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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 Unit Personnel System-Command Management System (UPS-CMS) 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.

15. SUBJECT TERMS

nutrition, physical fitness, Soldiers, health, weight, body fat

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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 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 (See Appendix A for the Study Timeline).

Data will be collected from two sources: 1) Unit Personnel System/Command Management System (UPS/CMS), 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 also 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.

Body

This project delivers a weight measurement system for the LANG Soldiers 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. (1), is integrated with a 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).

PBRC personnel work closely with a Louisiana Executive Advisory Committee (LEAC), 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 Unit Personnel System/Command Management System (UPS/CMS) 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 controlled 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 Year 2 APFT and height/weight 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 in year 3 of the H.E.A.L.T.H. promotion program and 3) preliminary analysis of the initial data that was 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. Upgrades to the website will continue to be made throughout the project.

The H.E.A.L.T.H. website was recently made mobile and is now able to be accessed and utilized via Smartphone devices, e.g. Droid, iphone, Blackberry. The launch of the program on Smartphones has enabled field managers to engage Soldiers more efficiently at events. At drill events, it has been noted that most Soldiers have Smartphones. As the Field Managers register Soldiers for the H.E.A.L.T.H. program, the smart phone capability of the website allows the Field Managers to reach more Soldiers in a shorter period of time. This capability also allows for more convenient and “portable” day-to-day use of the program by Soldiers and their family members.

Data Collection

As a part of an effort to establish objective and consistent measurement methods for the collection of HT/WT data from the LANG units, scales and stadiometers were purchased and

installed for all units of the LANG. While current promotions of the program only apply to those units in Intervention Arm 1 (active arm), it is important that the units that are part of Intervention Arm 2 (delayed intervention arm) have objective measurements of height and weight to provide for consistency and validity of measurement throughout the study. Thus, all units in the study (active and delayed arms) received scales and stadiometers.

Collection of data for the LANG study was collected electronically from LANG databases, including: Unit Personnel System/Command Management System (UPS/CMS). Additionally, 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 baseline data collection effort was facilitated by a collaboration of LANG and PBRC personnel, from January through March 2010. Data collection for year 1 commenced May 2011 and final data for this time point is still being collected. Year 1 data for the study is summarized below. Planning for data collection of year 2 data is currently underway and data draws will be initiated starting in May 2012.

Year 1 Data

As can be seen in Table 1, year 1 data (to date) consists of 2932 participants. Of those participants, 2430 (82.9%) are men and 502 (17.1%) are women. The men in the year 1 population are predominantly enlisted, 2070 (85.8%), while 86 (3.6%) are Warrant Officers, and 256 (10.6%) are officers. The women in the year 1 population are also predominantly enlisted, 443 (90%), while 6 (1.2%) are Warrant Officers, and 43 (8.7%) are officers. Additionally, the mean age for men is 31 while the mean age for women is 28. The mean BMI's for men is 28.0 and 25.6 for women respectively.

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

		n	Percent		
Sex	Male	2430	82.9		
	Female	502	17.1		
		Male		Female	
		n	Percent	n	Percent
Grade	Enlisted	2070	85.8	443	90.0
	Warrant Officer	86	3.6	6	1.2
	Officer	256	10.6	43	8.7
		n	Mean (sd)	n	Mean (sd)
Age		2430	31.0 (9.3)	502	28.2 (8.0)
BMI		2430	28.0 (4.5)	502	25.6 (4.4)

Table 2 outlines the weight deviation from the maximum allowable weight standards for men and women.

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

	Men (N = 2430)				Women (N = 502)			
	Mean	SD	Min	Max	Mean	SD	Min	Max
Height (inches)	70.0	2.7	60	80	64.9	2.7	58	72
Weight (lbs)	195.4	35.1	100	360	153.8	30.3	89	278
Wt Dev* (lbs)	8.1	30.6	-72	166	1.6	26.3	-58	110

Across the observation period (Apr 2010-Apr 2011), it was observed that 1359 (55.9%) men failed the weight screening test at least once, while 230 (45.8%) women failed the weight screening test 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 1071 (44.1%). The number of female Soldiers who passed the screening table weight was 272 (54.2%).

