obtained approval from our then GOR (at the time MAJ Burrell) and IRB institutions to conduct 6- to 12-month follow-up, confidential web-based self-administered questionnaires. We requested the range in months on the bases of our prior experience with military personnel, recognizing that it takes several tries to reach and receive a response from military personnel (similar to that of civilian counterparts). Of the participants enrolled in the research project, 151 study

participants have completed the follow up survey and 212 are currently in the follow-up window to complete the questionnaire. Of the remaining participants, 565 have not been reached due to undeliverable email addresses or no responses to our prior attempts to reach study participants; only 5 have declined further participation. To address the issue of undeliverable email addresses we were undertaking a number of strategies during our period of funding, including requesting that participants provide both their military and personal email addresses at study entry and request that they verify their email addresses prior to the end of the intervention participation in hopes that these additional efforts will reduce the number of invalid email addresses for follow-up going forward. Additionally, we have been working with the Battalion's leadership to identify viable military addresses for our prior participants. We hope that, with additional funding, we will be able to continue with our efforts of identifying the correct military email addresses of our research participants. Since it is our goal to complete the follow-up questionnaires we are including copies of our currently approved IRB information. See **Appendix 4** for our current IRB approval notification from the UCSF CHR (IRB #: 10-04317 Reference #: 056080; this approval will expire 10 December 2013). Please note that we are now using an electronic system, which explains the changes in our approval number from previous years. See also **Appendix 5** for the USAMRMC Human Subjects Research Review Board (HSRRB), HRPO Log Number A-12373.2; this approval will expire on 10 December 2013).

6. **Evaluate the effectiveness of each gender-specific intervention and compare differences across interventions on study participants' acquisition of STIs and UIPs during their first year of military service.**

   Deliverables for SOW 7: Activities related to this SOW has not been completed since it is contingent upon complementation of SOWs 5 and 6. Since the funding for the study was halted on July 31, 2013, we are not able to accomplish this SOW at this time. However, it is our goal to carry out this SOW with a request for new funding that would provide us the necessary resources to complete the follow-up questionnaires and to analyze the data and submit manuscripts for publication consideration as well as provide briefs to military-specific preventative medicine groups.

7. **Examine key sub-questions related to STIs and UIPs:** (1) assess psychosocial, behavioral, and contextual factors associated with STIs and STI-related risk at baseline and STIs and UIPS at follow-up; (2) document the prevalence of personal sexual violence at basic training entry; (3) examine relationships among personal sexual violence, STIs, and STI-related risk at baseline and STIs and UIPS at follow-up; and (3) determine the relationship between alcohol and other substance misuse and personal sexual violence and the relationship of these factors to STIs and STI-related risk at baseline and STIs and UIPS at follow-up.

   Deliverables for SOW 8: This SOW will reflect a large portion of our data analyses going forward. A complete and thorough assessment of these factors will be done if we are able to secure additional funding to carry out this SOW. Specifically, it is our goal to address a number of important research questions related to our primary outcomes of interest, STIs and UIPs, and other related health outcomes such as alcohol abuse and other substance use as well as factors associated with intimate partner violence. We also aim to extend this SOW to examine factors associated with nutrition, physical fitness, and injury prevention. To

accomplish this, we will involve Dr. Andrea Garber, a Nutrition faculty member with our Division of Adolescent and Young Adult Medicine. She has worked with our team in writing a seminal scientific paper on BMIs, disordered eating and weight dissatisfaction in Marine Corps Recruits (see Garber AK, Boyer CB, Pollack LM, Chang YJ & Shafer M-A. Body Mass Index and Disordered Eating Behaviors are Associated with Weight Dissatisfaction in Adolescent and Young Adult Female Military Recruits. *Military Medicine*, 173(2): 138-145, 2008).

Contingent upon successful acquisition of new funding to accomplish this SOW we will undertake an iterative series of univariate, bivariate, and multivariate statistical analyses allowing us to create multi-item measures using Cronbach's alphas and factor analyses, Pearson correlations, Chi-Square or t-tests, and multiple regression analyses (linear and logistic regressions, as appropriate). The results of this research will have important implications for military readiness, preventive medicine, and public health. There is a paucity of current literature that describes factors associated with health promoting and risk behaviors as well as motivational factors associated with health behaviors and outcomes among young enlisted soldiers. Specifically, we have a unique opportunity to shed light on factors related to knowledge, perceived risk, behavioral intentions, and peer influences among other factors that are associated with acquisition of STIs and other health risk behaviors. Also, a unique aspect of this research is the large number of males who are enrolled. So little is known about reproductive and sexual health factors in young adult men, military or civilian. If we secure new funding to accomplish these goals we will meet weekly and to discuss our plan and undertake appropriate data analyses in an iterative process. Drs. Boyer, Pollack, and Garber have a long productive history of collaboration with our previous USAMRMC-funded research. These activities will be ongoing and dissemination of our findings will occur in parallel.

