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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.

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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 were successfully completed during Year 1.

During Year 2, the objectives were: 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. These objectives were successfully completed during Year 2.

During Year 3 the objectives will be: 1) collection of Year 3 APFT and height/weight data from LANG data resources, 2) launch of the promotion of the H.E.A.L.T.H. program to units within Intervention Arm 2 clusters, 3) planning for Year 4 of the study, and 4) preliminary analysis of data 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 (April 1, 2010) 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. Additionally, the smartphone application has been updated to a more sophisticated design, to resemble an application that would be downloaded from the typical application store. These updates have greatly contributed to Soldiers’ use of the website.

Data Collection & Analyses

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 in Year 1 of the study. In Years 1 and 2, data was collected electronically from LANG databases, including: Unit Personnel System/Command Management System (UPS/CMS). Data was also 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 was completed November 2011. Data collection for Year 2 is currently underway and data draws were initiated beginning in May 2012. Additional data draws were conducted on July 31, 2012 and August 31, 2012 to judge the progress of APFT and height/weight reporting from the LANG to ensure maximum participation as well as satisfactory completion of established data milestones during Year 2 of the study. It is of note that these data draws were solely for the purpose of establishing the quantity and quality of data needed for the analysis of Year 2 results. The process of data cleaning and analyses will commence November 2012 for Year 2.

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 allows 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 1 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, 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/nutrition and exercise/fitness 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 at 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 two years of the study.

Table 1: H.E.A.L.T.H. Promotion Schedule

	Daily	Weekly	Monthly	Quarterly
Military Email			X	
Word of Mouth	X			
Newsletters			X	
Liaisons		X	X	X
Fliers	X			
Brochures	X			
Training	X			X
Contests				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 in Year 3 will be equally and possibly more successful (due to providing intervention access to the control group).

Intervention 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, 2424 (91%) Soldiers and 250 (9%) 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.