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

	Men (N = 2430)		Women (N = 502)	
Status	N	%	N	%
Fail	1359	55.9	230	45.8
Pass	1071	44.1	272	54.2

For the year 1 population, there were 1980 recorded APFT scores during the year 1 period of 1 April 2010-1 April 2011. There were 1665 (84%) men in the year 1 population and 315 (16%) women in the year 1 population (See Table 4). Of the men 282 (16.9%) failed the APFT test and 1383 (83.1%) passed the APFT test. Of the women, 72 (22.9%) failed the APFT test and 243 (77.1%) passed the APFT test. Given these data, there remains a meaningful number of Soldiers for whom the H.E.A.L.T.H. website could be used to assist with achieving/maintaining combat ready weight and passing the APFT.

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

	Men (N = 4844)		Women (N = 1135)	
Status	N	%	N	%
Fail	282	16.9	72	22.9
Pass	1383	83.1	243	77.1

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

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

- Step 1: An awareness campaign that will increase new registration in the intervention arm with a steady increase.
- 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 foster 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 (4) and the New England Reserve Command (94th RRC) (5). 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 2 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, etc. At each opportunity, the Field Managers communicate the key point of the H.E.A.L.T.H. website and provide an overview of how the website can be used to help an individual achieve their diet and exercise goals. Further, with the use of portable computers and the Soldier's Smartphones, Field Managers are able to register large amounts of Soldiers on site of these events.

The majority of the Field Managers' interactions with the population occur over a drill weekend. This is the time period when the Field Managers 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 H.E.A.L.T.H. 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.

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

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

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

Website Usage Data: Preliminary 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, 1473 (89%) Soldiers and 186 (11%) civilians have registered on the H.E.A.L.T.H. website. Figure 1 illustrates the cumulative enrollment on the LANG H.E.A.L.T.H. website since its launch.

Over the past 6 months, this study has been operationally affected as a result of the Mississippi River flooding that impacted most of Louisiana, 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 directly impact the rate of registration in the H.E.A.L.T.H. program (slowing the rate of

registrations across the deployed clusters), we have made significant progress in enrollment of Soldiers and their families on the H.E.A.L.T.H. website, and we have continued to see increased enrollment. Since last year's report we have tripled the amount of registrations and doubled the amount of return users on the LANG H.E.A.L.T.H. website. It is anticipated that the total registration will continue to increase at a steady rate, associated with drill and SRP events in Year 2.

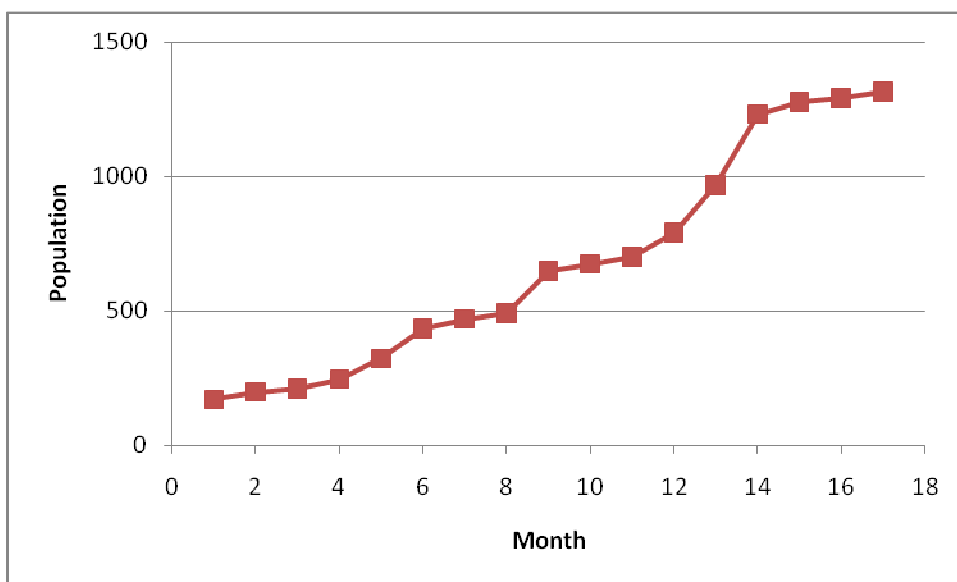


Figure 1: H.E.A.L.T.H. Soldier Website Enrollment

Figure 2 shows the association between promotion events and enrollment in the H.E.A.L.T.H. program. As seen in Figure 2, the largest increases in participant registration are associated with drill weekends. Over the last year, the majority of new registrations as well as return users to the website have occurred during the events scheduled by PBRC Field Managers on a monthly scheduled, drill weekend. In addition to drill weekend, there has been increased registration during specific events such as an SRP (Soldier Readiness Processing) event or YRT (Yellow Ribbon Training) events. These additional events have allowed for more face time for

our Field Managers in presenting the website program both to the Active Guard and Reserve (AGR) unit staff and traditional Soldiers.