8. **Disseminate study findings through: (1) briefs given to participating military commands; (2) presentations at military-specific preventive medicine meetings as well as annual scientific meetings; and (3) publications submitted to scientific journals**.

Deliverables for SOW 9: Dr. Boyer provided a scientific brief to Major General Bradley W. May, the Deputy Commanding General for Initial Military Training Center of Excellence, U.S. Army Training and Doctrine Command, Fort Eustis, Virginia on July 23, 2013. Other senior leaders in the attendance were: COL Carolyn Tiffany, TRADOC Surgeon General's Office, Mr. Michael McGurk, Director of Research and Development, MAJ Gail Evans, Physician Assistant Research and Analysis Directorate, among other senior Command leaders. COL Sonya Cable, our primary research advisor, was away on a temporary duty assignment. It is our goal that with additional funding we will be able to completely carry out this SOW.

Additionally, Drs. Boyer, Pollack, and Adrianse (an M.D. Adolescent and Young Adult Medicine Fellow here at UCSF) recently submitted a research abstract to the Society for Adolescent Health and Medicine (SAHM) for March 2014 scientific annual meeting. Moreover, we are currently working on a manuscript for publication submission to the journal *Military Medicine* to examine the association of sociodemographic, sexual health behaviors, contraceptive and condom use and a history of unintended pregnancy in soldiers.

Our project submission date is early January 2014. This aspect of research has the potential of providing key insights into factors associated with unintended pregnancy among young adult males females. Although the focus is on soldiers, there is clearly a broader public health implication for civilian young adults as well. **See Appendix 6** for a copy of the SAHM research abstract. It is important to note that our team has an excellent track record in producing manuscripts and presenting at scientific and military-specific preventive medicine meetings. With our previously funded USAMRMC research we published 16 scientific papers in high impact peer reviewed journals, including military-specific, public health, preventive medicine, and other scientific specialty journals.

KEY RESEARCH ACCOMPLISHMENTS

1. We conducted six separate male and female focus groups to provide formative research to help guide the development of the interventions to be studied in this research project. See a detailed description of the focus group findings above in SOW 2.

2. Based on our prior military-specific research, our formative research specific to this project, and best practices identified in the research literature, we developed two training manuals that provide content and instructions for the experimental and control interventions that were implemented as part of this research project.

    a. The experimental intervention is entitled, ***Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies.*** See SOW 3 above and **Appendix 1** for an overview of this intervention's goals and learning objectives.
    b. The control intervention is entitled, ***Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention***. See SOW 3 above and **Appendix 2** for an overview of this intervention's goals and learning objectives.

3. We developed an Army-specific video entitled, ***Off Post*** that was developed specifically for this project. The goal of this video was to address specific areas of health risks that were identified for soldiers during periods of leave during AIT. The content of the video was based our formative research and was produced to reinforce health promotion messages described in the experimental intervention.

4. As noted above in SOW 5 activities we enrolled 933 AIT soldiers in this randomized controlled intervention trial, 809 (86.7%) males and 124 (11.3%) females. The breakdown of study participants by gender accurately reflects the gender differences that occur in the training battalion in which this research project took place. See also **Appendix 3**, for a brief (selected) description of the study participants.

5. All participants enrolled were screened for *C. trachomatis* and *N. gonorrhoeae.* Of these individuals, 48 (5.0%) were identified with an infection. Each individual identified with an STI received confidential treatment and counseling at the post's Preventive Medicine clinic per the standard of care for all soldiers seeking care at the clinic.

REPORTABLE OUTCOMES

To date, we have only had the opportunity to submit one research abstract for consideration for presentation at the 2014 scientific meeting of the Society for Adolescent Health and Medicine (SAHM). In October 2013, we will learn whether this abstract is accepted for presentation at the upcoming SAHM meeting. See **Appendix 6** for a copy of this abstract, which is entitled, "Correlates of consistent use of effective contraceptive methods among male and female adolescent and young adult soldiers in training." This abstract focused on factors associated with effective contraceptive (birth control) methods used by young adult men and women. Since data analyses were still underway, the abstract only reflects the first 720 participants enrolled in the study. Given the goal of understating factors sociodemographic, knowledge, psychosocial factors and behaviors associated contraceptive use, only those study participants who self-identified as having a history of sexual experience were included in the data analyses that were conducted to produce this research abstract. This research is important in that it has the potential of shedding light on factors that may help in the prevention of unintended pregnancies in young adults, particularly among men where there is little to no understanding of these factors. The lead author is Stephanie Adrianse, MD who is an Adolescent Medicine Fellow in the Division of Adolescent Health and Medicine here at the University of California, San Francisco under the mentorship of Drs. Boyer and Pollack. Dr. Pollack is funded, in part, by this project to clean and analyze the data and to help with interpretation of study findings and writing up the results. Dr. Boyer, the Principal Investigator of this project and is the senior author on the abstract. She plays a key role in all aspects of the research, including the conceptualization of the research question(s), creating and identifying research measures, assisting with the data analytic planning and interpretation of the findings, as well as writing the results.