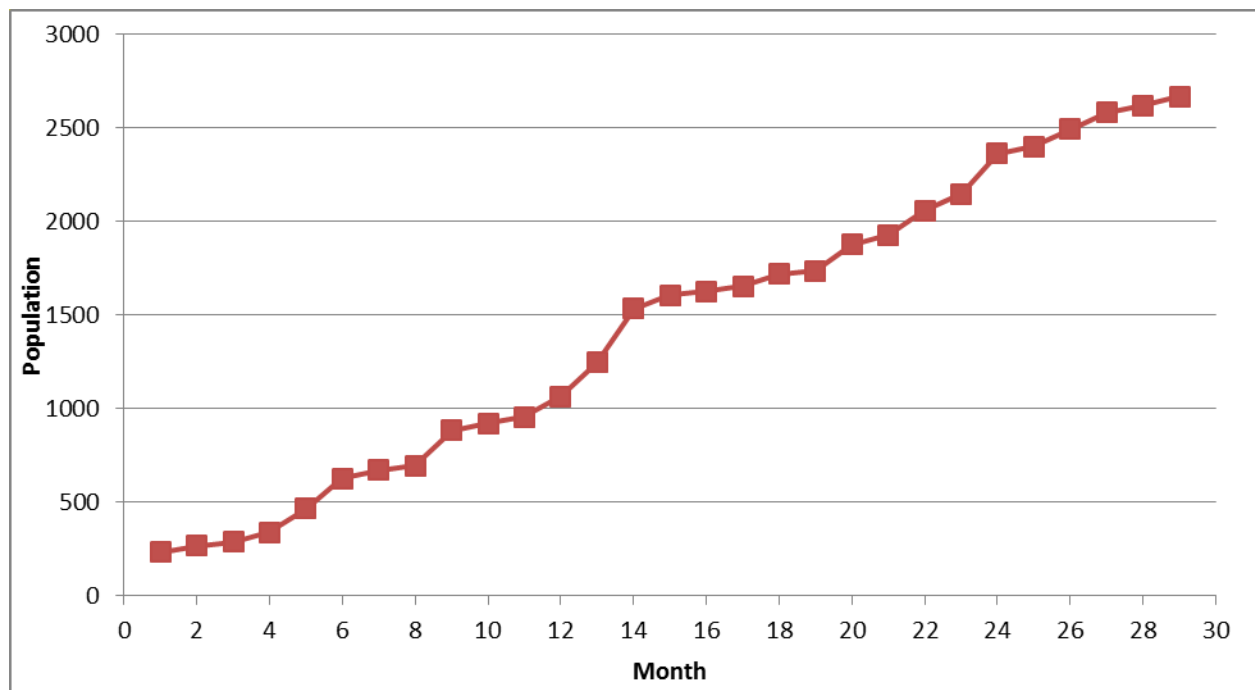


Figure 1: H.E.A.L.T.H. Website Enrollment

Over the past year, this study has been operationally affected as a result of the Mississippi River flooding that impacted most of Louisiana, Hurricane Isaac missions, as well as the Earthquake Relief missions in Haiti. The LANG was tasked with these humanitarian aid missions in addition to their missions in 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 impacting 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, the amount of registrations and return users on the LANG H.E.A.L.T.H website have more than doubled. It is

anticipated that the total return usage will continue to increase at a steady rate, associated with drill, YRT, SRP, and other promotions events in Year 3.

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.

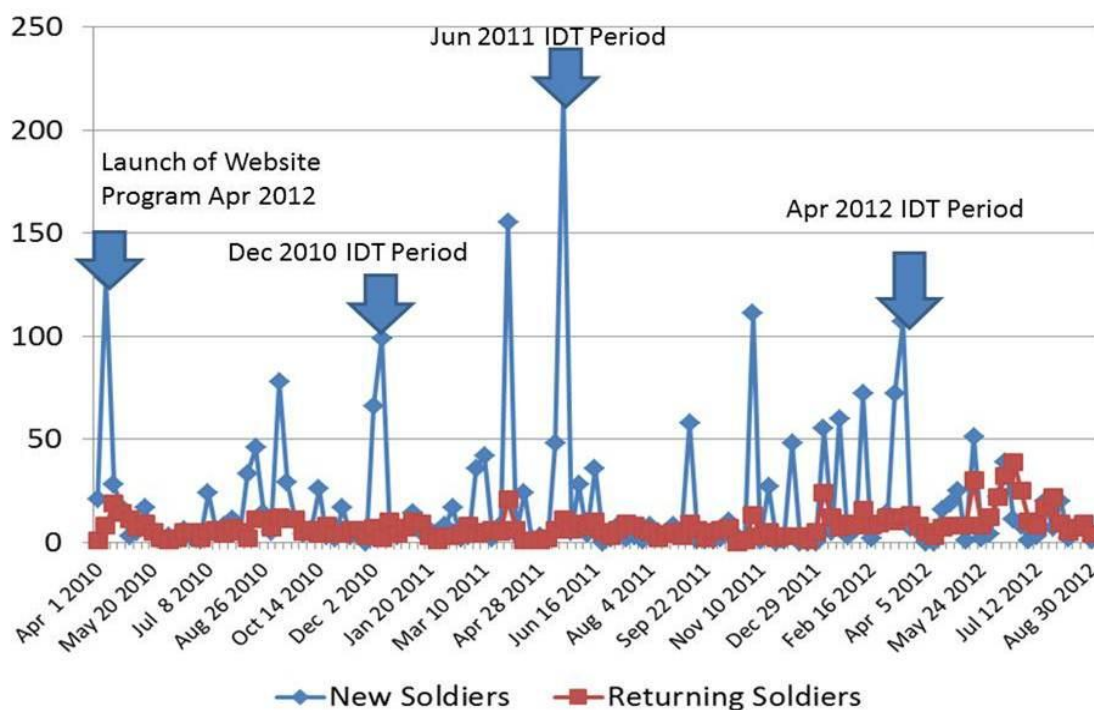


Figure 2: H.E.A.L.T.H. Website Soldier Registrations by Week

Finally, the most utilized operating system/browsers for website usage was Windows (XP, Vista, 7) (computer/web platform) and Internet Explorer. However, since the portable platform, i.e. Smartphone, has been launched (May 1, 2011), Iphone, Android, and Blackberry platforms systems have shown increased use. 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 the Android and Blackberry platforms. Additionally, with the upgrade of the mobile platform to a more sophisticated application design, usage is anticipated to increase substantially over the next year of the project.