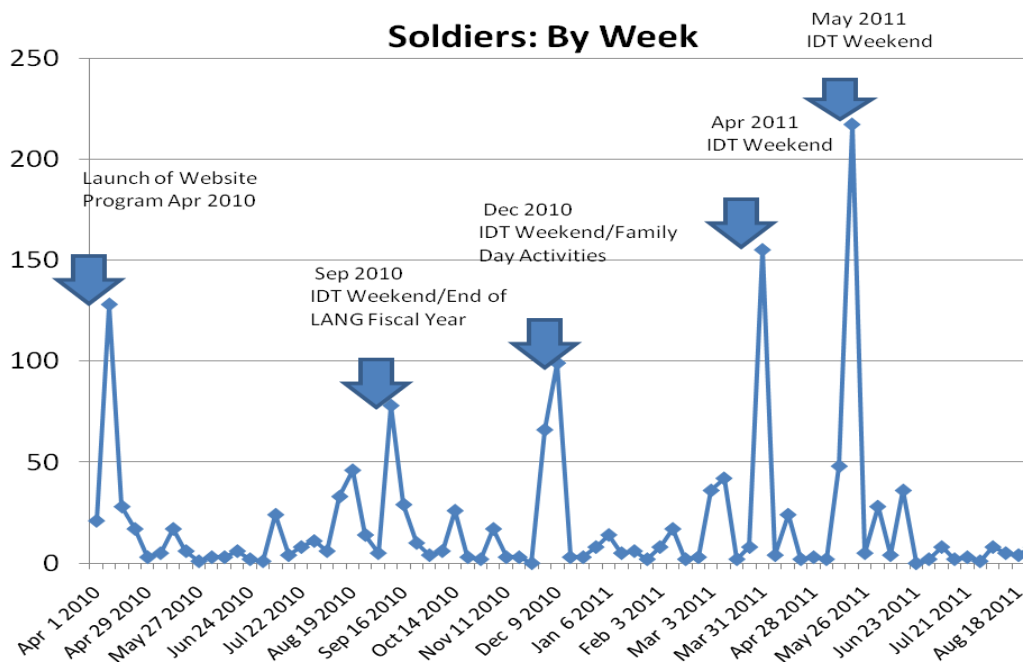


Figure 2: H.E.A.L.T.H. Website Soldier Registrations by Week

Finally, as illustrated in Table 6, the utilized operating system for website usage was Windows (XP, Vista, 7) (computer/web platform). However, since the portable platform, i.e. Smartphone, has been launched (May 1, 2011), Iphone, Android, and Blackberry platforms systems have been used as well. While there were some individuals utilizing the full version of the website on Smartphones prior to the mobile platform release, the number of people using it on Smartphones after the release increased, particularly for Android and Blackberry platforms.

Table 6: H.E.A.L.T.H. Operating System Usage

Operating System	4/1/10 – 4/30/11	5/1/11 – 9/1/11
Windows XP	33.5%	21.4%
Windows Vista	20.5%	12.4%
Windows 7	9.6%	12.4%
Mac OS	4.4%	9.5%
iPhone	3.6%	3.6%
Android OS	2.9%	19.4%
BlackBerry	1.3%	2.5%

Key Research Accomplishments-

- Meetings with the Louisiana Executive Advisory Committee (LEAC) were held on a monthly basis, (comprised of LANG and PBRC members) to act as a steering committee for the study's execution.
- The Smartphone application of the LANG H.E.A.L.T.H. website was completed and launched.
- The H.E.A.L.T.H. website program was promoted to the LANG Soldiers at drill, pre-mobilization training, Family Day, SRP, and YRT events.
- Publicity materials designed to promote use of the H.E.A.L.T.H. website, e.g. t-shirts, mugs, fliers, banners, etc. were distributed.
- The LANG H.E.A.L.T.H. electronic newsletter was distributed monthly to LANG Soldiers in the active intervention arm of the study by the LANG Public Affairs Office.
- Data available from the LANG for the 2010 time period (Year 1 data) was collected. This effort is still ongoing. Conducted preliminary analyses conducted on Year 1 data.
- Paul Mounts, BS- replaced Matt McGucken, as the new Project manager for the LANG H.E.A.L.T.H. study.
- Two new Field Managers (Michael Switzer, Christopher Dogay) in preparation for Year 3 of the study were interviewed and hired for an October 1, 2011 start date. In addition, Michael Switzer replaced Derrick Foster as a Field Manager and Christopher Dogay will serve as an additional Field Manager. It is anticipated that these two managers will be able to accelerate the promotion of the program as well as increase the efficiency of the data collection for the project.
- To date, 1473 Soldiers and 186 civilians have enrolled in the H.E.A.L.T.H. program.

