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14. ABSTRACT

Purpose: To test a nurse coaching intervention and an herbal supplement for Service Member (SM) weight reduction over a 12-week period to evaluate their effectiveness independently and synergistically. **Design:** Prospective, randomized placebo-controlled trial. **Methods:** Overweight SM, 18-57 years old, recruited from the Army overweight program, were randomized to one of 4 groups. Self-referrals not yet flagged for being overweight attended 12 weeks of dietitian-led lifestyle education. Primary outcome was weight loss, and secondary outcomes were % body fat, waist circumference, fasting blood sugar (FBS), lipid and vitamin D levels, bone mineral density (BMD), adherence, and motivation. Outcome measures were obtained at 3 time points. A nurse coach contacted participants weekly. Adherence was measured by classes attended and returns for data collection/blood draws. **Sample:** Demographics (N=435): mean age 30 + 8.2 yrs, 73.4% male, predominantly white (70.1%) and non-Hispanic (80%), 71% married, 91% enlisted, and 61% reported history of being overweight. **Analysis:** Change scores were compared across groups using general linear models adjusted for covariates imbalanced at baseline. **Findings:** 1) When comparing the 3 nurse health coaching (NHC) groups to the control group (CG) only, beneficial intervention effects were observed for heel BMD (d = 0.3), vitamin D levels (d = 0.43), and FBS (d = -0.4); 2) Supplement group showed no difference on any outcome; 3) There were no significant differences in any outcome between the CG and the self-referred group. Attrition rate was highest from Week 6 to 12 at 40%. **Implications for Military Nursing:** The primary outcome of weight loss proved difficult for all groups; similar motivation and adherence scores were recorded, excluding the CG. The education provided to participants about good health behaviors may diminish chronic disease risk and the related socioeconomic burden. Further research is needed to explore the continuing pattern of Warfighter overweight and low vitamin D status.

15. SUBJECT TERMS
nurse coaching intervention, weight management, low vitamin D status, bone mineral density

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Abstract

Purpose: To test a nurse coaching intervention and an herbal supplement for Service Member (SM) weight reduction over a 12-week period to evaluate their effectiveness independently and synergistically.

Design: Prospective, randomized placebo-controlled trial

Methods: Overweight SM, 18-57 years old, recruited from the Army overweight program, were randomized to one of 4 groups. Self-referrals not yet flagged for being overweight attended 12 weeks of dietitian-led lifestyle education. Primary outcome was weight loss, and secondary outcomes were % body fat, waist circumference, fasting blood sugar (FBS), lipid and vitamin D levels, bone mineral density (BMD), adherence, and motivation. Outcome measures were obtained at 3 time points. A nurse coach contacted participants weekly. Adherence was measured by classes attended and returns for data collection/blood draws.

Sample: Demographics (N=435): mean age 30 + 8.2 yrs, 73.4% male, predominantly white (70.1%) and non-Hispanic (80%), 71% married, 91% enlisted, and 61% reported history of being overweight.

Analysis: Change scores were compared across groups using general linear models adjusted for covariates imbalanced at baseline.

Findings: 1) When comparing the 3 nurse health coaching (NHC) groups to the control group (CG) only, beneficial intervention effects were observed for heel BMD (d = 0.3), vitamin D levels (d = 0.43), and FBS (d = -0.4); 2) Supplement group showed no difference on any outcome; 3) There were no significant differences in any outcome between the CG and the self-referred group. Attrition rate was highest from Week 6 to 12 at 40%.

Implications for Military Nursing: The primary outcome of weight loss proved difficult for all groups; similar motivation and adherence scores were recorded, excluding the CG. The education provided to participants about good health behaviors may diminish chronic disease risk and the related socioeconomic burden. Further research is needed to explore the continuing pattern of Warfighter overweight and low vitamin D status.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

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

Secondary Priority

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

Progress Towards Achievement of Specific Aims of the Study

The study has been closed with completion of all intended analyses. Progress is included with the Findings for each aim as described below.

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

Introduction: Operational demands on Soldiers in both peacetime and combat environments require the highest levels of nutritional status and physical health. However, today's Army Warfighter is not exempt from the influences of poor dietary choices, less structured physical activity in theater, injury-related limitations in garrison, and genetics. The number of overweight and obese Service Members (SM) has tripled since the beginning of Overseas Contingency Operations. The overwhelming evidence for links between obesity and increased risk for conditions including Type II diabetes, cardiovascular disease, hypertension, and certain cancers poses a real threat to the strength of our fighting force of the future.
Identification of the Problem: Overweight Soldiers face more immediate challenges such as retention in the service and chronic musculoskeletal conditions. These may result in an unanticipated need for civilian employment, and poor quality of life from pain and disability. This research addressed not only the Army Surgeon General's priorities of medical readiness and health promotion, but also the TriService Nursing Research Program funding priority of "Force Health Protection/Fit and Ready Force" and the Army Nursing priority related to the "Evaluation of CAM for…well-being". This effort to augment current initiatives for weight reduction was developed to benefit the Soldier, the Unit, and the Army, as a physically fit and healthy Warrior is the strongest asset the military has to defend our Nation. In 2011, an innovative approach to Army Soldier medical readiness and wellness through weight management was in great demand by Commanders on Joint Base Lewis-McChord and led to this proposal.

The Specific Aims, Hypotheses, and Findings of the research are as follows:

Specific Aim 1. Evaluate the impact of a nurse health coaching (NHC) intervention, with and without an herbal supplement, on the primary outcome of weight loss and the secondary outcomes of body fat, waist circumference, lipid profile [Fasting blood sugar (FBS), Trig, Chol, HDL, LDL, HDL Ratio], vitamin D level, motivation, and adherence at 6 weeks and 12 weeks, and bone mineral density (BMD) at 12 weeks only.
Hypothesis 1. A nurse health coaching intervention, delivered weekly by phone or email, will lead to greater success in meeting weight loss goals, decrease waist circumference, reduce percent body fat, improve lipid profile, raise vitamin D level, and increase bone mineral density as compared to the current MOVE! curriculum (Control Group).
Findings: When comparing the three (3) NHC groups to the Control Group (CG) only, from baseline to follow up (Week 6 +12), beneficial intervention effects were observed for heel BMD ($d = 0.3$), vitamin D levels ($d = 0.43$), and FBS ($d = -0.4$); cut off for relevance of effect size Cohen's d of ~0.3. Findings on vitamin D and FBS replicated in the multiple imputation analysis ($d = 0.28$, and $d = -.32$, respectively). However, at follow up (Weeks 6 + 12), no significant differences in change from baseline on outcomes among study groups were found at a False Discovery Rate (FDR) of 10%. See Table 1 for sample characteristics and Tables 2-7 for group comparisons over time.

Table 1. Sample characteristics*

Characteristics		Randomized study groups, N=335: Control, N=86	Coach, N=81	Supplement, N=83	Placebo, N=85	Difference among randomized groups: Effect size	Test	Test	Self-referred, N=100	Difference with control group: Effect size	Test	Test
		n (%)	n (%)	n (%)	n (%)	Cohen's w	P	FDR	n (%)	Cohen's w	P	FDR
Rank	E-1 to E-5	69 (80.2)	64 (79)	69 (83.1)	73 (85.9)	0.1713	0.287	0.615	39 (39)	0.4403	<.0001	0.0005
	E-6-to E-9	14 (16.3)	17 (21)	10 (12.1)	9 (10.6)				33 (33)			
	O-1-3, W-2-3	3 (3.5)	0 (0)	3 (3.6)	3 (3.5)				16 (16)			
	O-4 to O-6	0 (0)	0 (0)	1 (1.2)	0 (0)				12 (12)			
Male gender		67 (77.9)	63 (77.8)	65 (78.3)	58 (68.2)	0.0989	0.3506	0.6574	65 (65)	0.1418	0.0532	0.114
Age	18-23	25 (29.1)	24 (29.6)	25 (30.1)	37 (43.5)	0.2365	0.095	0.3563	3 (3)	0.4816	<.0001	0.0005
	23.1-28	23 (26.7)	22 (27.2)	28 (33.7)	20 (23.5)				18 (18)			
	28.1-30	8 (9.3)	4 (4.9)	4 (4.8)	10 (11.8)				7 (7)			
	30.1-36	20 (23.3)	15 (18.5)	12 (14.5)	6 (7.1)				23 (23)			
	36.1-57	10 (11.6)	16 (19.8)	14 (16.9)	12 (14.1)				49 (49)			
Marital status	Single	23 (26.7)	23 (28.4)	23 (27.7)	28 (32.9)	0.1392	0.7582	0.9818	25 (25)	0.138	0.3596	0.6025
	Married	21 (24.4)	20 (24.7)	25 (30.1)	26 (30.6)				23 (23)			
	Married w/children	42 (48.8)	37 (45.7)	35 (42.2)	31 (36.5)				48 (48)			
	S/o in household	0 (0)	1 (1.2)	0 (0)	0 (0)				4 (4)			
Hispanic or Latino *		22 (25.6)	16 (19.8)	18 (22.2)	19 (22.4)	0.0497	0.844	0.9818	9 (9.3)	0.212	0.0033	0.012
Race	White	60 (69.8)	49 (60.5)	66 (79.5)	62 (72.9)	0.1886	0.064	0.32	68 (68)	0.0433	0.8402	0.8644
	Black/African Am.	17 (19.8)	23 (28.4)	7 (8.4)	13 (15.3)				23 (23)			
	Other	9 (10.5)	9 (11.1)	10 (12.1)	10 (11.8)				9 (9)			
Tobacco use	None	38 (44.2)	40 (49.4)	46 (55.4)	42 (49.4)	0.0968	0.7913	0.9818	51 (51)	0.0774	0.5727	0.8591
	Used in past	24 (27.9)	19 (23.5)	15 (18.1)	18 (21.2)				27 (27)			
	Use today	24 (27.9)	22 (27.2)	22 (26.5)	25 (29.4)				22 (22)			
Alcohol intake *	None	16 (18.8)	18 (22.2)	16 (19.8)	15 (17.9)	0.0719	0.9427	0.9818	19 (19)	0.0579	0.7588	0.8644
	Min-moderate use	66 (77.7)	58 (71.6)	60 (74.1)	63 (75)				75 (75)			
	Likely excessive	3 (3.5)	5 (6.2)	5 (6.2)	6 (7.1)				6 (6)			
Previously overweight *		58 (67.4)	51 (63.8)	47 (56.6)	46 (54.1)	0.1102	0.2554	0.615	61 (61)	0.0669	0.3615	0.6025
Lost weight to enter army *		32 (37.2)	31 (38.8)	33 (39.8)	34 (40)	0.0228	0.9818	0.9818	36 (36)	0.0125	0.8644	0.8644
On profile limiting physical activ. *		48 (55.8)	39 (48.2)	45 (54.9)	43 (51.2)	0.061	0.7441	0.9818	37 (37)	0.1851	0.0102	0.0255
Exercise min/week	None	0 (0)	0 (0)	1 (1.2)	0 (0)	0.125	0.8986	0.9818	3 (3.3)	0.3248	0.0001	0.0005
	1-149	2 (2.3)	4 (4.9)	4 (4.8)	3 (3.5)				8 (8.8)			
	150-299	14 (16.3)	14 (17.3)	18 (21.7)	16 (18.8)				33 (36.3)			
	300+	70 (81.4)	63 (77.8)	60 (72.3)	66 (77.7)				47 (51.7)			
Taking Vitamin D	None	73 (84.9)	68 (84)	66 (79.5)	76 (89.4)	0.1645	0.1702	0.5106	70 (70)	0.2304	0.004	0.012
	Prescription	2 (2.3)	0 (0)	4 (4.8)	0 (0)				0 (0)			
	Other source	11 (12.8)	13 (16.1)	13 (15.7)	9 (10.6)				30 (30)			
Dropped out	at 6 weeks	14 (16.3)	21 (25.9)	26 (31.3)	29 (34.1)	0.1551	0.0448	0.32	15 (15)	0.0176	0.8105	0.8644
	at 12 weeks	27 (31.4)	29 (35.8)	47 (56.6)	42 (49.4)	0.2053	0.0026	0.039	29 (29)	0.026	0.7225	0.8644

*Chi-square or Fisher's exact tests, as appropriate; Cohen's w (Phi coefficient), small=0.1, medium=0.3, large=0.5