CONCLUSION

Since we have not had the opportunity to fully complete our SOW activities, it is premature to draw any final conclusions. However, what we have learned through the development, implementation, and preliminary process evaluation of this randomized controlled intervention trials the following preliminary observations were made:

1. Implementing health promotion and disease prevention interventions are both feasible and acceptable strategies for educating soldiers in the AIT context. With guidance and support of the Command's leadership, and with direct involvement of the training Sergeants, such educational activities can be integrated into AIT.
2. AIT soldiers are willing to participate in health education sessions, in addition to their AIT education and training. They reported that such heath education opportunities are desired and important to their health and careers. They often wanted additional health promotion education opportunities beyond the eight hours of time they spent in the educational sessions.
3. Our project utilized a multi-media and multi-session approach using didactic and interactive knowledge and skills building teaching modalities. Moreover, we used videos and experiential learning strategies to promote healthy communication and problem-solving techniques, which the soldiers found to be acceptable and preferable to just a didactic only education strategy.
4. Sexual and reproductive health as well nutritional and injury prevention are health topics that soldiers indicate are important, and thus, they are willing to learn about.

5. Soldiers are willing to undergo screening for STIs using non-invasive techniques. All of the soldiers who enrolled in this research project submitted biological specimens to for screening of asymptomatic STIs; urine specimens were used for males and self-administered vaginal swabs were used for females. It is important to note that this process was done confidentially within the AIT (group education) context. Given the 5% STI positivity rate we identified, it is evident that STI screening, especially for males, who rarely have opportunities to undergo sexual and reproductive health examinations, is warranted for all soldiers early in their military careers. Our prior research and other public health research have shown that screening for prevalent asymptomatic STIs among young adults is important and cost-effective in that it has the potential of adverting sequelae of STIs including pelvic inflammatory disease, chronic pelvic pain, future infertility, and increased risk for HIV. Moreover, identifying, treating, and counseling soldiers with an STI will likely prevent other STIs in other troops since many soldiers who work and train together do engage in social and sexual relationships.

Although we are not able to provide any conclusions about the effective of the intervention at this time, please note that we have a firm commitment to completing SOW-related activities, including completing the follow-up surveys (SOW 6), evaluating the effectiveness of the study interventions (SOW 7), an examining key sub-questions related to STIs, UIPs and other health related factors such as alcohol and other substance use, and intimate partner violence (SOW 8). With further funding, we are confident that we will be as productive in publishing the results of this research as we have in our previous USAMRMC projects.

REFERENCES

There are no published references to report at this time.

APPENDICES

1. Appendix 1: Overview of the modules for the Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies intervention
2. Appendix 2: An overview of the modules for the Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention intervention
3. Appendix 3: Table 1. Selected Sociodemographic, Behavioral, and Psychosocial Characteristics of Study Participants
4. Appendix 4: Current Institutional Review Board (IRB) approval letter from the University of California, San Francisco
5. Appendix 5: Current Institutional Review Board (IRB) approval email from the USAMRMC Human Subjects Research Review Board (HSRRB)
6. Appendix 6: Scientific Abstract submitted for presentation consideration at the Society for Adolescent Health and Medicine 2014 Annual Conference

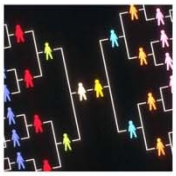
SUPPORTING DATA

1. Appendix 3: Table 1. Selected Sociodemographic, Behavioral, and Psychosocial Characteristics of Study Participants

Appendices

Appendix 1:

Overview of the modules for the *Staying Safe and in Control: Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancies* intervention



STAYING SAFE AND IN CONTROL

Increasing Knowledge and Building Skills to Prevent Sexually Transmitted Infections and Unintended Pregnancy

Cherrie B Boyer, Ph.D.
Regina Firpo-Triplett, M.P.H., C.H.E.S.
Anthony Kung, B.A.