Reportable Outcomes

Year 1 data was obtained from the UPS/CMS system. Data retrieval for Year 1 will be completed by Oct. 1, 2011. Data collected from Year 1 shows that there are a significant number of Soldiers that the H.E.A.L.T.H. website can assist in losing weight, losing body fat, and passing the APFT.

In addition to participant data, the browser, operating system, and usage data shows that the continued innovations (e.g. Smartphone platform), being introduced to the website is contributing to increased registrations on the website. Since the release of the mobile application we have seen increased registration and return usage of the website has been observed.

Conclusions

1. Overall Progress: Progress has been made in the development of new applications for the H.E.A.L.T.H. website and promotion of the website to Soldiers. The website will continue to be a dynamically updated program, incorporating cutting edge programming in nutrition and fitness, in order to keep the information on the site interesting, useful, current, and personalized for Soldiers and their families.

2. Data: Year 1 data on the deviation from weight standards and the failure rate for the APFT test shows the need for the H.E.A.L.T.H. program in the LANG Soldiers.

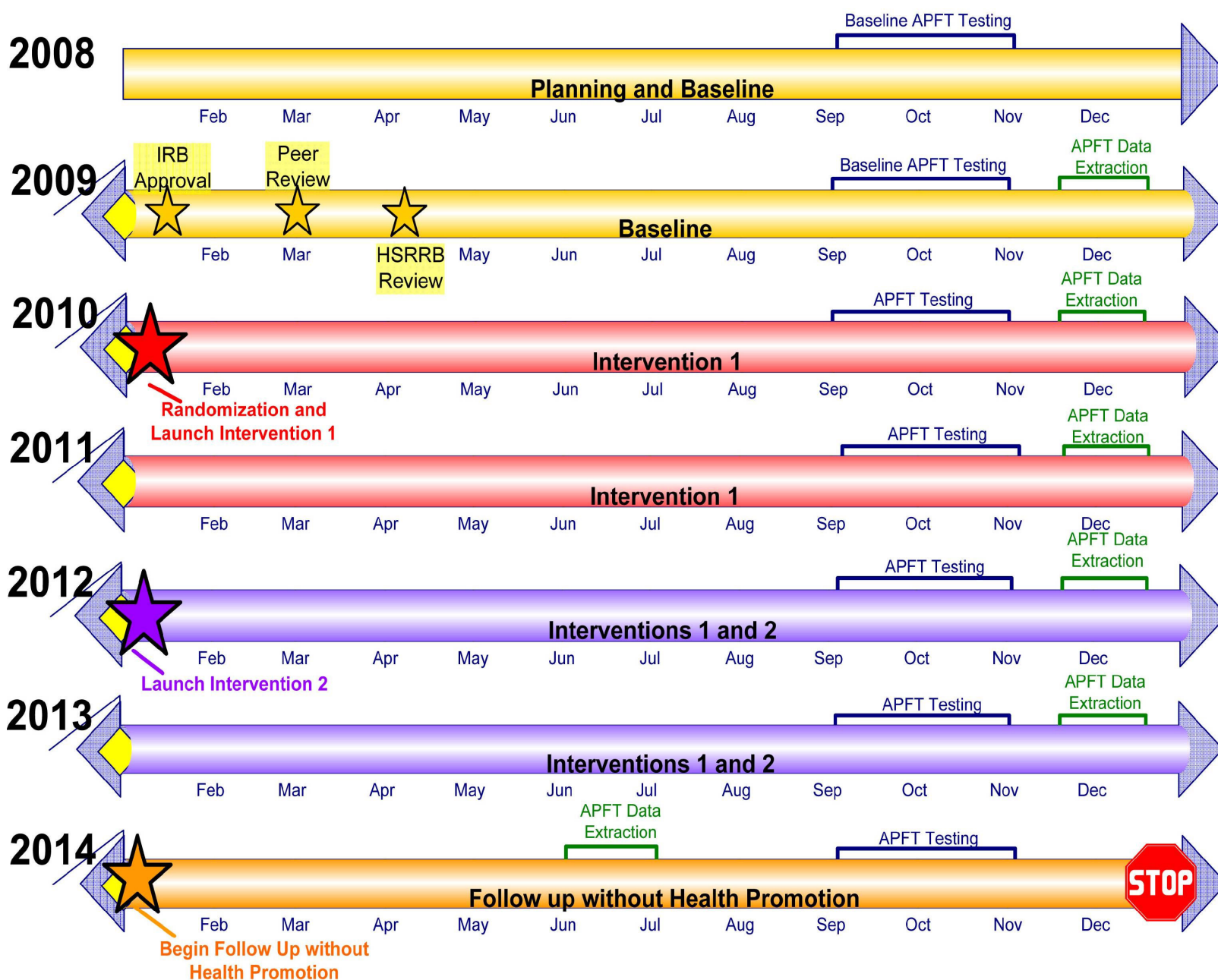
3: Future Directions:

