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TITLE: Weight Measurements and Standards for Soldiers, Phase 2

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14. ABSTRACT The specific aims of the study are to: 1) compare body weight and fat changes associated with participation in a population-based intervention in comparison to participation in a control group, 2) compare changes in fitness associated with participation in a population-based intervention in comparison to participation in a control group, 3) evaluate improvement in body weight, body fat, and fitness in the control group when these participants are provided access to the H.E.A.L.T.H. intervention, and 4) evaluate the maintenance of changes in body weight, body fat, and fitness after discontinuation of the promotion associated with the H.E.A.L.T.H. program. The study is a cluster (group) randomized controlled trial in which clusters of Army National Guard units will be randomly assigned to one of two treatment arms: 1) immediate access to the H.E.A.L.T.H. intervention or 2) delayed access to the H.E.A.L.T.H. intervention. The research design will include two years of baseline data, two years of the controlled comparison of the two treatment arms, followed by two years of delivery of the H.E.A.L.T.H. intervention to the treatment arm that received a delayed intervention. Access to the H.E.A.L.T.H. intervention will be continued for one additional year for both treatment arms to evaluate utilization and efficacy after discontinuation of the H.E.A.L.T.H. promotion program. Data will be collected from two sources: 1) the Defense Integrated Military Human Resource System (DIMHRS) and 2) the H.E.A.L.T.H. website. Data will be collected using routinely obtained annual Army Physical Fitness Tests (APFT). Participants will not be required to sign voluntary consent forms due to their anonymity. The H.E.A.L.T.H. intervention will be available for all population Soldiers during periods designated by the research study design.			
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Introduction

The Pennington Biomedical Research Center (PBRC) is delivering a program to the Louisiana Army National Guard (LANG) called Healthy Eating, Activity, and Lifestyle Training Headquarters (H.E.A.L.T.H.) (1). This program was designed to address weight management needs and non-compliance with the Army Weight Control Program (AWCP) (2) and the Army Physical Fitness Test (APFT) (3).

The H.E.A.L.T.H. program has two components: 1) an online program that includes personalized eating, fitness and APFT tools to help Soldiers stay fit and meet AR600-9 and APFT standards, and 2) a promotion program designed to prompt awareness and regular usage of the website program. The H.E.A.L.T.H. program aims to empower Soldiers in healthy and safe lifestyle change to sustain healthy weight and performance on a year-round basis. The H.E.A.L.T.H. website was specifically designed to aid military personnel in achieving healthy management of body weight, healthy nutrition, physical fitness, and combat readiness.

The H.E.A.L.T.H. study is a cluster (group) randomized controlled trial in which clusters of Louisiana Army National Guard (LANG) units will be randomly assigned to one of two treatment arms: 1) Intervention arm 1: Immediate access to the H.E.A.L.T.H. intervention or 2) Intervention arm 2: Delayed access to the H.E.A.L.T.H. intervention (control group). The research design will include two years of baseline data (collected retroactively), two years of the controlled comparison of the two intervention arms, followed by two years of delivery of H.E.A.L.T.H. to the intervention arm that received delayed access to H.E.A.L.T.H. Access to the H.E.A.L.T.H. intervention will be continued for one additional year for both treatment arms to evaluate utilization and efficacy after discontinuation of the H.E.A.L.T.H. promotion program (See Appendix A for the Study Timeline).

Data will be collected from two sources: 1) the Defense Integrated Military Human Resource System (DIMHRS) and 2) the H.E.A.L.T.H. website. The intervention will be delivered to the entire LANG population and all Soldiers in the LANG will be anonymous participants in the study. Data will be collected using routinely obtained annual Army Physical Fitness Tests (APFT).

Body

This project delivers a weight measurement system for Army National Guard Soldiers in the Louisiana Army National Guard (LANG) and an Internet-based intervention for assisting Soldiers' adherence to body weight and physical fitness standards described in AR 600-9. This Internet-based program, called H.E.A.L.T.H. (Healthy Eating, Activity, and Lifestyle Training Headquarters) (1), is integrated with an environmental health promotion program that uses the command structure and existing communication functions of the LANG to promote the use of the internet-based intervention. This approach can be viewed as a population-based health promotion program that will be integrated into existing programs that are designed to assist overweight or unfit Soldiers, e.g., the Army Weight Control Program (AWCP) (2).