Table 2. Baseline measures by group assignment*

Measure	Randomized study groups, N=335				Difference among randomized groups			Self-referred, N=100	Difference with control group		
	Control, N=86	Coach, N=81	Supplement, N=83	Placebo, N=85	Effect size	Test	Test		Effect size	Test	Test
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	FDR	M (SD); n	Partial eta^2	P	FDR
Motivational Inventory	153.33 (21.19); 86	153.43 (18.78); 81	152.46 (20.18); 83	148.84 (23.82); 85	0.008	0.4477	0.918	148.69 (18.06); 100	0.014	0.1089	0.1863
Heel bone mineral density	0.6 (0.1); 72	0.65 (0.14); 65	0.62 (0.12); 66	0.62 (0.14); 74	0.015	0.2472	0.918	0.63 (0.13); 68	0.019	0.1018	0.1863
Heel T score	0.19 (0.87); 72	0.59 (1.28); 65	0.38 (1.08); 66	0.36 (1.25); 74	0.016	0.2331	0.918	0.49 (1.12); 69	0.021	0.085	0.1863
Vitamin D	21.9 (8.54); 63	21.35 (7.7); 60	22.69 (6.64); 59	22.92 (7.42); 55	0.007	0.664	0.9371	26.15 (11.33); 79	0.042	0.0146	0.0786
Fasting Blood Sugar	90.87 (8.47); 78	91.31 (9.02); 71	90.29 (9.01); 70	91.8 (9.46); 75	0.004	0.7732	0.9371	91.86 (10.08); 96	0.003	0.489	0.5542
Total cholesterol	184.99 (33.3); 79	186.92 (35.69); 71	179.41 (29.86); 71	180.23 (34.59); 75	0.009	0.4614	0.918	193.99 (39.77); 98	0.015	0.1096	0.1863
High density lipoprotein	51.51 (11.83); 79	50.04 (10.37); 71	48.18 (10.64); 71	46.67 (9.79); 75	0.03	0.0318	0.8586	55.8 (15.96); 98	0.022	0.0483	0.1544
Triglycerides	108.72 (61.01); 79	109.52 (66.26); 71	111.03 (73.39); 71	133.39 (149.51); 75	0.012	0.3219	0.918	109.07 (81.57); 98	0	0.9748	0.9748
HDL to CHOL ratio	0.29 (0.08); 79	0.27 (0.06); 71	0.27 (0.07); 71	0.27 (0.07); 75	0.007	0.535	0.918	0.3 (0.1); 98	0.005	0.3295	0.436
Low density lipoprotein	116.89 (29.02); 79	119.58 (32.05); 71	114.23 (28.32); 71	112.65 (30.5); 75	0.008	0.5229	0.918	120.68 (37.29); 98	0.003	0.46	0.5542
Weight in lbs	217.08 (33.32); 86	217.27 (38.86); 81	218.87 (30.54); 83	214.12 (30.25); 85	0.003	0.8275	0.9371	206.79 (38.48); 100	0.02	0.0545	0.1544
Height in inches	68.42 (3.85); 86	68.38 (3.62); 81	68.97 (2.93); 83	67.85 (3.47); 85	0.013	0.2333	0.918	68.76 (3.65); 100	0.002	0.5395	0.5732
Body mass index	32.45 (3.19); 86	32.44 (3.65); 81	32.25 (3.2); 83	32.63 (3.02); 85	0.002	0.9036	0.9371	30.53 (3.78); 100	0.07	0.0003	0.0051
Waist circumference	38.53 (3.87); 86	38.22 (4.16); 81	38.65 (3.4); 82	38.13 (3.65); 84	0.003	0.784	0.9371	37.08 (4.41); 100	0.03	0.0185	0.0786
Inbody % fat	31.43 (5.77); 86	31.36 (5.65); 80	31.48 (5.66); 83	32.73 (6.56); 85	0.009	0.3782	0.918	30.15 (7.28); 100	0.009	0.1928	0.298
Inbody lean Mass	149.12 (27.15); 86	148.97 (28.78); 80	149.89 (23.07); 83	144.82 (28.3); 85	0.006	0.6082	0.9371	144.84 (32.22); 100	0.005	0.3334	0.436
Inbody fat mass	67.96 (15.58); 86	68.01 (18.03); 80	68.99 (16.36); 83	69.3 (13.47); 85	0.001	0.9275	0.9371	61.95 (18.28); 100	0.03	0.0177	0.0786
DXA Tissue % fat	-	34.15 (4.21); 15	34.8 (4.75); 44	34.81 (6.68); 46	0.002	0.9151	0.9371	-	-	-	-
DXA Region % fat	-	32.99 (4.1); 15	33.65 (4.65); 44	33.65 (6.52); 46	0.002	0.9121	0.9371	-	-	-	-
DXA Tissue mass	-	94422.4 (18773.11); 15	95350.36 (11201.89); 44	91045.17 (13223.5); 46	0.023	0.2976	0.918	-	-	-	-
DXA Fat mass	-	32157.67 (7244.48); 15	33186.91 (5967.9); 44	31267.59 (5380.73); 46	0.023	0.3102	0.918	-	-	-	-
DXA Lean mass	-	62264.87 (13073.44); 15	62163.43 (8433.73); 44	59777.52 (12541.29); 46	0.012	0.544	0.918	-	-	-	-
DXA Bone mineral content	-	3277.47 (627.01); 15	3311.57 (395.07); 44	3189.83 (571.78); 46	0.013	0.5239	0.918	-	-	-	-
DXA Fat free mass	-	65542.33 (13691.74); 15	65475 (8764.76); 44	62967.35 (13065.76); 46	0.012	0.5412	0.918	-	-	-	-
DXA Total mass	-	97.69 (19.37); 15	98.65 (11.48); 44	94.23 (13.71); 46	0.023	0.3015	0.918	-	-	-	-
DXA Bone mineral density	-	1.31 (0.12); 15	1.32 (0.09); 44	1.31 (0.1); 46	0.001	0.9371	0.9371	-	-	-	-
DXA T score	-	1.45 (0.98); 15	1.35 (0.88); 44	1.49 (0.8); 44	0.006	0.7422	0.9371	-	-	-	-

*Tests conducted with general linear models; Partial eta^2: small ~0.02, medium ~0.13, large ~0.26

N.B. DXA only performed for randomized NHC/pill groups

Table 3. Week 6 measures by group assignment*

Measure	Randomized study groups, N=231				Difference among randomized groups			Self-referred, N=84	Difference with control group		
	Control, N=70	Coach, N=58	Supplement, N=56	Placebo, N=55	Effect size	Test	Test		Effect size	Test	Test
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	FDR	M (SD); n	Partial eta^2	P	FDR
Motivational Inventory	154.74 (19.25); 69	152.79 (20.79); 56	156.78 (18.04); 51	148.58 (23.69); 55	0.021	0.194	0.7259	150.39 (20.29); 83	0.012	0.1797	0.292
Fasting Blood Sugar	92.9 (9.18); 69	91.28 (10.66); 58	93.59 (12.32); 56	91.87 (9.79); 53	0.007	0.6431	0.836	92.33 (9.72); 83	0.001	0.7111	0.7704
Total cholesterol	185.12 (33.41); 69	188.22 (35.5); 58	183.5 (30.54); 56	183.66 (33.35); 53	0.003	0.8639	0.9172	184.32 (37.34); 84	0	0.891	0.891
High density lipoprotein	50.16 (11.34); 69	50.53 (9.61); 58	47.73 (10.6); 56	46.34 (10.47); 53	0.026	0.1075	0.6988	54.02 (14.41); 84	0.021	0.0718	0.1333
Triglycerides	107.87 (55.53); 69	103.64 (41.41); 58	126.13 (65.76); 56	135.3 (92.6); 53	0.037	0.0312	0.4056	99.01 (57.51); 84	0.006	0.3372	0.4871
HDL to CHOL ratio	0.28 (0.07); 69	0.27 (0.06); 58	0.27 (0.07); 56	0.26 (0.08); 53	0.009	0.5725	0.836	0.3 (0.09); 84	0.021	0.0714	0.1333
Low density lipoprotein	118.26 (28.3); 69	119.87 (32.58); 58	116.23 (28.78); 56	116.88 (28.75); 53	0.002	0.9172	0.9172	114.1 (35.86); 84	0.004	0.4344	0.5134
Weight in lbs	214.62 (33.82); 70	210.96 (37.56); 57	223 (28.68); 49	213.07 (29.57); 54	0.017	0.2688	0.7259	203.16 (35.72); 83	0.026	0.0447	0.1238
Body mass index	32.28 (3.26); 70	31.68 (3.67); 57	32.11 (2.94); 49	32.24 (2.86); 54	0.006	0.7355	0.8692	29.97 (3.61); 83	0.101	<.0001	0.0013
Waist circumference	38.28 (3.72); 70	37.51 (4.08); 57	38.81 (3.49); 49	37.75 (3.43); 54	0.017	0.2792	0.7259	36.41 (4.31); 83	0.051	0.0052	0.0225
Inbody % fat	31.14 (6.03); 69	30.31 (5.8); 57	30.83 (5.35); 49	31.79 (6.93); 54	0.008	0.6338	0.836	28.85 (7.78); 81	0.026	0.0476	0.1238
Inbody lean Mass	148.14 (27.54); 69	147.07 (28.18); 57	154.15 (22.43); 49	146.04 (28.41); 54	0.012	0.4301	0.836	144 (30.56); 81	0.005	0.3884	0.5049
Inbody fat mass	66.78 (16.25); 69	63.92 (17.29); 57	68.83 (15.25); 49	67.03 (14.2); 54	0.012	0.4505	0.836	57.94 (18.36); 81	0.061	0.0023	0.015

*Tests conducted with general linear models; Partial eta^2: small ~0.02, medium ~0.13, large ~0.26

Table 4. Baseline to Week 6 change scores*

Measure	Randomized study groups: Control	Coach	Supplement	Placebo	Difference among randomized groups: Effect size	Test	Test	Self-referred	Difference with control group: Effect size	Test	Test
	M (SE)	M (SE)	M (SE)	M (SE)	eta^2	P	FDR	M (SE)	eta^2	P	FDR
Motivational Inventory	1.66 (1.98)	0.19 (1.45)	2.65 (1.51)	1.31 (1.78)	0.01	0.710084	0.7693	1.34 (1.26)	0.01	0.690575	0.7481
Fasting Blood Sugar	2.11 (0.81)	-0.01 (1.11)	2.49 (1.14)	0.02 (1.01)	0.03	0.177747	0.6688	0.61 (0.93)	0.01	0.36136	0.5254
Total cholesterol	0.62 (2.67)	0.2 (2.62)	3.81 (1.95)	2.48 (2.01)	0.01	0.657216	0.7693	-9.03 (2.27)	0.03	0.024207	0.1049
High density lipoprotein	-1 (0.66)	0.11 (0.73)	0 (0.63)	0.11 (0.75)	0.01	0.591334	0.7693	-1.89 (0.71)	0.01	0.363716	0.5254
Triglycerides	-0.34 (4.83)	-1.6 (5.06)	11.44 (5.08)	-0.64 (12.5)	0.02	0.257229	0.6688	-5.24 (6.95)	0.01	0.816859	0.8169
HDL to CHOL ratio	-0.01 (0)	0 (0)	-0.01 (0)	0 (0)	0.01	0.599955	0.7693	0 (0)	0.01	0.108805	0.2829
Low density lipoprotein	1.37 (2.1)	-0.61 (2.59)	1.66 (1.61)	2.81 (2.11)	0.01	0.787036	0.787	-6.87 (1.91)	0.04	0.011077	0.1049
Weight in lbs	-1.95 (0.52)	-3.7 (0.61)	-1.23 (0.49)	-1.97 (0.51)	0.05	0.021914	0.1424	-2.27 (0.55)	0.01	0.682338	0.7481
Body mass index	-0.28 (0.08)	-0.54 (0.09)	-0.18 (0.07)	-0.29 (0.08)	0.05	0.021451	0.1424	-0.32 (0.08)	0.01	0.685144	0.7481
Waist circumference	-0.28 (0.09)	-0.48 (0.12)	-0.37 (0.1)	-0.44 (0.12)	0.01	0.537826	0.7693	-0.53 (0.11)	0.01	0.310231	0.5254
Inbody % fat	-0.35 (0.18)	-0.76 (0.21)	-0.34 (0.19)	-0.52 (0.2)	0.02	0.41496	0.7693	-0.99 (0.17)	0.03	0.032446	0.1054
Inbody lean Mass	-0.66 (0.41)	-0.76 (0.49)	-0.06 (0.39)	-0.12 (0.46)	0.01	0.566588	0.7693	0.49 (0.43)	0.03	0.019928	0.1049
Inbody fat mass	-1.28 (0.47)	-2.77 (0.63)	-1.17 (0.53)	-1.6 (0.5)	0.02	0.209695	0.6688	-2.65 (0.46)	0.01	0.149656	0.3243

*Ten imputations with random forest; linear mixed model-estimated difference in change from baseline adjusted for probability of group membership estimated with: rank, age, Hispanic or Latino, on-profile, exercise min/week, taking vitamin D; eta^2 estimated from F statistic and df: small ~0.02, medium ~0.13,large ~0.26