SESSION 1

OVERVIEW

OBJECTIVES:
- Provide basic information on the effects of alcohol.
- Identify personal style of alcohol use, learn how one's style of alcohol use affects sexual risks and choices, and set limits for future alcohol consumption

TIME:
120 minutes

MATERIALS:
Computer, LCD projector, Screen (if necessary), Session 1 PowerPoint slide set, "Life Goals" worksheet, pencils, "My Leave Time" worksheet, markers, self-sticking chart paper for listing potential consequences for living in the "Out-of-Control Zone", "Pattern of Alcohol Use" handout, "Alcohol Use and Sexuality" handout, "Saturday Night" handout, five pieces of self-adhesive flip chart paper that states, "Working Together To Drink Safely: Things I Can Do to Stay Safe and in Control while Drinking Alcohol" handout, "My Drinking Assessment" Worksheet

FORMAT:
Interactive PowerPoint slide presentation

INTRODUCTION	10 MINUTES
Overview of the Program and Session 1	
MODULE 1	15 MINUTES
Life Goals	
MODULE 2	20 MINUTES
My Leave Time	
BREAK	5 MINUTES
MODULE 3	20 MINUTES
Alcohol Effects and Use	
MODULE 4	15 MINUTES
Saturday Night	
MODULE 5	20 MINUTES
Working Together to Drink Safely	
MODULE 6	12 MINUTES
Drinking Styles and Self-Assessment	
WRAP-UP	3 MINUTES
Summarize Session and Introduce Session 2	

SESSION 2

OVERVIEW

OBJECTIVES:

- Identify and simulate social and environmental factors that increase and reduce participants' risk for STIs and UIPs during AIT
- Examine strategies for reducing participants' risk for STIs and UIPs during AIT
- Identify factors that make talking about sex with a partner challenging for men and women
- Provide practical tips for making it easier to talk with a sex partner (about risk and prevention of STIs and UIPs)

TIME:
120 minutes

MATERIALS:
Computer, LCD projector, "Off Post" video, TV/DVD player, "Talking About Sex" handout, "Tips for Talking with Your Partner" handout

INTRODUCTION	5 MINUTES
Review of Previous Session and Overview of Session 2	
MODULE 1	50 MINUTES
"Off Post" Video Viewing and Discussion	
BREAK	5 MINUTES
MODULE 3	55 MINUTES
Talking About Sex	
WRAP-UP	5 MINUTES
Summarize Session and Introduce Session 3	

SESSION 3

OVERVIEW

OBJECTIVES:

- Review basic reproductive anatomy and physiology as it relates to STI risk
- Define sexual behaviors related to risk for STIs
- Examine prevalent STIs with a focus on risk, transmission, symptoms, treatment, and consequences
- Discuss concrete and specific strategies for preventing STIs
- Assess risk for acquiring an STI, including HIV
- Identify personal limits regarding their risky behaviors and intentions
- Discuss effective use of condoms
- Examine and discuss barriers to condom use
- Review strategies for talking to sex partner(s) about condom use
- Examine information about intimate partner violence (IPV) and how to prevent becoming a victim of it

TIME:
120 minutes

MATERIALS:
Computer, LCD projector, Session 2 PowerPoint slide set, STI Fact Sheet Handout series (stapled together to be given to each participant), "Personal Risk Assessment" handout, "Scoring Guide" handout

INTRODUCTION	2 MINUTES
MODULE 1	15 MINUTES
Anatomy and Physiology Basics	
MODULE 2	30 MINUTES
Sexually Transmitted Infections: Knowing the Facts	
BREAK	5 MINUTES
MODULE 3	15 MINUTES
Assessing Your Personal Risk	
MODULE 4	20 MINUTES
"Let's Talk About Condoms"	
MODULE 5	25 MINUTES
Preventing Intimate Partner Violence	
WRAP-UP	3 MINUTES
Summarize Session and Introduce Session 4	

SESSION 4

OVERVIEW

OBJECTIVES:

- Provide accurate information about factors that contribute unintended pregnancy
- Examine basic information about prescription and non-prescription methods of contraceptives
- Increase awareness of the impact of an unintended pregnancy on personal goals and career
- Give information about non-prescription methods of contraceptives, including condoms, spermicides, and the Morning After Pill
- Analyze and discuss personal preference and lifestyle factors related to preventing unintended pregnancies and STIs
- Increase motivation to seek reproductive health care by providing them information on when and how to access health care

TIME:
120 minutes

MATERIALS:
Computer, LCD projector, Session 4 PowerPoint slide set, two different types of candy (e.g., peppermint and butterscotch), "Myth Or Fact?" handout, "Myth Or Fact?" answer sheet, "Pregnancy Test: Going To The TMC" facilitator Sheet, "Pregnancy Test: Getting The Results" facilitator sheet, "Best Case Scenario" worksheet