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 was reconfigured to a more sophisticated and user friendly design.
- The H.E.A.L.T.H. website program was promoted to the LANG Soldiers at drill, pre-mobilization training, Family Day, SRP, State Family Workshops 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 2011-2012 time period (Year 2 data) is ongoing. Final Year 2 data will be collected October 31, 2012, and data cleaning and analysis will begin in November 2012.

- Two new Field Managers (Michael Switzer, Russell Bouillion) in preparation for Year 3 of the study were hired and began work on October 1, 2011. It is anticipated that these two managers will continue to accelerate the promotion of the program as well as increase the efficiency of the data collection for the project.
- To date, 2424 Soldiers and 250 civilians have enrolled in the H.E.A.L.T.H. program.
- An orientation/briefing for LTC Ronald Green who replaced COL Michael Borrel as the Senior Liaison between the PBRC team and the LANG leadership was conducted by Dr. Stewart, Paul Mounts, and Michael Switzer on May 31, 2012.
- Dr. Tiffany Stewart, Principal Investigator, and Paul Mounts, Project Manager, conducted an information briefing on June 14, 2012 at Aberdeen Proving Grounds, Maryland to the Army Institute of Public Health in an effort to link the technology and program fundamentals of LANG H.E.A.L.T.H. to the needs of the Department of Defense for fielding throughout the agency for a date yet to be determined.

Reportable Outcomes

Not applicable at this time.

Conclusions (Summary)

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: Collection of available Year 2 is ongoing and will be completed October 31, 2012. Website data collection is ongoing and up to date preliminary results are presented in other sections of this report.

3: Future Directions:

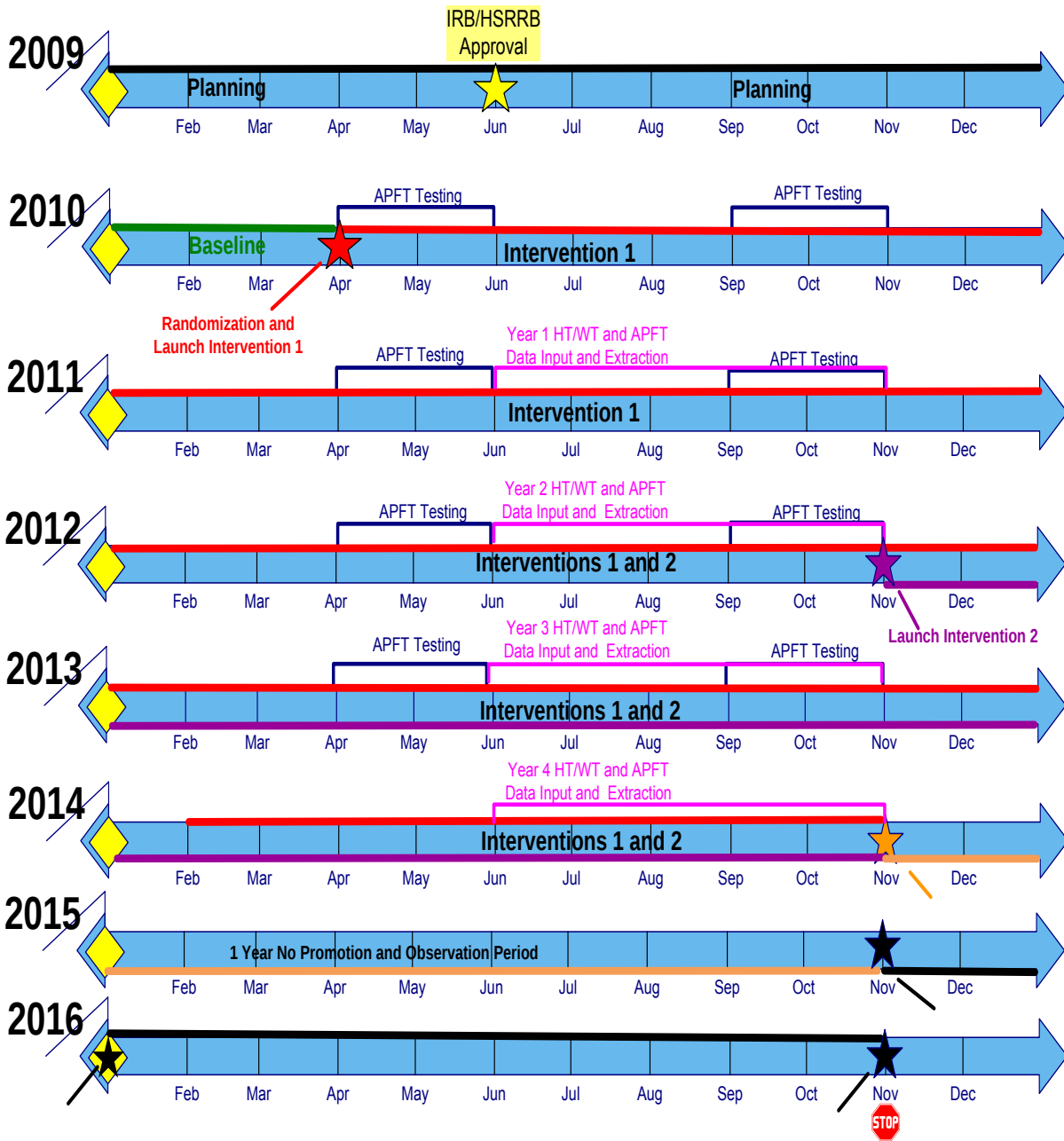
- a. Collection of Year 3 data (November 2012-October 2013). This data will be collected via electronic databases of the LANG, and through hand written Physical Fitness Test cards.
- b. We will continue to work with the LANG Executive Committee in refining the UPS/CMS data process and making it a more efficient and productive system for collecting and analyzing the study data
- c. The launch of the website to Intervention Arm 2 (delayed condition) will occur in November 2012. Preparation for this launch is already underway and will continue throughout the upcoming year.