Table 5. Week 12 measures by group assignment*

Measure	Randomized study groups, N=193: Control, N=58	Coach, N=51	Supplement, N=39	Placebo, N=45	Difference among randomized groups: Effect size	Test	FDR	Self-referred, N=75	Difference with control group: Effect size	Test	FDR
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	P	M (SD); n	Partial eta^2	P	P
Motivational Inventory	155.54 (20.2); 57	153.81 (20.7); 47	154.58 (21.1); 33	149.38 (22.67); 42	0.013	0.5273	0.7358	152.48 (19.75); 75	0.006	0.3836	0.4384
Heel bone mineral density	0.61 (0.1); 47	0.69 (0.13); 33	0.6 (0.12); 28	0.65 (0.17); 32	0.065	0.027	0.234	0.65 (0.1); 40	0.03	0.1068	0.1553
Heel T score	0.26 (0.9); 47	0.95 (1.17); 33	0.17 (1.09); 28	0.61 (1.47); 32	0.067	0.0235	0.234	0.59 (0.9); 40	0.033	0.0924	0.1478
Vitamin D	22.6 (6.94); 42	26.3 (6.24); 36	25.16 (6.58); 32	26.21 (7.59); 28	0.052	0.0652	0.4238	27.4 (8.62); 53	0.085	0.0042	0.0168
Fasting Blood Sugar	93.05 (9.14); 57	89.22 (9.93); 51	92.82 (9.63); 38	92.17 (10.47); 46	0.026	0.1776	0.5642	91.6 (8.2); 73	0.007	0.3435	0.4384
Total cholesterol	188.48 (32.32); 58	185 (30.79); 51	182.08 (27.53); 39	182.82 (32.82); 45	0.007	0.7318	0.906	184.67 (33.32); 72	0.003	0.5118	0.5459
High density lipoprotein	50.34 (10.41); 58	51.33 (10.92); 51	45 (10.06); 39	47.6 (11.09); 45	0.049	0.024	0.234	55.67 (14.25); 72	0.042	0.0189	0.0398
Triglycerides	131.88 (83.68); 58	120.35 (73.96); 51	142.05 (85.4); 39	140.11 (95.94); 45	0.01	0.5922	0.7699	102.06 (60.4); 72	0.042	0.0199	0.0398
HDL to CHOL ratio	0.28 (0.07); 58	0.28 (0.07); 51	0.25 (0.07); 39	0.27 (0.07); 45	0.023	0.2127	0.5642	0.31 (0.1); 72	0.042	0.0195	0.0398
Low density lipoprotein	119.6 (27.12); 58	117.16 (27.18); 51	116.62 (25.36); 39	115.02 (29.96); 45	0.004	0.8632	0.9635	114.94 (32.12); 72	0.006	0.3801	0.4384
Weight in lbs	213.82 (35.32); 57	208.45 (37.42); 47	219.92 (23.59); 33	211.73 (26.8); 42	0.014	0.466	0.7127	202.54 (34.24); 75	0.026	0.0665	0.1182
Body mass index	32.54 (4.04); 57	31.28 (3.65); 47	31.69 (3.18); 33	31.5 (2.41); 42	0.022	0.2672	0.5789	29.91 (3.37); 75	0.113	<.0001	0.0016
Waist circumference	38.25 (4.13); 56	37.21 (4.13); 47	38.75 (3.36); 33	37.77 (3.27); 42	0.021	0.3019	0.6038	35.92 (3.91); 71	0.078	0.0015	0.008
Inbody % fat	31.83 (5.88); 56	29.34 (5.26); 47	29.83 (5.25); 33	30.38 (5.91); 41	0.031	0.1363	0.5642	28.4 (7.98); 73	0.054	0.008	0.0256
Inbody lean Mass	145.8 (29.19); 56	147.13 (26.99); 47	153.83 (15.61); 33	147.81 (25.07); 41	0.012	0.5377	0.7358	145.61 (30.33); 73	0	0.9716	0.9716
Inbody fat mass	67.32 (15.69); 56	61.33 (16.8); 47	66.09 (15.69); 33	63.92 (12.8); 41	0.024	0.2387	0.5642	57.42 (18.27); 73	0.076	0.0015	0.008
DXA Tissue % fat	-	32.67 (5.66); 9	32.87 (5.27); 20	32.64 (5.96); 25	0	0.9909	0.9924	-	-	-	
DXA Region % fat	-	31.53 (5.55); 9	31.74 (5.18); 20	31.55 (5.84); 25	0	0.9924	0.9924	-	-	-	
DXA Tissue mass	-	88271.56 (16566.31); 9	95864.45 (7666.42); 20	90376.16 (12126.87); 25	0.067	0.1717	0.5642	-	-	-	
DXA Fat mass	-	28781.56 (7308.71); 9	31683.9 (6377.19); 20	29329.76 (5508.24); 25	0.04	0.3518	0.6091	-	-	-	
DXA Lean mass	-	59489.89 (12254.67); 9	64180.55 (5324.48); 20	61046.48 (10614.8); 25	0.038	0.3748	0.6091	-	-	-	
DXA Bone mineral content	-	3181.22 (589.12); 9	3417.3 (335.65); 20	3189.31 (509.23); 25	0.057	0.2269	0.5642	-	-	-	
DXA Fat free mass	-	62671.11 (12836.64); 9	67597.85 (5566.52); 20	64235.79 (11059.43); 25	0.039	0.364	0.6091	-	-	-	
DXA Total mass	-	91.46 (17.09); 9	99.28 (7.77); 20	93.57 (12.52); 25	0.068	0.1681	0.5642	-	-	-	
DXA Bone mineral density	-	1.3 (0.11); 9	1.31 (0.1); 20	1.31 (0.09); 25	0.005	0.8894	0.9635	-	-	-	
DXA T score	-	1.36 (0.84); 9	1.19 (1.11); 20	1.32 (0.67); 24	0.006	0.8516	0.9635	-	-	-	

*Tests conducted with general linear models; Partial eta2: small ~0.02, medium ~0.13, large ~0.26

Table 6. Baseline to Week 12 change scores*

Measure	Randomized study groups				Difference among randomized groups			Self-referred	Difference with control group		
	Control	Coach	Supplement	Placebo	Effect size	Test	Test		Effect size	Test	Test
	M (SE)	M (SE)	M (SE)	M (SE)	eta^2	P	FDR	M (SE)	eta^2	P	FDR
Motivational Inventory	2 (1.85)	0.57 (1.41)	1.96 (1.42)	1.85 (1.64)	0.01	0.884167	0.8842	2.64 (1.12)	0.01	0.867328	0.8673
Heel bone mineral density	0.01 (0.01)	0.02 (0.01)	0.01 (0.01)	0.01 (0.01)	0.01	0.555049	0.6212	0.01 (0.01)	0.01	0.462551	0.6167
Heel T score	0.09 (0.05)	0.18 (0.06)	0.05 (0.04)	0.13 (0.06)	0.02	0.311455	0.5538	0.06 (0.05)	0.01	0.537258	0.6204
Vitamin D	1.32 (0.53)	3.67 (0.55)	2.45 (0.54)	2.37 (0.64)	0.05	0.027694	0.1536	0.79 (0.7)	0.01	0.542892	0.6204
Fasting Blood Sugar	2.09 (0.76)	-0.65 (0.9)	2.32 (0.88)	0.09 (0.86)	0.05	0.038358	0.1536	0.52 (0.86)	0.01	0.39802	0.6167
Total cholesterol	1.01 (2.21)	-1.5 (2.25)	2.84 (1.8)	2.38 (1.84)	0.01	0.462877	0.5697	-7.98 (2.19)	0.03	0.02673	0.1426
High density lipoprotein	-1.08 (0.57)	0.31 (0.61)	-0.13 (0.57)	0.58 (0.64)	0.02	0.223108	0.4462	-1.36 (0.7)	0.01	0.628668	0.6706
Triglycerides	9.6 (4.74)	6.86 (4.98)	15.25 (4.79)	2.38 (12.08)	0.01	0.582361	0.6212	-2.71 (6.95)	0.01	0.205618	0.4112
HDL to CHOL ratio	-0.01 (0)	0 (0)	-0.01 (0)	0 (0)	0.03	0.160731	0.3673	0 (0)	0.02	0.084534	0.2388
Low density lipoprotein	1.23 (1.75)	-1.93 (2.09)	1.02 (1.54)	2.58 (1.88)	0.01	0.448684	0.5697	-5.2 (1.81)	0.02	0.054724	0.2189
Weight in lbs	-2.22 (0.55)	-4.39 (0.66)	-2 (0.5)	-2.49 (0.5)	0.05	0.030746	0.1536	-2.34 (0.6)	0.01	0.4165	0.6167
Body mass index	-0.32 (0.08)	-0.65 (0.1)	-0.29 (0.07)	-0.37 (0.08)	0.05	0.023739	0.1536	-0.34 (0.09)	0.01	0.428206	0.6167
Waist circumference	-0.31 (0.1)	-0.56 (0.12)	-0.43 (0.1)	-0.47 (0.12)	0.01	0.449552	0.5697	-0.69 (0.11)	0.02	0.089535	0.2388
Inbody % fat	-0.4 (0.18)	-1.02 (0.21)	-0.5 (0.19)	-0.81 (0.19)	0.03	0.109305	0.2915	-1.13 (0.18)	0.03	0.025244	0.1426
Inbody lean Mass	-0.73 (0.42)	-0.69 (0.45)	-0.17 (0.38)	0.15 (0.47)	0.01	0.441358	0.5697	0.61 (0.35)	0.05	0.003633	0.0581
Inbody fat mass	-1.51 (0.5)	-3.43 (0.65)	-1.7 (0.54)	-2.28 (0.47)	0.03	0.108811	0.2915	-2.95 (0.51)	0.01	0.200055	0.4112

*Ten imputations with random forest; linear mixed model-estimated difference in change from baseline adjusted for probability of group membership estimated with: rank, age, Hispanic or Latino, on-profile, exercise min/week, taking vitamin D; eta2 estimated from F statistic and df: small ~0.02, medium ~0.13,large ~0.26

Table 7. Control vs Combined Coaching Groups Week 12 change scores*

Measure	Baseline Measures	Change at follow-up											
		Original data						Imputed data					
	Control	Control	Coach	Difference	Effect size			Control	Coach	Difference	Effect size		
	M (SD); n	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR
Motivational Inventory	153.33 (21.19); 86	2.75 (2.09)	1.02 (1.94)	-1.73 (2.85)	-0.08	0.5438	0.6259	2 (1.85)	0.57 (1.41)	-1.43 (2.33)	-0.07	0.5394	0.6165
Heel bone mineral density	0.6 (0.1); 72	0 (0.01)	0.03 (0.01)	0.03 (0.01)	0.3	0.0027	0.0216	0.01 (0.01)	0.02 (0.01)	0.01 (0.01)	0.1	0.3173	0.4231
Heel T score	0.19 (0.87); 72	0.03 (0.07)	0.23 (0.09)	0.2 (0.11)	0.23	0.069	0.1562	0.09 (0.05)	0.18 (0.06)	0.09 (0.08)	0.1	0.2606	0.417
Vitamin D	21.9 (8.54); 63	0.81 (0.71)	4.45 (0.85)	3.64 (1.11)	0.43	0.001	0.016	1.32 (0.53)	3.67 (0.55)	2.35 (0.76)	0.28	0.002	0.032
Fasting Blood Sugar	90.87 (8.47); 78	2.07 (0.91)	-1.3 (1.16)	-3.37 (1.47)	-0.4	0.0219	0.0876	2.09 (0.76)	-0.65 (0.9)	-2.74 (1.18)	-0.32	0.0202	0.0646
Total cholesterol	184.99 (33.3); 79	2.02 (2.89)	-0.41 (2.56)	-2.43 (3.86)	-0.07	0.529	0.6259	1.01 (2.21)	-1.5 (2.25)	-2.51 (3.15)	-0.08	0.4256	0.5238
High density lipoprotein	51.51 (11.83); 79	-0.89 (0.69)	0.31 (0.78)	1.2 (1.04)	0.1	0.2486	0.3978	-1.08 (0.57)	0.31 (0.61)	1.39 (0.83)	0.12	0.094	0.2149
Triglycerides	108.72 (61.01); 79	8.58 (5.51)	4.08 (6.53)	-4.5 (8.54)	-0.07	0.5982	0.6381	9.6 (4.74)	6.86 (4.98)	-2.74 (6.88)	-0.04	0.6904	0.7364
HDL to CHOL ratio	0.29 (0.08); 79	-0.01 (0)	0 (0.01)	0.01 (0.01)	0.13	0.3173	0.4615	-0.01 (0)	0 (0)	0.01 (0.01)	0.13	0.3173	0.4231
Low density lipoprotein	116.89 (29.02); 79	1.79 (2.27)	-0.17 (2.34)	-1.96 (3.26)	-0.07	0.5477	0.6259	1.23 (1.75)	-1.93 (2.09)	-3.16 (2.73)	-0.11	0.2471	0.417
Weight in lbs	217.08 (33.32); 86	-1.82 (0.63)	-3.53 (0.8)	-1.71 (1.02)	-0.05	0.0936	0.1664	-2.22 (0.55)	-4.39 (0.66)	-2.17 (0.86)	-0.07	0.0116	0.0619
Body mass index	32.45 (3.19); 86	-0.13 (0.17)	-0.5 (0.12)	-0.37 (0.21)	-0.12	0.0781	0.1562	-0.32 (0.08)	-0.65 (0.1)	-0.33 (0.13)	-0.1	0.0111	0.0619
Waist circumference	38.53 (3.87); 86	-0.31 (0.1)	-0.7 (0.14)	-0.39 (0.17)	-0.1	0.0218	0.0876	-0.31 (0.1)	-0.56 (0.12)	-0.25 (0.16)	-0.06	0.1182	0.2364
Inbody % fat	31.43 (5.77); 86	-0.32 (0.21)	-0.95 (0.24)	-0.63 (0.32)	-0.11	0.049	0.1312	-0.4 (0.18)	-1.02 (0.21)	-0.62 (0.28)	-0.11	0.0268	0.0715
Inbody lean Mass	149.12 (27.15); 86	-0.63 (0.44)	-0.56 (0.51)	0.07 (0.67)	0	0.9168	0.9168	-0.73 (0.42)	-0.69 (0.45)	0.04 (0.62)	0	0.9486	0.9486
Inbody fat mass	67.96 (15.58); 86	-1.15 (0.59)	-2.92 (0.68)	-1.77 (0.9)	-0.11	0.0492	0.1312	-1.51 (0.5)	-3.43 (0.65)	-1.92 (0.82)	-0.12	0.0192	0.0646

*Cohen's d: small ~0.2, medium ~0.5, large ~0.8

Vitamin D
An exploratory analysis was done to examine vitamin D levels separately, after amending the protocol to include vitamin D as a biomarker. Using the original data, under the assumption that the missing data were missing at random (the analysis was adjusted for characteristics associated with dropout), and using a cutoff for relevance in the effect size eta^2 of ~0.07, suggestion of beneficial intervention effect on vitamin D levels was found (eta^2=0.13), with the CG having the lowest increase in vitamin D compared to all other groups. Examining the change scores over time between the CG and all NHC groups combined reveals a statistically significant difference with NHC groups improving their levels of vitamin D; 0.81(0.71) vs 4.45 (0.85), FDR = 0.016. However, the finding did not fully replicate in the multiple imputation analysis (eta^2=0.05). See Tables 8 & 9.