INTRODUCTION	5 MINUTES
Brief Review of Previous Session and Preview of Session 5	
MODULE 1	10 MINUTES
Pregnancy Facts	
MODULE 2	55 MINUTES
Contraceptive Methods Overview and Prescription Methods of Contraceptives (25 minutes) Pregnancy Test: Going to the TMC (10 minutes) Non-Prescription Methods of Contraceptives (10 minutes) Pregnancy Test: Getting the Results (10 minutes)	
BREAK	5 MINUTES
MODULE 3	20 MINUTES
Best Case Scenario	
MODULE 4	10 MINUTES
Health Care Access	
WRAP-UP	15 MINUTES
Chalk Talk Wrap-Up Forms	

Appendix 2:

Overview of the modules for the
Fit You: Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention intervention






FITYOU

Practical Tools for Healthy Eating, Physical Fitness, and Injury Prevention

Cherrie B. Boyer, Ph.D.
Kelli Betsinger, B.A.
Anthony Kung, B.A.

SESSION 1

OVERVIEW

OBJECTIVES:

- Identify individual, cultural, social influences on nutritional choices
- Encourage personal responsibility for setting goals, increasing motivation, and building skills required to meet individualized dietary needs and fitness goals
- Discuss dietary recommendations (introduction to military-based nutrition for physical performance)
- Define nutritional requirements for peak physical performance
- Define basic fitness concepts
- Encourage personal responsibility for setting goals, increasing motivation, and building skills required to meet individualized dietary needs and fitness goals (develop a personal risk assessment)
- Assess personal risk for health related illnesses and injuries often associated with unhealthy nutrition and poor fitness.
- Define basic concepts of fitness (set training goals)
- Build skills for developing a personal fitness program for peak performance

TIME:
120 minutes

MATERIALS:
DVD with Supersize Me clip, Laptop, LCD projector, extension cord, and handout of follow-up questions, PowerPoint Files, paper, pencils “Personal Risk Assessment” worksheet.

FORMAT:
Interactive PowerPoint slide presentation

MODULE 1	5 MINUTES
Welcome and Program Overview	
MODULE 2	25 MINUTES
“Supersize Me” – A Film of Epic Proportions	
MODULE 3	40 MINUTES
Nutrition and Health for Peak Performance	
MODULE 4	15 MINUTES
Personal Risk Assessment	
MODULE 5	35 MINUTES
Fitness and Physical Activity	

SESSION 2

OVERVIEW

OBJECTIVES:

- Discuss USDA dietary recommendations
- Identify healthier choices of foods when shopping in markets or eating in restaurants and mess halls
- Evaluate daily dietary intake
- Provide skills for understanding food labels in order to meet nutritional needs (introduce food label reading)
- Identify individual, cultural, and social influences on nutritional choices (introduce decision-making skills for eating out, snacking, and shopping)
- Develop decision-making skills for eating out, snacking, and shopping
- Discuss dietary recommendations for healthy nutrition
- Define basic concepts for using a training log
- Introduce practical online tools to aide in developing peak performance
- Define nutritional requirements for peak physical performance
- Develop a personal fitness program for peak performance
- Develop a personal fitness program for peak performance (introduce practical online tools to aide in developing peak performance)
- Reduce risk of physical training and work place injuries

TIME:
120 minutes

MATERIALS:
Worksheet and pencils, Food labels, TV, Laptop, LCD projector, extension cord, Reading and Understanding the New Food Label DVD, Training Log handouts.

FORMAT:
Interactive PowerPoint slide presentation

MODULE 1	15 MINUTES
Introduction to the Dietary Recall Worksheet	
MODULE 2	30 MINUTES
Food Label Video	
MODULE 3	40 MINUTES
Restaurant, Snacking and Shopping Basics Slide Set	
MODULE 4	15 MINUTES
Starting and Working with a Training Log	
MODULE 5	20 MINUTES
Demonstration of Online Tools	

SESSION 3

OVERVIEW

OBJECTIVES:

- Increase knowledge and skills for choosing foods to enhance peak physical performance while eating in Army specific settings
- Increase knowledge and build skills to prevent physical training, sports, and workplace injury
- Increase knowledge about "First Aid" for initiating care after physical injury
- Discuss nutritional environments within the Army context
- Identify healthier food choices in markets, restaurants and mess halls
- Provide practical tips for preparing for Army Physical Fitness Test (APFT) Day
- Define nutritional requirements for peak physical performance
- Develop a personal fitness program for peak performance
- Establish short- and long-term goal setting skills for healthy food choices and physical activity
- Increase personal responsibility for goals, motivation and skills required to meet individualized dietary needs and fitness goals.