Pennington Biomedical Research Center (PBRC) personnel work closely with a Louisiana Executive Advisory Committee, as well as a National Executive Committee to guide this research project. During the first year, the primary objectives were: 1) collection of baseline data from the Defense Integrated Military Human Resource System (DIMHRS) and the Army Physical Fitness Test (APFT) (3), i.e., height, weight, fatness estimates, and measures of fitness, 2) assess the unique health risk communication, weight management, and fitness needs of the Louisiana Army National Guard, 3) development of the randomized clusters of the H.E.A.L.T.H. intervention, 4) Installation of measurement equipment (scales and stadiometers) in all LANG units, 5) launch of H.E.A.L.T.H. program to intervention arm 1, and 6) future planning of promotion campaigns and novel communication methods. These objectives have been successfully completed during year 1.

During year 2 the objectives will be: 1) collection of APFT data from LANG data resources, 2) continued promotion of the H.E.A.L.T.H. program to those units in intervention arm 1, 3) planning for inclusion of intervention arm 2 (delayed access arm) in year 3 of the H.E.A.L.T.H.

promotion program and 3) analysis of the initial data that will be collected since the start of the H.E.A.L.T.H. intervention.

H.E.A.L.T.H. Website

The H.E.A.L.T.H. website was launched (1Apr2010) and is currently being used by the LANG population. PBRC is continuing to making upgrades to the website in order to make it more user-friendly and accommodating to LANG Soldiers and their families, as well as add fresh content and tools to encourage use of the website for weight management purposes.

Recently, part of the H.E.A.L.T.H. website known as "JumpStart", a feature designed to orient Soldiers to the website and establish nutrition and fitness plans, has been updated with two new features. First, the "Exceeding the Standards" section was launched. This section provides a portal for military leaders to guide a non-compliant Soldier (failure to meet a requirement or some combination of requirements set forth in the AR 600-9 or FM 21-20) through the registration and orientation processes of the H.E.A.L.T.H. website, while also helping them understand their obligation to meet military standards. This section is a direct result of the feedback that was received in the previous pilot studies, which suggested that such a feature was necessary to provide involvement and a "hands-on" approach to bringing Soldiers, that we capable of being retained, back into compliance. Second, The Body Morph Assessment (4) was added in order to aide Soldiers in selecting body size goals for their weight management plan. The BMA measures current body size, ideal body size, and acceptable body size. This is an assessment tool that was developed by Dr. Tiffany Stewart, of PBRC (4). This program can provide an estimate of body dissatisfaction and body size over/underestimation compared to individuals of the same sex and body mass index.

Finally, upgrades to the website will be made throughout the project. Within year 2 of the project, it is anticipated that the H.E.AL.T.H. website will also be able to be utilized by mobile phone devices, e.g. Droid, iphone, Blackberry.

Data Collection

Collection of baseline data was done electronically from LANG databases, including: Defense Integrated Military Human Resource System (DIMHRS), MedPros, and WebUps. Additionally, secondary data was collected from Army Physical Fitness Test (APFT) cards, which were on hand at the armories of the LANG. These data were double entered into a spreadsheet and identified as manual entry by PBRC before being aggregated with the electronic data of the LANG databases. The data collection effort was facilitated by a collaboration of LANG and PBRC personnel, from January through March 2010.