Table 8. Vitamin D status at baseline*

Vitamin D level	Randomized study groups, N=237				Difference among randomized groups		Self-referred, N=79	Difference with control group	
	Control, N=63	Coach, N=60	Supplement, N=59	Placebo, N=55	Effect size	Test		Effect size	Test
	n (%)	n (%)	n (%)	n (%)	Cohen's w	P	n (%)	Cohen's w	P
Deficient or insufficient	53 (84.1)	52 (86.7)	51 (86.4)	46 (83.6)	0.0378	0.9525	54 (68.4)	0.1818	0.0303
Normal	10 (15.9)	8 (13.3)	8 (13.6)	9 (16.4)			25 (31.7)		

*Chi-square test; Cohen's w (Phi coefficient), small ~0.1, medium ~0.3, large ~0.5

Table 9. Vitamin D status at 12 weeks*

Vitamin D level	Randomized study groups, N=138				Difference among randomized groups		Self-referred, N=53	Difference with control group	
	Control, N=42	Coach, N=36	Supplement, N=32	Placebo, N=28	Effect size	Test		Effect size	Test
	n (%)	n (%)	n (%)	n (%)	Cohen's w	P	n (%)	Cohen's w	P
Deficient or insufficient	33 (78.6)	27 (75)	23 (71.9)	19 (67.9)	0.0891	0.778	35 (66)	0.138	0.1786
Normal	9 (21.4)	9 (25)	9 (28.1)	9 (32.1)			18 (34)		

*Chi-square test; Cohen's w (Phi coefficient), small ~0.1, medium ~0.3, large ~0.5

Specific Aim 2. Evaluate the effect of an herbal supplement, used in conjunction with MOVE!, on the primary outcome of weight loss and the secondary outcomes of body fat (BF), waist circumference (WC), lipid profile, and adherence at 6 weeks and 12 weeks, and bone mineral density (BMD) at 12 weeks only.
Hypothesis 2. An herbal supplement provided to Soldiers in conjunction with MOVE! over 12 weeks will achieve weight loss goals, decrease waist circumference, reduce percent body fat, improve lipid profile, raise vitamin D level, and increase bone mineral density as compared to the other study groups.
Findings: For the herbal supplement group, there were no significant differences from baseline to follow up on weight loss, percent (%) BF, WC, BMD, lipid panel, or adherence when compared to all other study groups. At follow up (Weeks 6 + 12), no significant differences in change from baseline on outcomes among study groups were found at an FDR of 10%. The

effect sizes suggested no relevant differences in change on outcomes across groups. These results were also observed when comparing the CG and supplement groups, and placebo and supplement groups. See above Tables 2-7 and Table 9 below.

Table 10. Control vs Supplement group change scores*

		Change at follow-up											
		Original data						Imputed data					
Measure	Baseline Measures												
	Control	Control	Supplement	Difference	Effect size			Control	Supplement	Difference	Effect size		
	M (SD); n	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR
Motivational Inventory	153.33 (21.19); 86	2.75 (2.09)	2.23 (1.77)	-0.52 (2.74)	-0.02	0.8495	1	2 (1.85)	1.96 (1.42)	-0.04 (2.33)	0	0.9863	1
Heel bone mineral density	0.6 (0.1); 72	0 (0.01)	0.02 (0.01)	0.02 (0.01)	0.2	0.0455	0.728	0.01 (0.01)	0.01 (0.01)	0 (0.01)	0	1	1
Heel T score	0.19 (0.87); 72	0.03 (0.07)	0.08 (0.07)	0.05 (0.1)	0.06	0.6171	1	0.09 (0.05)	0.05 (0.04)	-0.04 (0.06)	-0.05	0.505	1
Vitamin D	21.9 (8.54); 63	0.81 (0.71)	2.12 (0.93)	1.31 (1.17)	0.15	0.2629	1	1.32 (0.53)	2.45 (0.54)	1.13 (0.76)	0.13	0.1371	1
Fasting Blood Sugar	90.87 (8.47); 78	2.07 (0.91)	3.05 (1.43)	0.98 (1.69)	0.12	0.562	1	2.09 (0.76)	2.32 (0.88)	0.23 (1.16)	0.03	0.8428	1
Total cholesterol	184.99 (33.3); 79	2.02 (2.89)	3.31 (2.35)	1.29 (3.72)	0.04	0.7288	1	1.01 (2.21)	2.84 (1.8)	1.83 (2.85)	0.05	0.5208	1
High density lipoprotein	51.51 (11.83); 79	-0.89 (0.69)	-0.43 (0.76)	0.46 (1.03)	0.04	0.6552	1	-1.08 (0.57)	-0.13 (0.57)	0.95 (0.81)	0.08	0.2409	1
Triglycerides	108.72 (61.01); 79	8.58 (5.51)	17.8 (7.21)	9.22 (9.07)	0.15	0.3094	1	9.6 (4.74)	15.25 (4.79)	5.65 (6.74)	0.09	0.4019	1
HDL to CHOL ratio	0.29 (0.08); 79	-0.01 (0)	-0.01 (0)	0 (0.01)	0	1	1	-0.01 (0)	-0.01 (0)	0 (0.01)	0	1	1
Low density lipoprotein	116.89 (29.02); 79	1.79 (2.27)	0.86 (1.93)	-0.93 (2.98)	-0.03	0.755	1	1.23 (1.75)	1.02 (1.54)	-0.21 (2.33)	-0.01	0.9282	1
Weight in lbs	217.08 (33.32); 86	-1.82 (0.63)	-2 (0.7)	-0.18 (0.94)	-0.01	0.8481	1	-2.22 (0.55)	-2 (0.5)	0.22 (0.74)	0.01	0.7662	1
Body mass index	32.45 (3.19); 86	-0.13 (0.17)	-0.29 (0.1)	-0.16 (0.2)	-0.05	0.4237	1	-0.32 (0.08)	-0.29 (0.07)	0.03 (0.11)	0.01	0.7851	1
Waist circumference	38.53 (3.87); 86	-0.31 (0.1)	-0.44 (0.14)	-0.13 (0.17)	-0.03	0.4444	1	-0.31 (0.1)	-0.43 (0.1)	-0.12 (0.14)	-0.03	0.3914	1
Inbody % fat	31.43 (5.77); 86	-0.32 (0.21)	-0.33 (0.25)	-0.01 (0.33)	0	0.9758	1	-0.4 (0.18)	-0.5 (0.19)	-0.1 (0.26)	-0.02	0.7005	1
Inbody lean Mass	149.12 (27.15); 86	-0.63 (0.44)	-0.72 (0.49)	-0.09 (0.66)	0	0.8915	1	-0.73 (0.42)	-0.17 (0.38)	0.56 (0.57)	0.02	0.3259	1
Inbody fat mass	67.96 (15.58); 86	-1.15 (0.59)	-1.19 (0.69)	-0.04 (0.91)	0	0.9649	1	-1.51 (0.5)	-1.7 (0.54)	-0.19 (0.74)	-0.01	0.7974	1

*Cohen's d: small ~0.2, medium ~0.5, large ~0.8

Table 11. Placebo vs Supplement group change scores*

		Change at follow-up											
		Original data						Imputed data					
Measure	Baseline Measures												
	Placebo	Placebo	Supplement	Difference	Effect size			Placebo	Supplement	Difference	Effect size		
	M (SD); n	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR	M (SE)	M (SE)	M (SE)	Cohen's d	P	FDR
Motivational Inventory	148.84 (23.82); 85	2.04 (2.09)	2.23 (1.77)	0.19 (2.74)	0.01	0.9447	0.9464	1.85 (1.64)	1.96 (1.42)	0.11 (2.17)	0	0.9596	1
Heel bone mineral density	0.62 (0.14); 74	0.01 (0.01)	0.02 (0.01)	0.01 (0.01)	0.07	0.3173	0.9017	0.01 (0.01)	0.01 (0.01)	0 (0.01)	0	1	1
Heel T score	0.36 (1.25); 74	0.06 (0.08)	0.08 (0.07)	0.02 (0.11)	0.02	0.8557	0.9464	0.13 (0.06)	0.05 (0.04)	-0.08 (0.07)	-0.06	0.2531	0.8334
Vitamin D	22.92 (7.42); 55	2.86 (1.45)	2.12 (0.93)	-0.74 (1.72)	-0.1	0.667	0.9017	2.37 (0.64)	2.45 (0.54)	0.08 (0.84)	0.01	0.9241	1
Fasting Blood Sugar	91.8 (9.46); 75	-0.2 (1.16)	3.05 (1.43)	3.25 (1.84)	0.34	0.0773	0.9017	0.09 (0.86)	2.32 (0.88)	2.23 (1.23)	0.24	0.0698	0.8334
Total cholesterol	180.23 (34.59); 75	3.09 (2.27)	3.31 (2.35)	0.22 (3.27)	0.01	0.9464	0.9464	2.38 (1.84)	2.84 (1.8)	0.46 (2.57)	0.01	0.8579	1
High density lipoprotein	46.67 (9.79); 75	0.15 (0.99)	-0.43 (0.76)	-0.58 (1.25)	-0.06	0.6426	0.9017	0.58 (0.64)	-0.13 (0.57)	-0.71 (0.86)	-0.07	0.409	0.8334
Triglycerides	133.39 (149.51); 75	7.45 (7.97)	17.8 (7.21)	10.35 (10.75)	0.07	0.3357	0.9017	2.38 (12.08)	15.25 (4.79)	12.87 (13)	0.09	0.3222	0.8334
HDL to CHOL ratio	0.27 (0.07); 75	0 (0.01)	-0.01 (0)	-0.01 (0.01)	-0.14	0.3173	0.9017	0 (0)	-0.01 (0)	-0.01 (0.01)	-0.14	0.3173	0.8334
Low density lipoprotein	112.65 (30.5); 75	3.02 (2.1)	0.86 (1.93)	-2.16 (2.85)	-0.07	0.4485	0.9017	2.58 (1.88)	1.02 (1.54)	-1.56 (2.43)	-0.05	0.5209	0.8334
Weight in lbs	214.12 (30.25); 85	-2.56 (0.72)	-2 (0.7)	0.56 (1)	0.02	0.5755	0.9017	-2.49 (0.5)	-2 (0.5)	0.49 (0.71)	0.02	0.4901	0.8334
Body mass index	32.63 (3.02); 85	-0.45 (0.13)	-0.29 (0.1)	0.16 (0.16)	0.05	0.3173	0.9017	-0.37 (0.08)	-0.29 (0.07)	0.08 (0.11)	0.03	0.4671	0.8334
Waist circumference	38.13 (3.65); 84	-0.42 (0.15)	-0.44 (0.14)	-0.02 (0.21)	-0.01	0.9241	0.9464	-0.47 (0.12)	-0.43 (0.1)	0.04 (0.16)	0.01	0.8026	1
Inbody % fat	32.73 (6.56); 85	-0.46 (0.22)	-0.33 (0.25)	0.13 (0.33)	0.02	0.6936	0.9017	-0.81 (0.19)	-0.5 (0.19)	0.31 (0.27)	0.05	0.2509	0.8334
Inbody lean Mass	144.82 (28.3); 85	-0.87 (0.44)	-0.72 (0.49)	0.15 (0.66)	0.01	0.8202	0.9464	0.15 (0.47)	-0.17 (0.38)	-0.32 (0.6)	-0.01	0.5938	0.8637
Inbody fat mass	69.3 (13.47); 85	-1.57 (0.62)	-1.19 (0.69)	0.38 (0.93)	0.03	0.6828	0.9017	-2.28 (0.47)	-1.7 (0.54)	0.58 (0.72)	0.04	0.4205	0.8334
DXA Tissue % fat	34.81 (6.68); 46	-1.05 (0.31)	-0.57 (0.51)	0.48 (0.6)	0.07	0.4237	0.9017	-	-	-	-	-	-
DXA Region % fat	33.65 (6.52); 46	-1.03 (0.3)	-0.57 (0.49)	0.46 (0.57)	0.07	0.4197	0.9017	-	-	-	-	-	-
DXA Tissue mass	91045.17 (13223.5); 46	-1136.38 (612.97)	-468.75 (997.3)	667.63 (1170.62)	0.05	0.5685	0.9017	-	-	-	-	-	-
DXA Fat mass	31267.59 (5380.73); 46	-1362.08 (403.56)	-799.12 (628.72)	562.96 (747.09)	0.1	0.4511	0.9017	-	-	-	-	-	-
DXA Lean mass	59777.52 (12541.29); 46	296.12 (522.94)	756.66 (832.98)	460.54 (983.53)	0.04	0.6396	0.9017	-	-	-	-	-	-
DXA Bone mineral content	3189.83 (571.78); 46	1 (16.73)	12.62 (18.32)	11.62 (24.81)	0.02	0.6395	0.9017	-	-	-	-	-	-
DXA Fat free mass	62967.35 (13065.76); 46	297.57 (539.99)	785.09 (853.28)	487.52 (1009.79)	0.04	0.6292	0.9017	-	-	-	-	-	-
DXA Total mass	94.23 (13.71); 46	-1.16 (0.57)	-1.02 (0.52)	0.14 (0.77)	0.01	0.8557	0.9464	-	-	-	-	-	-
DXA Bone mineral density	1.31 (0.1); 46	0 (0)	-0.01 (0)	-0.01 (0.01)	-0.1	0.3173	0.9017	-	-	-	-	-	-
DXA T score	1.49 (0.8); 44	-0.01 (0.03)	-0.08 (0.04)	-0.07 (0.05)	-0.09	0.1615	0.9017	-	-	-	-	-	-