TIME:
120 minutes

MATERIALS:
PowerPoint File, Laptop, LCD projector, extension cord (if necessary), Daily Menu and Salad Bar Selection Sheets, pencils

FORMAT:
Interactive PowerPoint slide presentation

MODULE 1	30 MINUTES
High Caliber Nutrition	
MODULE 2	30 MINUTES
Sports and Work Place Injury Prevention and "First Aid"	
MODULE 3	30 MINUTES
But I Eat in the Mess Hall	
MODULE 4	20 MINUTES
Peak Performance for APFT	
MODULE 5	10 MINUTES
Healthy Goal Setting Journal	

SESSION 4

OVERVIEW

OBJECTIVES:

- To provide participants with information about the effects of alcohol use
- Encourage participants to take personal responsibility for goals, motivation and skills required to meet individualized dietary needs and fitness goals
- Encourage self-assessment and goal setting for a healthy lifestyle
- Recognize factors that factors that lead to stress
- Build skills for using stress reduction techniques

TIME:
120 minutes

MATERIALS:
Whiteboard, dry erase markers (or butcher paper and markers, if whiteboard is not available), PowerPoint File, Laptop, LCD projector and extension cord (if necessary), "Pattern of Alcohol Use" and "Alcohol Use and Sexuality" handouts

FORMAT:
Interactive PowerPoint slide presentation

MODULE 1	45 MINUTES
Alcohol Effects and Use	
MODULE 2	15 MINUTES
Building on Personal Commitment to a Healthy Lifestyle	
MODULE 3	30 MINUTES
Stress and Stress Reduction Techniques	
MODULE 4	15 MINUTES
Online Fitness Communities	
MODULE 5	15 MINUTES
Review and Wrap-Up Discussion	

Appendix 3:

Table 1. Selected Sociodemographic, Behavioral, and Psychosocial Characteristics of Study Participants

Table 1. Selected Sociodemographic, Behavioral, and Psychosocial Characteristics of Study Participants

Variable	Percent/Mean[1]
Sample Size	933
Gender	
Male	86.7%
Female	13.3%
Age	
Mean	20.8
Median	20.0
Marital Status	
Single (never married)	85.4%
History of sexual experience	93.8%
Number of sexual partners (ever)	
One	9.9%
2 -5	32.8%
6-10	24.9%
$\geq$ 11	19.7%
History of unintended pregnancy	
Once	12.6%
$\geq$ 2	6.2%
Diagnosed with an STI at baseline	5.0%
Self-reported history of STIs	
Once	4.1%
$\geq$ 2	1.6%

[1] All variables do not add to 100% due to missing data or data that are not applicable for some participants

Variable	Percent/Mean[1]
Sex partner with other current partners (prior 3 months)	
Yes	2.3%
Possible/Not sure	10.9%
Frequency of birth control use	
Every time	28.4%
Inconsistent use	51.9%
Never	12.7%
Frequency of condom use	
Every time	17.9%
Inconsistent use	64.2%
Never	11.4%
Sex under the influence of alcohol (prior 3 months)	
Every time	2.4%
Some of the time	14.2%
Never	33.0%
Status of last sexual partner	
Steady	74.5%
Casual	17.1%
Birth control use during last sex	
No	44.1%
Condom use during last sex	
No	51.4%
Frequency of drinking $\geq$ 5 drinks on one occasion	
Once/month	13.1%
2-3 times/month	6.2%
Once or more/week	7.4%

Variable	Percent/Mean[1]
Friends think intimate partner violence (IPV) is no big deal	
Strongly Disagree/Disagree	78.6%
Friend has been a victim of IPV	
Strongly Agree/Agree	40.8%
Friend has been violent toward a partner	
Strongly Agree/Agree	24.0%
Chances of being involved in IPV in next year	
Small/Moderate/Good /Very Good Chance	13.7%
Compared to other soldiers, chance of being involved in IPV in next year	
Same/Little more/Much More	8.7%
Confident would get help if experienced violence in close relationships	
Strongly Agree/Agree	89.4%

Appendix 4:

Current Institutional Review Board (IRB) approval letter from the University of California, San Francisco

UCSF
University of California
San Francisco

Human Research Protection Program
Committee on Human Research

Notification of Full Committee Approval

Principal Investigator	**Co-Principal Investigator**
Cherrie B Boyer	Mary-Ann B Shafer

Type of Submission: Continuing Review Submission Form
Study Title: Preventing Health Damaging Behaviors in Male and Female Army Soldiers

IRB #: 10-04317
Reference #: 056080

Reviewing Committee: Parnassus Panel

Study Risk Assignment: Greater than minimal

Approval Date: 10/25/2012 **Expiration Date:** 12/10/2013

Regulatory Determinations Pertaining to This Approval (if applicable):

This research is not subject to HIPAA rules.