Baseline Data

As can be seen in Table 1, the baseline for this study consists of 5979 participants. Of those participants, 4844 (81%) are men and 1135 (19%) are women. The men in the baseline population are predominantly enlisted, 2841 (88%), while 93 (3%) are Warrant Officers, and 300 (9%) are officers. The women in the baseline population are also predominantly enlisted, 661 (93%), while 42 (6%) are Warrant Officers, and 11 (1%) are officers. Additionally, the mean age for men is 29.4 while the mean for women is 26.6.

		n	Percent		
Sex	Male	4844	81.1		
	Female	1135	18.9		
		Male		Female	
		n	Percent	n	Percent
Grade	Enlisted	2841	87.9	661	92.6
	Warrant Officer	93	2.9	42	5.9
	Officer	300	9.3	11	1.5
		n	Mean (sd)	n	Mean (sd)
Age		4844	29.4 (9.7)	1135	26.6 (8.4)

Table 1: Baseline Demographics for LANG H.E.A.L.T.H. Soldiers

Table 2 outlines the mean weight and weight deviation from the maximum allowable weight standards for men and women. Mean weight is 147.5 lbs. for women and 188.7 lbs. for men. Weight deviation from the standard (allowed maximum weight) for women is -2.8 and 2.8 for men.

	Men (N = 4844)				Women (N = 1135)			
	Mean	SD	Min	Max	Mean	SD	Min	Max
Height (inches)	69.9	2.74	60	80	64.6	2.6	58	78
Weight (lbs)	188.7	35.6	96	380	147.5	28.6	90	279
Wt Dev* (lbs)	2.8	30.7	-76	186	-2.8	24.7	-69	106

*Current weight – Allowed maximum weight

Table 2: Height and Weight for LANG H.E.A.L.T.H. Soldiers

Across the 2 year baseline observation period (2008-2009), it was observed that 2343 (48%) men failed the weight screening test at least once, while 423 (37%) women failed weight screening at least once (Table 3). The records of Soldiers who failed the screening table weight and should have been taped were not available. The number of male Soldiers who passed the

screening table weight was 2501 (51%). The number of female Soldiers who passed the screening table weight was 721 (62%). These data show that there is a population of at least 46% Soldiers for whom the website would be directly useful in assisting them in losing weight.

	Men (N = 4844)		Women (N = 1135)	
Status	N	%	N	%
Fail	2343	48.4	423	37.3
Pass	2501	51.6	712	62.7

Table 3: Body Weight Pass/Fail for LANG H.E.A.L.T.H. participants

Of the baseline population, 3790 had multiple recorded APFT scores during the 2 year baseline period. There were 3097 men (64% of the total male population in the baseline dataset) and 693 females (61% of the total female population in the baseline data set), which had recorded entries as having taken the APFT in consecutive years (2008-2009) (See Table 4). Of these, 563 (18%) men failed a portion of the APFT at least once. Similarly, 165 (23%) women failed a portion of the APFT at least once. Given these data, there are a meaningful number of Soldiers for whom the website could be used to assist with passing the APFT.

	Men		Women	
Status	N	%	N	%
Fail	563	18.2	165	23.8
Pass	2534	81.8	528	76.2

Table 4: APFT Test Pass/Fail for LANG H.E.A.L.T.H. Participants

Ongoing Data Collection

As a part our effort to establish objective and consistent measurement methods for the collection of HT/WT data from the LANG, scales and stadiometers have been purchased and installed for all units of the LANG. While we are only promoting to those units in Intervention Arm 1 (active arm) at the present time, the units that are part of Intervention Arm 2 (delayed intervention arm) will still need to have objective measurements of height and weight to provide for consistency and validity of measurement throughout the study. The installation of the scales and stadiometers will provide for better and more reliable data in the future.

Promotion of the Use of H.E.A.L.T.H.

The promotion strategy for the H.E.A.L.T.H. program consists of a 2 step program:

- Step 1: An awareness campaign that will increase new registration in the intervention arm with a steady increase (3-5%) per month in registration
- Step 2: A reinforcement program that will actively communicate new features of the H.E.A.L.T.H. website and tips for usage to existing users to help in return usage and continued long-term use of the H.E.A.L.T.H. website for weight loss and weight maintenance.

This 2- step promotion strategy is based on the enrollment outcomes of the H.E.A.L.T.H. pilot studies at Fort Bragg, NC and a New England Reserve Command (94th RRC). The unique design of this promotion program will allow both steps 1 and 2 to occur repetitively in years 1 and 2, while also occurring simultaneously in years 3 and 4 with the inclusion of intervention arm 1 to the H.E.A.L.T.H. program.