*Cohen's d: small ~0.2, medium ~0.5, large ~0.8

Specific Aim 3. Describe the influence of motivation on the primary outcome of weight loss and the secondary outcome of adherence at 6 weeks and 12 weeks. (Tables 11-13; note unique N)
Hypothesis 3. Motivation as measured by the Self-Motivation Inventory will positively influence weight loss and adherence.
Findings: Although the effect size was in the right direction with an increase in motivation associated with a decrease in weight, the observed relationship was too small in magnitude for statistical significance. The correlation between baseline motivation and 12-week change in BMI was negligible, estimated at 0.021 (p = 0.70, n=329). The correlation between change in motivation and change in BMI was estimated at -0.075 (p = 0.19, n=329). [Data not shown]
The adherence score was calculated using a point system for MOVE! attendance, return for measures, response to emails/phone calls, and keeping RD appointments; the score was compiled at the final data collection point or 12 weeks following enrollment. Scores ranged from 8.92 for the CG to 53.78 for the self-referred group. The differences in scores were statistically significantly different among randomized groups and for the self-referred group when compared to the control group. See Table 13.

Table 12. Week 6 Motivational Inventory results*

Measure	Randomized study groups, N=231				Difference among randomized groups			Self-referred, N=84	Difference with control group		
	Control, N=70	Coach, N=58	Supplement, N=56	Placebo, N=55	Effect size	Test	Test		Effect size	Test	Test
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	FDR	M (SD); n	Partial eta^2	P	FDR
Motivational Inventory	154.74 (19.25); 69	152.79 (20.79); 56	156.78 (18.04); 51	148.58 (23.69); 55	0.021	0.194	0.7259	150.39 (20.29); 83	0.012	0.1797	0.292

*Tests conducted with general linear models; Partial eta^2: small ~0.02, medium ~0.13, large ~0.26

Table 13. Week 12 Motivational Inventory results*

Measure	Randomized study groups, N=193				Difference among randomized groups			Self-referred, N=75	Difference with control group		
	Control, N=58	Coach, N=51	Supplement, N=39	Placebo, N=45	Effect size	Test	FDR		Effect size	Test	FDR
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	P	M (SD); n	Partial eta^2	P	P
Motivational Inventory	155.54 (20.2); 57	153.81 (20.7); 47	154.58 (21.1); 33	149.38 (22.67); 42	0.013	0.5273	0.7358	152.48 (19.75); 75	0.006	0.3836	0.4384

*Tests conducted with general linear models; Partial eta^2: small ~0.02, medium ~0.13, large ~0.26

Table 14. Adherence measure all groups*

Measure	Randomized study groups, N=355				Difference among randomized groups		Self-referred, N=100	Difference with control group	
	Control, N=86	Coach, N=81	Supplement, N=83	Placebo, N=85	Effect size	Test		Effect size	Test
	M (SD); n	M (SD); n	M (SD); n	M (SD); n	Partial eta^2	P	M (SD); n	Partial eta^2	P
Percent adherence	8.92 (4.19); 86	47.07 (24.95); 81	40.66 (25.14); 83	41.12 (24.92); 85	0.328	<.0001	53.78 (22.56); 100	0.642	<.0001

*Tests conducted with general linear models; Partial eta^2: small ~0.02, medium ~0.13, large ~0.26

Specific Aim 4. Evaluate a Unit-based healthy lifestyle curriculum for self-referred Soldiers who are within 3-5% of Army body fat standards for the impact on weight loss goals, waist circumference, lipid profile, adherence, and satisfaction.
Hypothesis 4. Self-referred Soldiers (Group 5) will achieve similar or greater success in achieving weight loss goals when compared to all other study arms.
Findings: At Week 12, outcome measures appeared to reflect significant differences for the self-referred group and the CG on vitamin D, HDL, Trig, HDL:CHOL, BMI, WC, %body fat, and fat mass; however, after adjusting for differences in baseline characteristics, there were no significant changes from baseline to follow up (Weeks 6 + 12) on any outcome between the CG and the self-referred group at an FDR of 10%. The observed effect sizes did not cross the threshold of relevance ($eta^2 \sim 0.07$). The same results were observed in the multiple imputation analysis. See Tables 2-6 and 12-14.

Additional Exploratory Analyses

In summary, the exploratory analysis revealed these profiles:
1. Participants not taking vitamin D at baseline trended towards higher positive change than those already taking vitamin D ($p = 0.007$);
2. Self-referred group decreased cholesterol levels while randomized groups did not ($p = 0.002$);
3. Participants in ranks E-6 to E-9 and O-4 to O-6 tended to slightly decrease LDL while those in ranks E-1 to E-5 and O1-3/WO 2-3 did not decrease LDL;
4. Males tended to lose more weight than females ($p = 0.012$);
5. Among those 27 years old or younger, participants who did not lose weight to enter the Army (LOSTWTENTER) had larger decreases in WC. Among those older than 27 years, males tended to have a slightly larger decrease in WC; and
6. Participants over the age of 31 had a greater decrease in % BF and fat mass compared to younger participants ($p < 0.001$, $p = .002$, respectively).

This analysis consisted of determining whether any of the predictors below were associated with increases or decreases in an outcome level. The aim was to find profiles of participants who benefited the most and the least during the study. The imputed data were used since the procedure is exploratory in nature and requires a full data matrix. See Figures 1-6.

The first step consisted of computing the change scores (follow-up minus baseline).
Step two was to model the residual on the following predictors:
Group, Gender, Rank, Age, Marital Status, Ethnicity, Race, History of being overweight, Lost weight to enter Army, Amount of weight lost to enter, Tobacco use, Alcohol use, Exercise in minutes per day, Profile limiting PT, and Taking vitamin D prior to enrollment in the study.
Non-linear non-parametric tree models were used as the regression approach.

Findings: No profiles were found for the following outcomes:
Motivation, Heel bone mineral density, FBS, HDL, TRIG, HDLRATIO, BMI, InBody Lean mass.

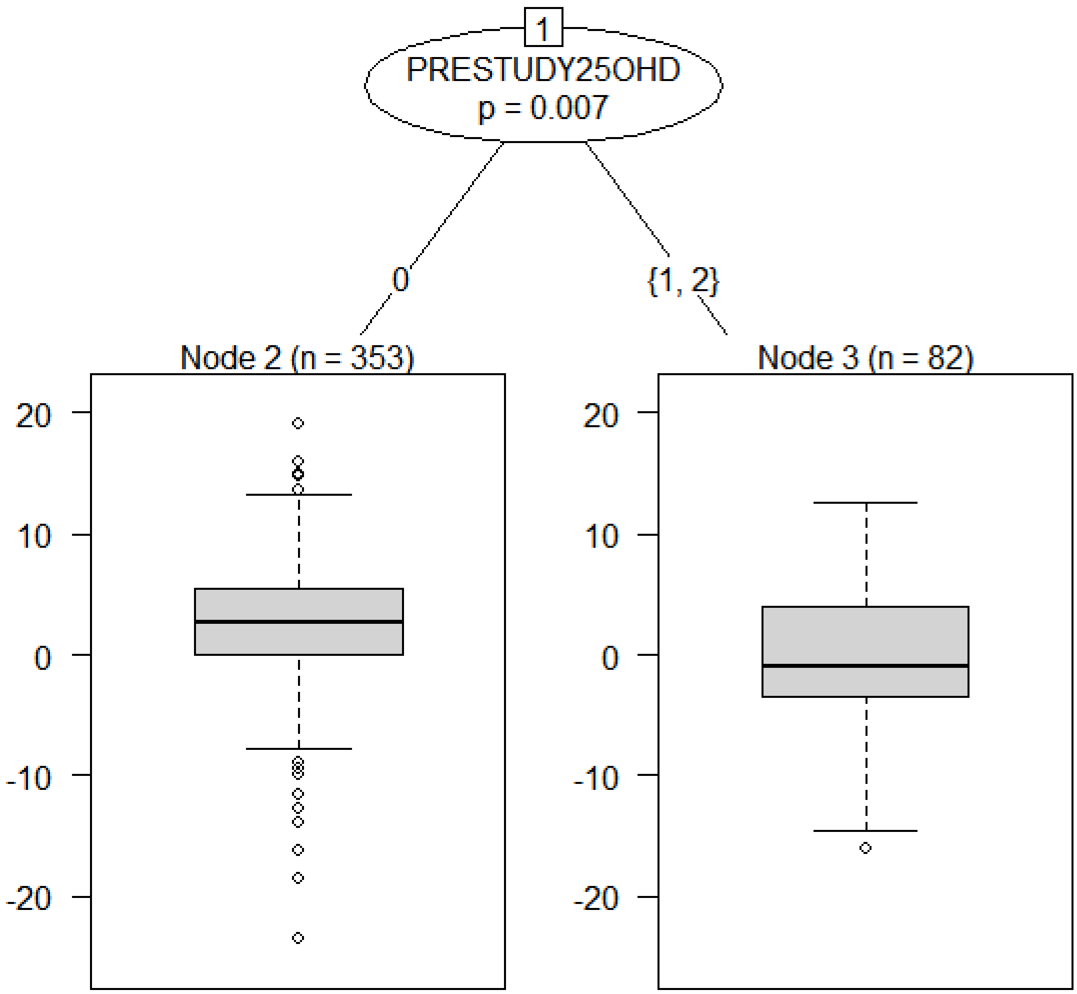

Figure 1. Profile for vitamin D (25OHD) levels

Findings: Participants who were not taking vitamin D (Node 2) at the beginning of the study (PRESTUDY25OHD), tended towards higher positive change than those who were already taking vitamin D

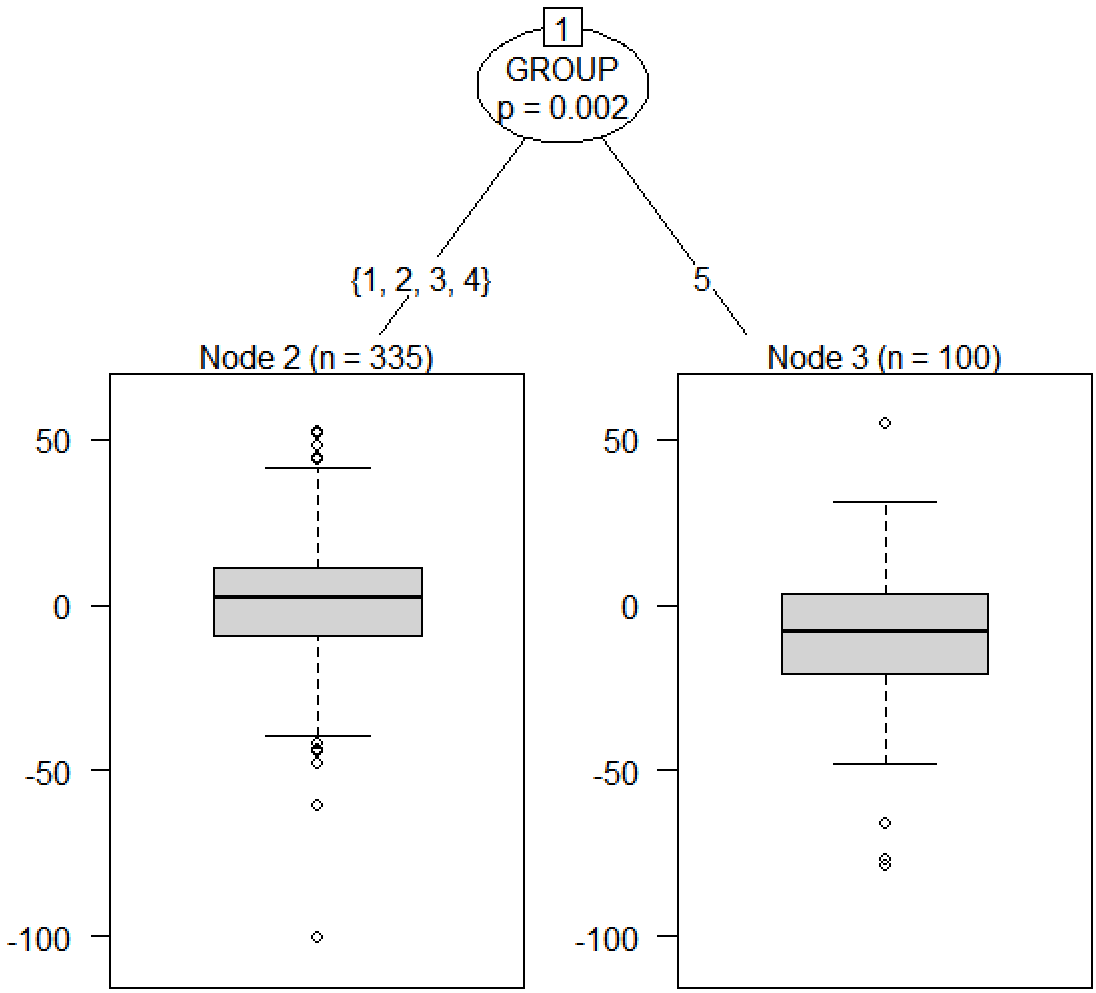

Figure 2. Profile for total cholesterol (CHOL) between groups

Findings: Participants in the self-referred group (Node 3) tended to slightly decrease cholesterol levels, while those in the randomized groups did not.