IRB Comments (if applicable):

All changes to a study must receive CHR approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iMedRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR website has more information.

Appendix 5:

Current Institutional Review Board (IRB) approval email from the USAMRMC Human Subjects Research Review Board (HSRRB)

On 1/17/13 12:56 PM, "Eaton, Karen M Ms CTR US USA MEDCOM USAMRMC"
<Karen.M.Eaton@us.army.mil> wrote:

>Classification: UNCLASSIFIED
>Caveats: NONE
>
>SUBJECT: Acknowledgement of the Continuing Review documents for the
>protocol, "Preventing Health Damaging Behaviors in Male and Female Army
>Soldiers," Submitted by Cherrie B. Boyer, PhD, University of
>California, San Francisco, San Francisco, California, in Support of the
>Proposal, "Preventing Health Damaging Behaviors and Negative Health
>Outcomes in Army and Marine Corps Personnel During the First Tour of
>Duty," Proposal Log Number 03210001, Award Number W81XWH-04-1-0159,
>HRPO Log Number
>A-12373.2
>
>
>1. The subject protocol received initial approval by the U.S. Army
>Medical Research and Materiel Command's (USAMRMC), Office of Research
>Protections (ORP), Human Research Protection Office (HRPO) on 17 March
>2010.
>
>2. The USAMRMC ORP HRPO received the Institutional Review Board (IRB)
>approval for the continuation of the subject protocol on 10 January 2013.
> The University of California San Francisco (UCSF) Committee on Human
>Research approved continuation of the protocol on 25 October 2012; this
>approval will expire on 10 December 2013.
>
>3. This correspondence serves to acknowledge receipt of the continuing
>review documents for the protocol. No further action related to this
>continuing review will be taken. The documents in support of this
>continuing review will be placed in the HRPO file.
>
>4. Please note the following reporting requirements:
>
>   a. Major modifications to the research protocol and any
>modifications that could potentially increase risk to subjects must be
>submitted to the HRPO for approval prior to implementation. Major
>modifications include a change in Principal Investigator, change or
>addition of an institution, elimination or alteration of the consent
>process, change in age range or change in/addition to the study
>population or a change that could potentially increase risks to subjects.
>
>
>   b. All unanticipated problems involving risk to subjects or others
>must be promptly reported by telephone (301-619-2165), by email
>(hrpo@amedd.army.mil), or by facsimile (301-619-7803) to the HRPO. A
>complete written report will follow the initial notification. In
>addition to the methods above, the complete report can be sent to the
>U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RP, 504
>Scott Street, Fort Detrick, Maryland 21702-5012.
>
>   c. Suspensions, clinical holds (voluntary or involuntary), or
>terminations of this research by the IRB, the institution, the Sponsor,
>or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.
>
>   d. Any deviation to the protocol that may have an adverse effect
>on the safety or rights of the subject or the integrity of the study
>must be reported to the HRPO as soon as the deviation is identified.
>
>   e. A copy of the continuing review approval notification by the
>UCSF Committee on Human Research must be submitted to the HRPO as soon
>as possible after receipt of approval. According to our records, it

>appears the next continuing review by the UCSF Committee on Human
>Research is due no later than 10 December 2013. Please note that the
>HRPO also conducts random audits at the time of continuing review and
>additional information and documentation may be requested at that time.
>
>   f. The final study report submitted to the UCSF Committee on Human
>Research, including a copy of any acknowledgement documentation and any
>supporting documents, must be submitted to the HRPO as soon as all
>documents become available.
>
>   g. The knowledge of any pending compliance inspection/visit by the
>Food and Drug Administration (FDA), Office for Human Research
>Protections, or other government agency concerning this clinical
>investigation or research; the issuance of Inspection Reports, FDA Form
>483, warning letters or actions taken by any Regulatory Agencies
>including legal or medical actions; and any instances of serious or
>continuing noncompliance with the regulations or requirements must be
>reported immediately to the HRPO.
>
>5. Please Note: The USAMRMC ORP HRPO conducts random site visits as
>part of its responsibility for compliance oversight. Accurate and
>complete study records must be maintained and made available to
>representatives of the USAMRMC as a part of their responsibility to
>protect human subjects in research. Research records must be stored in
>a confidential manner so as to protect the confidentiality of subject
>information.
>
>6. Do not construe this correspondence as approval for any contract
>funding. Only the Contracting Officer or Grants Officer can authorize
>expenditure of funds. It is recommended that you contact the
>appropriate contract specialist or contracting officer regarding the
>expenditure of funds for your project.
>
>7. The HRPO point of contact for this study is Karen M. Eaton, MS,
>Human Subjects Protection Scientist, at 301-619-9268/karen.m.eaton@us.army.mil.
>
>Regards,
>Karen Eaton
>
>Karen M. Eaton, M.S.
>Human Subjects Protection Scientist (General Dynamics Information
>Technology)
>Human Research Protection Office (HRPO) Office of Research Protections
>(ORP) United States Army Medical Research and Materiel Command
>(USAMRMC) Fort Detrick, Maryland
>Phone: 301-619-9268
>Fax: 301-619-7803
>Karen.M.Eaton@us.army.mil
>
>Mailing Address:
>U.S. Army Medical Research and Materiel Command
>ATTN: MCMR-RPH/ Karen M. Eaton
>504 Scott Street
>Fort Detrick, Maryland 21702-5012
>
>Classification: UNCLASSIFIED
>Caveats: NONE