- d. Continued promotion of the H.E.A.L.T.H. website will commence. Awareness building, new registrations, and return usage of the site will be the goal of the next two years of the study.
- e. 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, and improved APFT results.

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Appendix A Study Timeline



Appendix B
Summary of Travel

Nov 5-6 2011	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
Nov 16 2011	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Dec 10-11 2011	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	-Conducted LANG Drill registration drives and promotions
Dec 21 2011	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Jan 7-8 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
Jan 18 2012	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Feb 11-12 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
Feb 23 2012	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Mar 16-18 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
Mar 22 2012	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan	-Monthly meeting with members of the LANG Executive Committee to discuss project status

		Zeno, Jeremy Bouillion, Dr. Tiffany Stewart	
Apr 18 2011	Monthly Camp Beau Meeting	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Dr. Tiffany Stewart	-Monthly meeting with members of the LANG Executive Committee to discuss project status
Apr 21-22 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
May 2 2011	Senator Vitter Staff Visit to PBRC	Dr. Tiffany Stewart, Paul Mounts, Michael Switzer	Meeting with Senator David Vitter's Staff followed by news /press conference at PBRC.
May 19-20 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	- Conducted LANG Drill registration drives and promotions
May 31 2012	J1 Visit to PBRC	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion, Tiffany Stewart	- Meeting with the new LANG J1, LTC Greene. Introduced him to the project with a brief orientation and background history. We followed with our monthly meeting with members of the LANG Executive Committee to discuss project status
Jun 9- 10 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	-Conducted LANG Drill registration drives and promotions
Jun 12-14 2012	PBRC visit to the Army Institute of Public Health	Dr. Tiffany Stewart, Paul Mounts	-Dr. Tiffany Stewart and Paul Mounts conducted an information briefing at Aberdeen Proving Grounds, Maryland to the Army Institute of Public Health to link the technology and program fundamentals of LANG H.E.A.L.T.H. to the needs of the Department of Defense for fielding throughout the agency for a date yet to be determined
Jul 7- 21 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	-Conducted LANG Annual Training registration drives and promotions
Aug 4- 5 2012	LANG Units throughout Louisiana	Paul Mounts, Michael Switzer, Verdis Walker, Jonathan Zeno, Jeremy Bouillion	-Conducted LANG Drill registration drives and promotions
Aug 17-19 2012	2012 State Family Programs Workshop	Michael Switzer, Jeremy Bouillion	- Conducted LANG registration drives and promotions

*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.