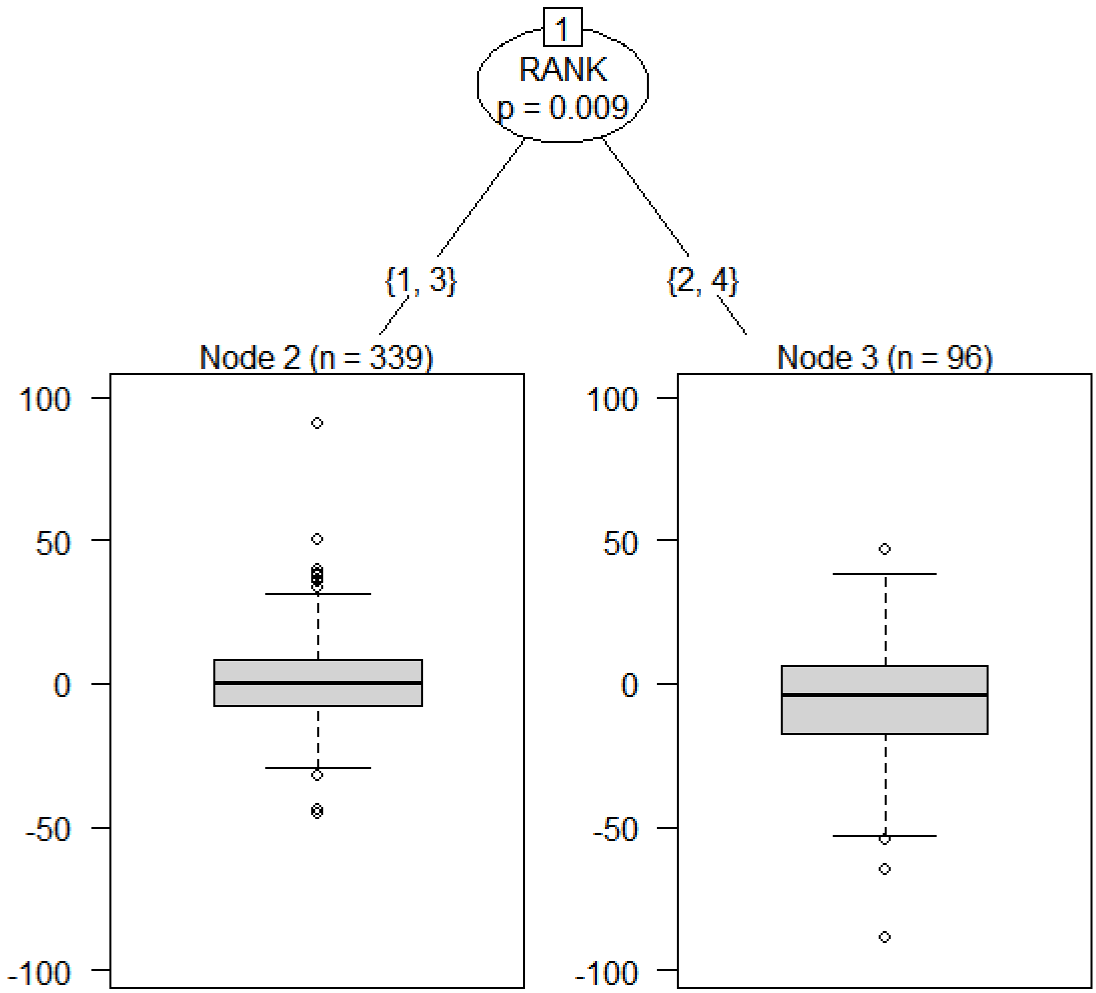

Figure 3. Profile for low density lipoprotein (LDL) between groups

Findings: Participants in ranks E-6 to E-9 and O-4 to O-6 (Node 3) tended to slightly decrease LDL while those in ranks E-1 to E-5 and O1-3/WO 2-3 did not decrease LDL.

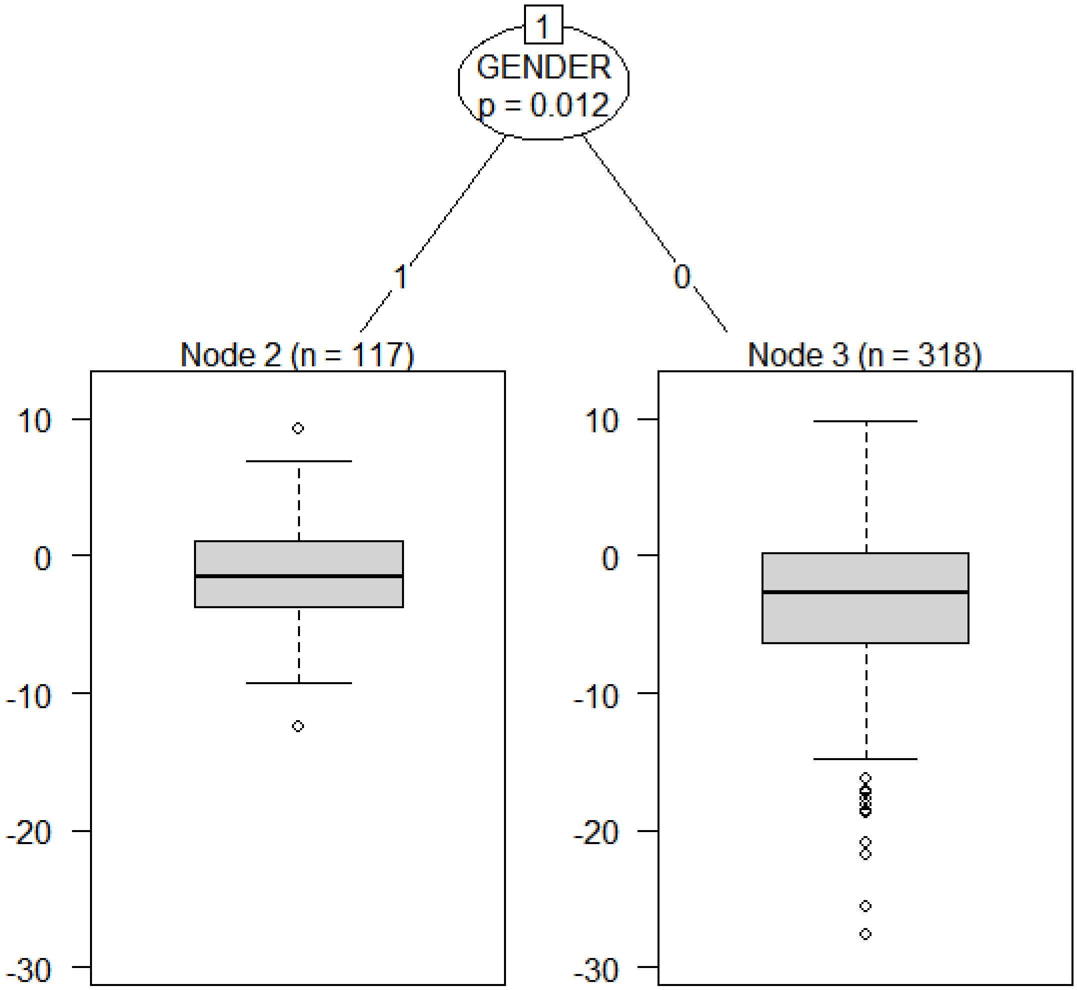

Figure 4. Profile for gender and weight loss (lbs) across all groups

Findings: Males (Node 3) tended to lose more weight than females.

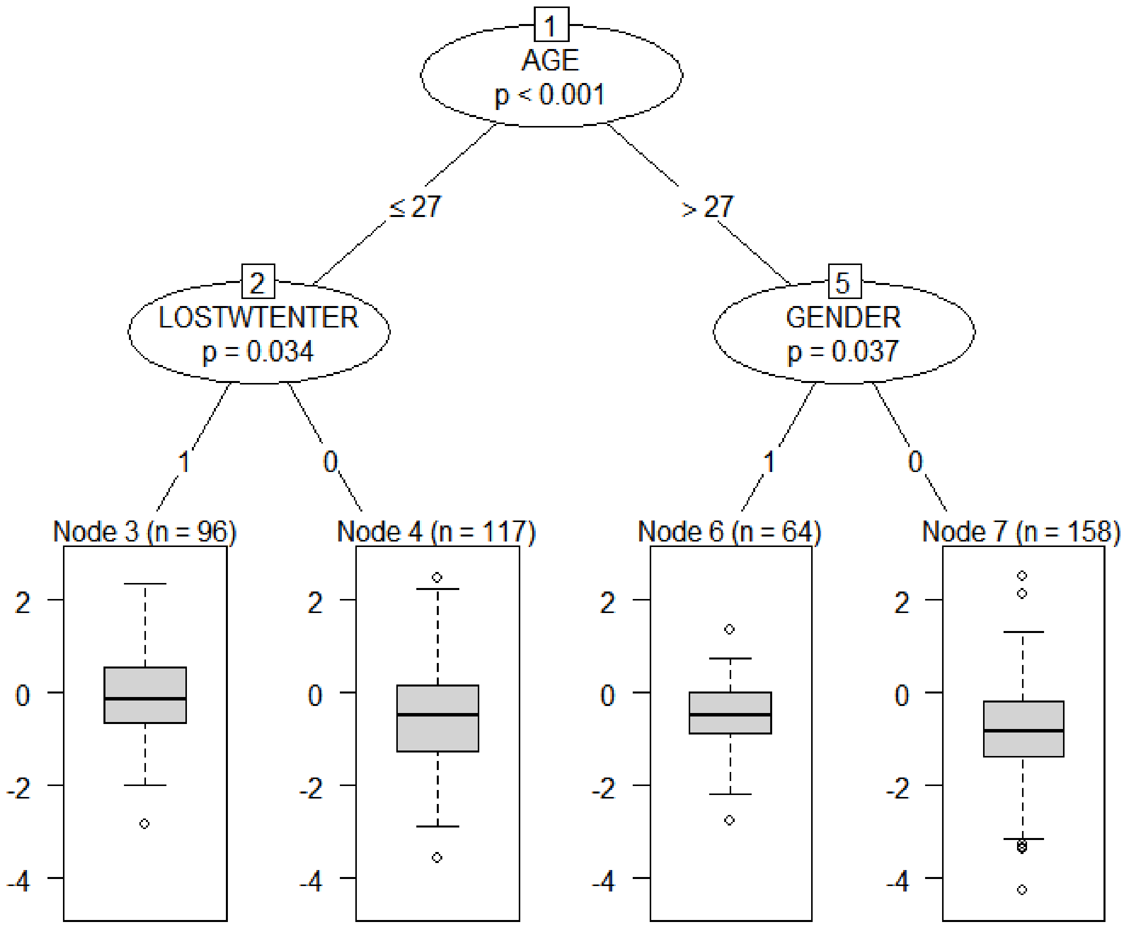

Figure 5. Profile for waist circumference (WC), age, weight lost to enter the Army, and gender across groups

Findings: Among those 27 years old or younger (Node 4), participants who did not lose weight to enter the Army (LOSTWTENTER) had larger decreases in WC. Among those older than 27 years, males tended to have a slightly larger decrease in WC (Node 7).