Appendix 6.

Scientific abstract submitted for presentation consideration at the Society for Adolescent Health and Medicine 2014 Annual Conference

Correlates of consistent use of effective contraceptive methods among male and female adolescent and young adult soldiers in training

Stephanie Adrianse, MD[1], Lance M. Pollack, Ph.D[2], Cherrie B. Boyer, Ph.D[1]. University of California, San Francisco, CA [1]Division of Adolescent Medicine and [2]Center for AIDS Prevention Studies

MeSH tag keywords: unintended pregnancy, prevention, contraceptive use, adolescents/young adults, psychosocial factors

Purpose: Over 50% of pregnancies among adolescents and young adults in the US are unintended. Similar to civilians, the high rates of unintended pregnancy (UIP) in Army soldiers are, in part, attributed to ineffective and inconsistent use of contraceptive methods. This study aimed to identify the sociodemographic, psychosocial, and behavioral factors associated with consistent use of effective contraceptive methods (consistent-effective use) in male and female soldiers in training.

Methods: This cross-sectional study reflects baseline data of a randomized-controlled intervention trial to prevent sexually transmitted infections and UIP in Army soldiers, aged 17-36 years, during their first year of military service. Participants completed a self-administered baseline questionnaire, including measures on sociodemographic factors (gender, age, race/ethnicity, marital status, education), psychosocial factors (condom and UIP knowledge, condom and UIP attitudes, perceived vulnerability for UIP, and self-efficacy, behavioral skills and behavioral intentions for preventing UIP) and behavioral risk factors (age at coitarche, number of sexual partners, history of prior unintended or intended pregnancies, and type and frequency of contraceptive method(s) used). Bivariate logistic regression analyses were performed to determine variables for entry into the multivariate analyses. Iterative implementation of a two-block hierarchical logistic regression model identified statistically significant correlates of consistent-effective use (i.e., use of any of the following during each sexual encounter: condoms, hormonal pills/patch/ring/implant, Depo-Provera, intrauterine device, tubal ligation, sterilization, avoidance of vaginal sex, and engaging only in same-gender sex).

Results: Only participants who reported a history of sexual experience (n=672, 93.5%) were included in this research. Participants were young (mean age= 21), male (86.2%), racially/ethnically diverse (52% white, 22% black, 16% Hispanic, 9.7% other), and unmarried (86%). Overall, 27% reported a prior pregnancy of which 77% reported an UIP and 22% were consistent-effective users. Compared with non-consistent-effective users, consistent-effective users were significantly more likely to report: higher condom (OR=1.9, CI=1.16-3.12) and UIP knowledge (OR=1.82, CI=1.18-2.80), more positive condom attitudes (OR=1.36, CI=1.05-1.75), disagreement that their sexual behaviors place them at high UIP risk (OR=0.36, CI=0.14-0.95), neutral agreement that UIP would hurt their career (OR=1.85, CI=1.09-3.15), higher levels of behavioral skills (OR=2.53, CI=1.42-4.51), greater behavioral intentions for preventing UIP (women only; OR=7.91, CI=1.86-33.65), and no prior unintended (OR=0.30, CI=0.10-0.93) or intended pregnancies (OR=0.56, CI=0.32-0.97).

Conclusions: Consistent-effective contraceptive use is associated with having knowledge, positive condom attitudes, lower perceived UIP risk, and behavioral skills to prevent UIP. With the exception of behavioral intentions for preventing UIP, no gender differences were found. UIP prevention interventions to increase consistent-effective use in adolescents/young adults are still warranted.

Sources of Support: U.S. Army Medical Research and Material Command, Fort Detrick, MD, and the Health Resources and Services Administration/Maternal and Child Health Bureau, Leadership Education in Adolescent Health Training Grant.