Table 5 illustrates the website promotion schedule for distribution of materials to full time members and Traditional Guardsmen of the LANG. A typical day of promotion (during the week) requires that Field Managers make calls, have in-person meetings, and give talks to LANG full time personnel, interact with unit Family Readiness Groups (FRG), and attend Soldier Readiness Programs (SRP) when they occur. The interactions of the Field Managers in each of these instances is dependent upon available time and level of awareness by the Soldier, FRG member, speed at which the SRP moves. At each opportunity, the Field Managers communicate the key point of the HEALTH website and provides an overview of how the website can be used to help an individual achieve their diet and exercise goals.

The majority of the Field Managers' interactions with the population occur over a drill weekend. This is the time period when the Field Managers would have the greatest opportunity to communicate to a large portion of a unit's Soldiers. During drill, the Field Managers are responsible for educating Traditional Guardsmen on the H.E.A.L.T.H. program and being the single point resource for issue resolution (i.e. technical problems, application issues, etc.) to all Soldiers present.

Similarly, the HEALTH program has been able to develop a working relationship with the LANG Public Affairs Office (PAO), which has allowed for the targeted distribution of electronic newsletters and promotional materials. This tactic, used in combination with the in-person message distribution plan, has worked exceptionally well over the first year of the study.

	Daily	Weekly	Monthly
Military Email			**X**
Word of Mouth	**X**		
Newsletters			**X**
Liaisons		**X**	
Fliers	**X**		
Brochures	**X**		
Training	**X**		
Promo Material			**X**

Table 5: H.E.A.L.T.H. Promotion Schedule

In sum, our model for promotion and communication, as well as issue resolution for the study population has proven to be quite effective in achieving our HEALTH awareness and promotion goals. We anticipate that in the expansion of this model to Intervention arm 2 will be equally successful.

Website usage: Preliminary Data Report

The H.E.A.L.T.H. website has been available to the Soldiers and families of the LANG since April 1, 2010. To date, 515 (82%) Soldiers and 114 (18%) civilians have registered on the H.E.A.L.T.H. website. 365 (71%) Soldiers have completed the JumpStart program, 63 (12%) have made 3 or more visits to the site, and 7 (1%) have made 10 or more visits.

Over the past 7 months, this study has been operationally limited as a result of the Deep Water Horizon oil spill in the Gulf of Mexico, as well as the Earthquake Relief missions in Haiti. The LANG was tasked with these humanitarian aid missions in addition to their missions in Iraq and Afghanistan. The majority of the clusters that exist in Intervention Arm 1 make up the bulk of those units that were activated in response to those missions. Despite these missions, we have made significant progress in enrollment of Soldiers and their families on the H.E.A.L.T.H. website and continue to see increased enrollment.