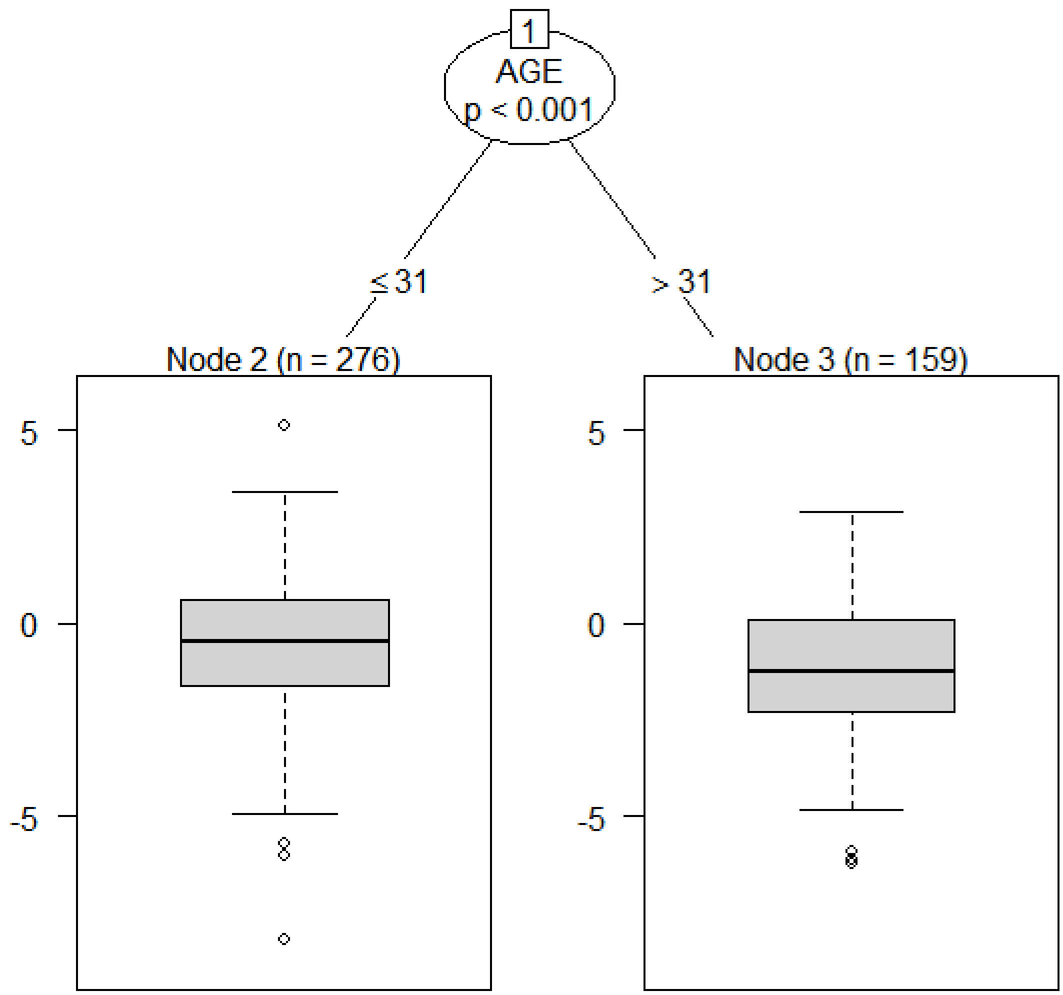

Figure 6. Body fat (using bioelectrical impedance) and age across groups

Findings: Participants older than 31 years of age (Node 3) tended to have slightly larger decrease in percent body fat (using bioelectrical impedance) compared to those 31 years old or younger.

Relationship of current findings to previous findings:

Lifestyle interventions

The primary outcome of weight loss proved difficult for all groups; there were no significant differences for primary or secondary outcomes across the 4 randomized groups of 335 Soldiers referred to MOVE!, the weight management initiative for the Army Body Composition Program (AR 600-9), who also volunteered to participate in our 12-week study. There were no significant results for 100 Soldiers who self-referred to our study due to concerns about their weight challenges and the need to meet Army AR 600-9 standards either. A review of the published literature since the start of this RCT in Fall 2012 reveals similar results from many studies, although interventions and populations are varied. Limited evidence is available to describe Army efforts to address weight management using lifestyle interventions for Soldiers. It is important to point out that the relatively minimal effect of the MOVE! plus NHC from this study leaves a large pool of overweight and over-fat Soldiers; at 12 weeks the average BMI was 31.4 kg/m^2, (categorized as obese; CDC, 2015) and body fat was 29.9%.

In 2014, an Army program called Operation Live Well, incorporated into the Healthy Base Initiative, was designed to help active duty service members, their families, and Department of Defense civilians shape up and give up tobacco. It is touted as one of the DOD success stories for 2014. The program was deemed necessary for the same reasons that the current RCT was developed; statistics show that obesity [and tobacco use] among U.S. military health care beneficiaries adds more than $3 billion per year to the Defense Department's budget in health care costs and lost duty days. In addition, failure to meet weight standards is a leading cause of involuntary separation from the military. Army leaders have also identified obesity in the civilian community as a limiting factor in the military's ability to recruit qualified personnel. To combat these problems, military installations were determined to provide environments that encourage good nutrition, active lifestyles, and tobacco-free living. In 2013, the program was launched at 14 sites focusing on promoting a healthy and fit force through educational awareness of the serious consequences of sedentary lifestyles and poor nutrition choices; Soldiers were encouraged to come with a buddy or as a team. Today, interested individuals can go to the Operation Live Well website and find a set of tools, resources, and original content, such as cookbooks, to build a healthy lifestyle plan when ready to make the commitment. Encouraging the buddy system was one approach used by our team but this only seemed to work well for the self-referred group. The four randomized groups were comprised of Soldiers who were Command-referred to the MOVE! Program, therefore they were not usually accompanied by a buddy. The buddy system worked well for our self-referred group and this was manifested in their high adherence scores which means they kept their registered dietitian (RD) appointments, they responded to the nurse health coaching interventions, they showed up for weekly classes, and had laboratory studies and body composition measures completed on schedule.

The MOVE! Program in Madigan's Outpatient Nutrition Clinic consisted of one initial group session, six group follow-up sessions, and optional appointments with a clinic RD. During the study, MOVE! session attendance and RD appointment attendance was collected for each participant. A content score was utilized to quantify dose of engagement in the MOVE! Program. Participants received 2 points for attending the initial MOVE! Session, 2 points for an individual appointment with a study RD or Nutrition Clinic RD, and 1 point for each of the six follow-up MOVE! sessions, for a maximum of 10 points. Participants generally had only one individual RD appointment during the study period. The CG, which represents "standard of care" for Soldiers attending the MOVE! Program, had the lowest average content score at 3.84. The coaching only group had an average of 6.02, supplement group averaged 6.31, and placebo group 6.52. Participants who did not complete the study are not included in these numbers. When reviewing the adherence and motivation scores one can see there was little change over time. The CG total adherence scores were very low compared to all other groups (8.9 vs 45.6); however, they were equally motivated (MVI score CG 155.5 vs Self-referred 152.5 at Week 12) and achieved similar outcomes as any other randomized group (See Tables 2-9 and 12-14), which is an unexpected finding.

Nurse Health Coaching/RD Expertise

Two factors likely contributed to the CG having much lower attendance at MOVE! sessions, and therefore lower adherence scores. First, they were not offered an appointment with a study RD, while the other groups were encouraged to schedule this specialty appointment. CG participants could schedule an appointment with the Nutrition Clinic RD upon request if they were personally motivated to do so. Secondly, the CG did not receive weekly email or phone reminders of the MOVE! sessions being offered that week like the other groups. The poor attendance at content sessions observed in the CG is representative of the generally poor attendance by all groups at the MOVE! Program. This is a confounding factor for the success of the study. Soldiers cannot be expected to apply principles of weight management and healthy behaviors they have not had a chance to learn, and they did not have a chance to learn these if they did not attend the six available sessions. In addition to the buddy system, numerous strategies appealing to young adults were recommended to promote active participation in study activities such as journaling, smartphone applications (apps) related to healthy weight management (e.g. myfitnesspal), and health coach contact was arranged according to the preference of the participant, i.e. email vs phone, and preferred day and time for contact. These strategies were met with limited success. It is possible that building our study methods around the expected participation in MOVE! diminished our ability to be successful with nurse health coaching and/or the herbal supplement intervention when this did not take place.

A recent publication (Svetkey et al., 2015) describes a randomized, controlled comparative effectiveness trial with 365 obese young adults (18-35 years old) who were assigned to receive 24 months of mHealth intervention delivered by interactive smartphone application on a cell phone, via personal coaching enhanced by smartphone self-monitoring, or Control. Despite high intervention engagement and a low attrition rate (24%) cell phone mHealth was not superior to Control at any measurement point. The personal coaching group lost significantly more weight than Controls at 6 months (-1.92 kg; 95%CI -3.17, -0.67, P = .003) but not at 12 or 24 months. This study included behavioral principles and tools in both interventions and incorporated the highly appealing mobile applications for young adults. The researchers concluded, "effective intervention for weight loss may require the efficiency of mobile technology, the social support and human interaction of personal coaching, and an adaptive approach to intervention design" (Svetkey et al., 2015, p. 2133). This study has many similarities with our design incorporating mHealth. While our nurse health coaching intervention group did not achieve greater success in primary or secondary outcomes, much feedback from participants focused on their satisfaction with this approach to reinforcing educational content and providing follow up reminders. No formal behavioral principles were included in our study and the study period was much shorter but both of these elements could be considered in a future trial examining weight loss in young adults. We have seen some support for technology in the form of mobile applications to be useful in the researchers' toolkit to build adherence and success in existing weight management programs for military populations (Piche et al., 2014).

One recent review (Appelhans et al., 2015) on lifestyle interventions for obesity suggests that weight loss outcomes are primarily a function of sustained adherence to a reduced-energy diet, and that lapses in diet adherence are the result of temptation from palatable food. The authors believe that neurobehavioral processes impact temptation resistance and temptation prevention strategies and are prone to disruption by common occurrences such as stress, insufficient sleep, and even exposure to tempting stimuli (Appelhans et al., 2015). This review provides ample evidence for including neurobehavioral aspects in any program targeting a change in eating behaviors to achieve weight loss in military populations.

Biomarker Selection

One novel element in our study was the incorporation of resting metabolic rate data into the dietary prescription plan for participants. Most individuals have no occasion to undergo indirect calorimetry to receive an evaluation of how many calories they are actually burning at rest. This provides a basis for a personalized approach to weight loss using the simple theory that energy expended (activity) must exceed energy intake (diet) in order to burn off calories. A report published in Nutrients (2015) provides results from a six-month intervention to assess changes in energy expenditure, physical activity patterns, and nutritional habits in 105 obese participants performing self-directed weight loss. The energy expenditure and physical activity measures were obtained from a portable armband device. Mean weight loss was -1.5 $\pm$ 7.0 kg ($p = 0.028$) with slightly more substantial weight loss (>5%) noted in 20 participants. The researchers concluded that an increase in energy expenditure or changes in physical activity patterns were not employed by obese adults to achieve self-directed weight loss. The food frequency questionnaire used did accurately capture modified nutritional habits. The Army's Performance Triad pilot started in September of 2013 at battalions on Fort Bliss, Fort Bragg, and Joint Base Lewis-McChord. It includes educational resources and technological tools, like a portable activity monitoring device, for both leaders and Soldiers. The project is ongoing and it remains to be seen whether or not training leaders at the squad, platoon, or company level will result in enhanced fitness, health, and resilience for unit Soldiers (HPRC, 2015).

In our study, we used a handheld indirect calorimeter (MedGem, Microlife, USA), regarded as a highly accurate device, to measure resting metabolic rate (energy expenditure). Participants were then counseled on how to use this information to monitor their daily calorie consumption and balance energy intake and output. Anecdotally, participants appreciated the information and in some cases used the daily calorie goal to direct their new dietary intake plan. This was not the case for all participants. Lower levels of physical activity, along with more sedentary behaviors, appears to be identified by numerous investigators as a cause of overweight and obesity in the military (Carlson et al., 2014; McCarthy et al., 2014; Sharp et al., 2008; Lester et al., 2010). In a previous study led by Dr. McCarthy, a similar pattern emerged when many Soldiers returning from overseas deployments reported less work and leisure activities during the year of deployment which manifested in a higher percent of body fat upon return. Sport-related activity had increased in this study, but it did not result in lower body fat (McCarthy et al., 2014). In the current study, approximately 50% of overweight Soldiers were on a profile limiting their physical activity (See Table 1) that likely contributed to a lack of engagement in physically demanding activities as part of their self-directed weight loss. This physical deconditioning that occurs from a lack of physical training that meets unit standards makes these young Soldiers vulnerable to injuries, particularly stress fractures. This is the reason we included biomarkers of bone health in this current study. It is a vicious cycle of injury, deconditioning, weight gain, and repeated or new injury.

The supplement provided in this study, Garcinia cambogia, or hydroxycitric acid, is a promising botanical that reduces food intake and body weight through its effect on neuroendocrine pathways related to satiety. The formulation of G. cambogia used in the study included a calcium-potassium salt of HCA-SX. Both minerals have benefits in dietary weight loss efforts and contribute a necessary mineral to the diet of adults and Soldiers. We were optimistic that those taking the supplement would also experience benefits on bone health, such as increased bone mineral density by DXA or calcaneal (heel BMD) reading. Participants who were randomized to the supplement or placebo group were initially pleased that they would receive a pill that might help their weight loss efforts but they soon lost interest in taking the supplement when they did not "feel any different". They were expecting to experience some sense of heightened metabolism, such as a rapid heart rate, sweating, etc. and when this did not occur they assumed they were taking the placebo and discontinued taking their pills altogether. The supplement group experienced the highest dropout rate with 26 (31.3%) at 6 weeks, and 47 (56.6%) at 12 weeks. The placebo group had the next highest dropout rate with 29 (34.1%) at 6 weeks and 42 (49.4%) at 12 weeks. Regarding bone health biomarkers, there was no difference in BMD from DXA or calcaneal ultrasound readings over time, however, the results for vitamin D levels were interesting. Of note, there are no reports of comparisons between DXA BMD and heel BMD, nor body fat by DXA and by bioelectrical impedance, so we intend to collaborate with our Nuclear Medicine colleagues to report our findings in the literature.