- a. Year 1 data will be finalized (April 2010-April 2011). To date, complete LANG data (from the databases only) for Year 1 has been unavailable for collection by PBRC. We anticipate a complete Year 1 data set by October 1, 2011.
- b. Collection of Year 2 data (April 2011-April 2012). This data will be collected via electronic databases of the LANG, hand written Physical Fitness Test cards.
- c. We will continue to work with the LANG committee in refining the UPS/CMS data process and making it a more efficient and productive system for collecting and analyzing the study data
- d. The launch of the website to Intervention Arm 2 (delayed condition) will occur in April 2012. Preparation for this launch is already underway and will continue throughout the upcoming year.
- e. Continued promotion of the H.E.A.L.T.H. website will commence. While the goal for the first year of the study was to increase awareness and register as many Soldiers on the site in the active arm as possible, awareness and return usage of the site will be the goal of the next two years of the study.

- f. Website and Smartphone application upgrades will continue throughout the duration of the program. We will continue to improve the feature and tools of the website to increase usage and provide the participants with a path to weight loss/maintenance, improved body fat percentages, and improved APFT results.

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Appendix B

Summary of Travel

Nov12-14 2010	LANG Units throughout Louisiana	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken	- Conduct LANG Drill registration drives and promotions
17 Nov 2010	Monthly Camp Beau Meeting	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Dec 4-5 2010	LANG Units throughout Louisiana	Verdis Walker, Jonathan Zeno, Matt McGucken	- Conduct LANG Drill registration drives and promotions
Dec 15 2010	Monthly Camp Beau Meeting	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Jan 8-9 2011	LANG Units throughout Louisiana	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken	- Conduct LANG Drill registration drives and promotions
Jan 19 2011	Monthly Camp Beau Meeting	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Feb 5- 62011	LANG Units throughout Louisiana	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken	- Conduct LANG Drill registration drives and promotions
Feb 16 2011	Monthly Camp Beau Meeting	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Mar 11- 13 2011	LANG Units throughout Louisiana	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken	- Conduct LANG Drill registration drives and promotions
Mar 16 2011	Monthly Camp Beau Meeting	Derrick Foster, Verdis Walker, Jonathan Zeno, Matt McGucken, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Apr 2-3 2011	LANG Units throughout Louisiana	Paul Mounts, Verdis Walker, Jonathan Zeno	- Conduct LANG Drill registration drives and promotions
Apr 20 2011	Monthly Camp Beau Meeting	Paul Mounts, Verdis Walker, Jonathan Zeno, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status

May 14-15 2011	LANG Units throughout Louisiana	Paul Mounts, Verdis Walker, Jonathan Zeno	- Conduct LANG Drill registration drives and promotions
May 25 2011	Monthly Camp Beau Meeting	Paul Mounts, Verdis Walker, Jonathan Zeno, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Jun 11-25 2011	LANG Units throughout Louisiana	Paul Mounts, Verdis Walker, Jonathan Zeno	- Conduct LANG Annual Training registration drives and promotions
Jul 9-10 2011	LANG Units throughout Louisiana	Paul Mounts, Verdis Walker, Jonathan Zeno	- Conduct LANG Drill registration drives and promotions
Aug 5-7 2011	LANG Units throughout Louisiana	Paul Mounts, Verdis Walker, Jonathan Zeno	- Conduct LANG Drill registration drives and promotions
Aug 10 2011	Senator Landrieu Visit to PBRC	Dr. Tiffany Stewart, Paul Mounts, Verdis Walker, Jonathan Zeno	-Meeting with Senator Mary Landrieu followed by news /press conference at PBRC. Conducted a meeting with LANG executive committee members .

*Note: Travel included for key events in the LANG H.E.A.L.T.H. project are listed in the table. This table does not include all daily visits to units for promotion purposes as it would be too cumbersome for the purposes of this report.