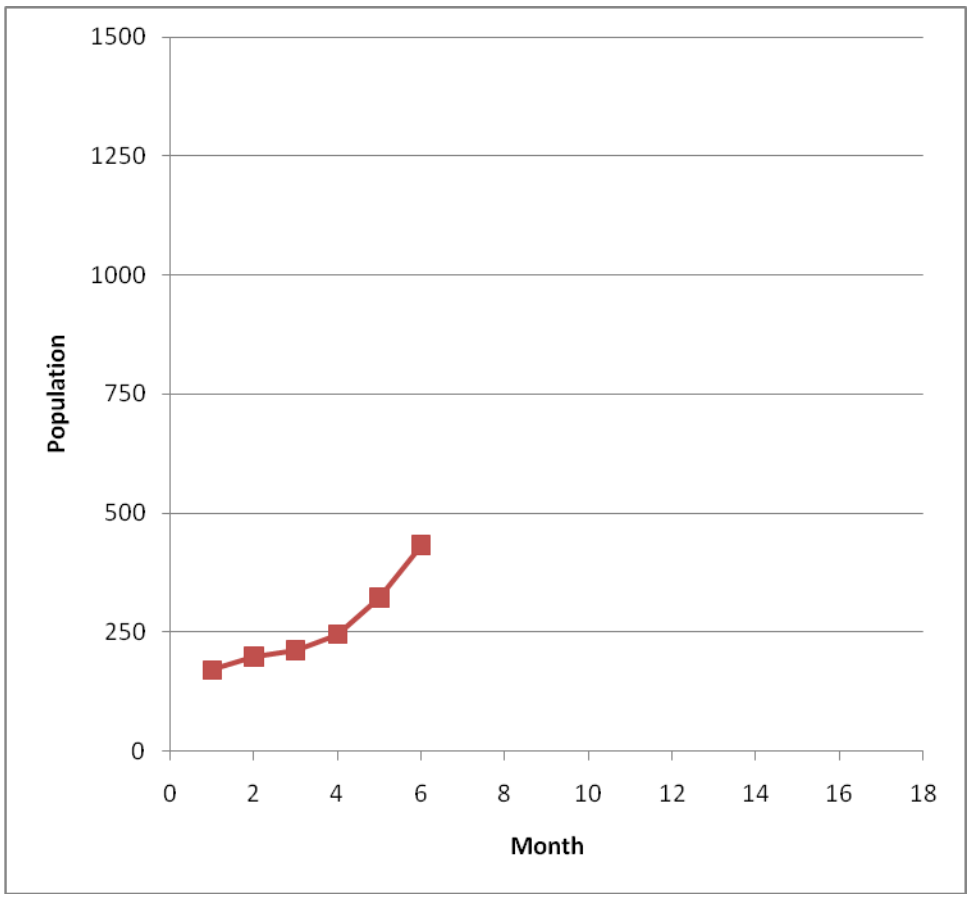

Figure 1: H.E.A.L.T.H. Soldier Website Enrollment

Our future efforts will focus on continuing to develop communication methods to reach the Soldiers and families of those units in Intervention Arm 1. Additionally, to increase the likelihood of regular usage, PBRC field mangers will continue visiting units during monthly drill and organizational Soldier Readiness Program (SRP) functions, as well as continue to explore and evaluate new and potentially useful communication methods.

In sum, the strategy that the PBRC team has employed to promote the H.E.A.L.T.H. website has been effective. It is the goal of the PBRC team to have a minimal registration of 1500 (25%) of the Intervention Arm 1 population at 15 months (post-launch). It is anticipated that the total registration will continue to increase.

Key Research Accomplishments

- Developed and met with the Louisiana Executive Advisory Committee, which is comprised of LANG and PBRC members to act as a steering committee for the study's execution.
- Conducted statistical analyses on all collected baseline date available from the LANG for the 2008 thru 2009 time period.
- Randomized units to create Intervention Arms 1(active intervention arm) and 2 (delayed intervention arm) to solidify randomized controlled trial format.
- Developed the Field Team by recruiting and hiring the following new employees:

  Paul Mounts, BS – Field Manager

  Derrick Foster, BS – Field Manager

  Jonathan Zeno, BS – Field Manager

  Verdis Walker – Field Manager
- Completed the installation of scales and stadiometers in all LANG units.
- Launched the H.E.A.L.T.H. program to the LANG.
- Developed publicity materials designed to promote use of the H.E.A.L.T.H. website, e.g. t-shirts, mugs, fliers
- Developed the H.E.A.L.T.H. Leaders Guide, which provides a step-by-step guide to achieve compliance
- Established the "Exceeding the Standard" program on the website which serves as an electronic extension of the Leaders' Guide. This program aides Soldiers' in a guided program to achieve the standards and/or guides the Soldiers' superiors in supporting them through the process.
- Developed a list of organizational contacts for dissemination of publicity materials

- Established a monthly electronic newsletter that is distributed by the LANG Public Affairs Office.
- To date, 515 Soldiers have enrolled in the H.E.A.L.T.H. program.

Reportable Outcomes

Not applicable at this time

Conclusions

Not applicable at this time.

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Appendix A: Study Timeline