Vitamin D

Early in the course of this study we requested an amendment to include vitamin D status as an outcome measure based on the high prevalence of vitamin D insufficiency and deficiency noted in the most recent study conducted by McCarthy (TSNRP Final Report N10-C02). Vitamin D remains a major area of research with many questions regarding links to overweight and obesity. Current literature suggests overweight individuals commonly experience low vitamin D status; this makes sense because vitamin D is a fat-soluble vitamin and is often stored in adipose tissue leaving less in circulating body pools. The statistics for low vitamin D status in Service Members (SM) are similar to the general population with a significant number of young adults categorized as insufficient (< 30 ng/mL) or deficient (< 20 ng/mL). Evolving evidence supports the updated Clinical Practice Guidelines by the Endocrine Society (Ekwaru et al., 2014) suggesting that body weight differentials be used when dosing vitamin D. In a large sample of healthy volunteers (n=17,614) researchers learned the importance of body weight for dose response; the recommendation is that vitamin D supplementation be 2-3 times higher for obese adults and 1.5 times higher for overweight adults in order to achieve normal 25(OH)D targets. This information must be taken into consideration for future research involving vitamin D supplementation.

In our study, the vast majority of the Soldiers had insufficient or deficient levels of vitamin D; this was across all groups with only the self-referred group reporting more individuals (31.7% vs 14.8%; p=.03) with normal levels compared with the average for all randomized groups. Levels remained low and relatively unchanged across the 12-week study period but the self-referred group no longer had a significantly greater number of Soldiers with normal values compared to the control group (34% vs 26.6%; p = .17). We did find that as Soldiers lost weight, vitamin D levels increased. This can be seen in the CG data which show the least rise in vitamin

D level and lowest change in body mass index. We did not see any correlation between higher vitamin D levels and increased BMD. The team believes that the rise in vitamin D levels may also be a reflection of the education received as part of the course content in the MOVE! program, as well as the reinforcement from the RD and nurse health coach on a regular basis. Even the CG experienced an overall increase in the percent of Soldiers (15.9% to 21.4%) with a normal vitamin D level. One other observation is that the self-referred group, which had the lowest BMI upon entry into the study, also had the highest mean level of vitamin D at that time and this trend remained unchanged at the final measurement point (See Table 5). One must keep in mind that this group received weekly educational sessions with an RD and RN that included content on a healthy balanced diet.

While we did not track stress fractures or other musculoskeletal injuries in this cohort over time, we do know that 50% or more of the participants were on a profile limiting physical activity at any time during the study, as previously mentioned. This makes these individuals vulnerable for stress injuries once they return to former levels of activity, and low vitamin D stores compound the risk. A recent systematic review (Dao et al., 2014) included eight observational studies on lower extremity stress fractures. A total of 2634 military personnel (18-30 years old; 44% male) with 761 cases (16% male) and 1873 controls (61% male) were included in the analysis. Three of the 8 studies measured serum 25(OH)D levels at the time of stress fracture diagnosis, and the 5 remaining studies measured serum 25(OH)D levels at the time of entry into basic training. The mean serum 25(OH)D level was lower in stress fracture cases than in controls at the time of entry into basic training (MD, –2.63 ng/mL; 95% CI, –5.80 to 0.54; P = .10; I2 = 65%) and at the time of stress fracture diagnosis (MD, –2.26 ng/mL; 95% CI, –3.89 to –0.63; P = .007; I2 = 42%). While there are limitations to any systematic review due to heterogeneity of studies, results suggest some association between low serum 25(OH)D levels and lower extremity stress fractures in military personnel. The authors conclude that given the rigorous training of military personnel, focusing attention on ensuring sufficient 25(OH)D levels may be beneficial for reducing the risk of stress fractures. Vitamin D metabolism and the links with diet, exercise, and other environmental factors deserves more in-depth investigation in order to provide clinical recommendations to providers in medical treatment facilities and policy advice to leaders in combat and combat support units.

<u>Body fat</u>

Primary and secondary outcomes were not analyzed with gender differences in mind. However, the exploratory analyses that created a series of profiles did uncover that males, especially those over 27 years of age, tended to lose more weight and reduce waist circumference when compared to females. The National Institutes of Health has recently highlighted the importance of sexual dimorphisms and has mandated inclusion of both sexes in clinical trials and basic research (Palmer & Clegg, 2015). We are gaining an appreciation for the new and novel ways sex hormones influence body adiposity and the metabolic syndrome. Understanding how and why metabolic processes differ by sex will enable clinicians to target and personalize therapies based on gender in the near future. What we do know is that adipose tissue function and deposition differ by sex. Females accrue more fat in the subcutaneous regions prior to menopause, a feature which provides protection from the negative consequences associated with obesity and the metabolic syndrome. Following menopause, fat deposition favors a shift to visceral regions and risk for metabolic syndrome rivals that of males. Males tend to accrue more visceral fat, leading to the classic android body shape, which has been highly correlated to increased cardiovascular risk. Sex hormones clearly influence adipose tissue function and deposition but determining how to capture and utilize their function in a time of caloric excess requires more information. The key will be harnessing the beneficial effects of sex hormones in such a way as to provide a more 'healthy' adiposity. Further work will be done with the current data set to examine comparisons between bioelectrical impedance (InBody) for fat mass and DXA fat mass results, but clearly more research is needed to elucidate gender differences with respect to strategies that result in successful weight loss.

Effect of problems or obstacles on the results: Our participants had poor rates of compliance with taking the herbal supplement or placebo as recommended. This appeared to be in part due to perceived ineffectiveness of the supplement as the participants reported no physiologic reaction to the supplement and therefore assumed it was an inert compound/placebo. Attempts were made to encourage taking the supplement (weekly reminders, providing a pill box to have supplements on hand at work), and Soldiers were informed they would not feel physical effects of the supplement. The requirement to pick up the supplements monthly at the research pharmacy was a barrier to compliance, as was the necessity of taking six pills daily to reach the desired dosage. Because of the poor compliance, our analysis does not allow for any conclusions regarding the effectiveness of the herbal supplement. Our participants also had low rates of completing all the required classes in the Army MOVE! Program. This fact makes it difficult to draw conclusions about the effectiveness of our study which was developed to augment education and skills received by Soldiers attending the MOVE! Program.

As every Principal Investigator knows, the Declaration of Helsinki states that "Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports" (Boutron, 2010, p. 2058). The scientific community takes it very seriously when investigators attempt to draw conclusions that are not evident in the data presented. In one report by Boutron (2010), he focused on trials with statistically non-significant primary outcomes because the interpretation of these results are more likely to lead to a preconceived notion of effectiveness, resulting in a biased interpretation. The problem is more widespread than one would believe; more than 40% of the reports examined had "spin" included in main sections of the text (Boutron, 2010). Despite the disappointing results of this robust prospective, randomized, controlled trial, it was perhaps the first study implemented for Soldiers, developed by Soldiers, with a keen interest in a novel approach to weight management. The research process taught us many important lessons that will be incorporated into the study design for future research.

Limitations: Overall, our randomization schema performed exactly as intended. The research pharmacist handled all aspects of the randomization; therefore, study team members introduced no bias. Records of all dispensed bottles of supplement/placebo, counts remaining at the time of refill, and bottles never picked up are in the possession of the PI and locked in a file cabinet. Table 1 of sample characteristics shows no significant difference amongst the four randomized groups at baseline. The only evidence of a difference across the sample population comes at Week 12 when dropout rates vary greatly with a range of 31.4% for the CG and 56.6% for the supplement group ($p = .039$). The self-referred group only had a 29% dropout rate. These rates are typical for military research based on our previous experience but it is unusual that the CG who received no benefit from the research study beyond learning their body composition details had the lowest dropout rate. It is not uncommon to plan a military study sample size taking into account a 50% attrition rate. This attrition most definitely influences findings in a protocol such as this. While we do not have all the reasons for the attrition, we know that the younger enlisted Soldiers would often inform the study team that their Commander no longer supports their participation and they will not be returning to MOVE! or the study. Also, Soldiers experienced unexpected deployments and even service discharge after enrollment. We do not know if any of these Soldiers were successful in their weight loss efforts after terminating their participation.

Conclusion: The results are congruent with current literature suggesting healthy lifestyle interventions meet with disappointing results in research conducted with all adult populations to include the military. We have extended our work on bone health and vitamin as well with the discovery that overweight individuals commonly experience low vitamin D status and the status may improve with weight loss. Assisting Soldiers to attain/maintain healthy weight may support normal vitamin D status, minimize musculoskeletal injury, and optimize physical performance. Full-scale implementation of the revised AR 600-9 in July 2013 may result in greater support from Unit Leaders. The education provided to this group of mostly young adults about self-directed health behaviors may diminish chronic disease risk and the related socioeconomic burden, leading to a productive and healthy career in the military.

Significance of Study or Project Results to Military Nursing

Innovative strategies for weight loss in unhealthy weight Service Members are greatly needed. A review of the literature confirms that this is also a challenge for public health agencies, schools, medical treatment facilities, and outpatient clinics across all age ranges, ethnicities, and genders. This is a particularly sensitive issue in the military when downsizing the force is a top priority and SM who do not meet the fitness or body composition standards of the respective service will be the first to be discharged. There are countless stories of drastic measures taken by SM who strongly desire a military career yet cannot seem to stay ahead of the weight battle (Piche et al., 2014). When developing this grant proposal, the PI and team met in-person with Brigade Commanders and their staff seeking input on the design and interventions in order to create a program appealing to combat and combat support Unit Leaders who were experiencing high numbers of overweight Soldiers post-deployment. These Leaders themselves expressed their struggles with unhealthy weight and often asked us to divulge the name of the supplement before we were even convinced we would be using it for the study.

In general, there was good support from Units for the MOVE! Program at the Army medical center but opportunities for Soldiers to receive this education were limited on more remote areas of the base. It was difficult to allow Soldiers to attend classes at the medical center because they would be away from the Unit for up to 2 hours for each class. Soon after this study started, the concept of the Soldier-Centered Medical Home (SCMH) rolled out. This presented Commanders with additional options for their overweight troops. The SCMH initiative hired a full complement of registered dietitians/nutritionists to provide nutrition counseling, mostly one-on-one. The problem with this is that the educational content was not structured, nor standardized, and nutritionists could only offer single or only occasional appointments, which have been shown to be less effective than group sessions. Generally, body composition measures were limited to height/weight/BMI/body fat and follow-up was haphazard. It is critical that the Army or the DOD create **one program** that can be administered at **any location**, any base, any hospital/clinic, any unit. The curriculum should be coordinated by dietitians/nutritionists trained in weight management, with knowledge of sports nutrition being ideal. This curriculum should be based on solid principles to include motivational interviewing/nurse coaching, technological applications/devices (pedometer, actigraphy, smartphone apps), behavior change along with neurobehavioral processes, and the health promotion model. This curriculum may need to have different subject matter experts as instructors to facilitate different exercises and introduce telehealth options, as well as mindfulness and resilience concepts. We also believe that the program should last a minimum of 12 weeks with monthly check-ins for the next 3 months for a full re-evaluation of outcomes at 6 months. Some studies would advocate for a one year follow up as one large trial found that weight loss in the first month of at least 2% in a lifestyle intervention program predicted weight loss success at 2 months and one year later. Participants who successfully lost ≥2% at one month were 5.6 times more likely to achieve a >10% weight loss at one year compared to those who failed to achieve ≥2% weight loss. (Unick et al., 2014)

Soldiers with a history of overweight (61% of our participants) or of losing weight to enlist (38% of our participants) should be identified early and followed closely for weight management as they begin their military career. Unit leaders at all levels should be more alert to changes in weight status so interventions can be started in a timely manner, not after the Soldier has already gained 10 pounds. Performance Triad initiatives must be embraced by Unit leaders and subordinates/troops. Many of our participants were on a profile limiting physical activity and reported weight gain subsequent to their injury. Providers should be attuned to this issue and routinely refer Soldiers on any profile to a dietitian/nutritionist for weight management.

Brigade nurses are in an influential position at the Soldier level and can assume the role of health coach, encouraging Soldiers to meet weight loss goals whether attending MOVE! or not. In addition, further study of vitamin D at the genomics level may yield insight into the ubiquitous phenomenon of insufficient vitamin D status of today's Warfighter so that prevention and supplementation protocols may be used to optimize musculoskeletal and immune health. The Brigade nurse needs a situational awareness of this phenomenon; he/she should inform Unit leaders and observe dietary and exercise habits as part of the Unit wellness and readiness assessment.

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

None to date.

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Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications	Invited manuscript follow MHSRS Conference—due 1 January 2016	
Publications in Press	None at this time.	
Published Abstracts	All poster presentations preceded by abstract submission – published in conference proceedings only.	
Podium Presentations	Emerging Role of Vitamin D in Mental, Physical, and Nutritional Resilience. Juanita Warman Nursing Excellence Conference, Madigan Army Medical Center, 6 March 2015.	Madigan Conference - deemed not necessary to have PAO approval
Poster Presentations	An RCT of Nurse Coaching vs. Herbal CAM for Soldier Weight Reduction. Abstract submitted for Western Institute of Nursing Conference Anaheim, CA. April 2016	Submitted
	The Relationship Between Body Composition, Vitamin D Levels, and Bone Health in Overweight Service Members. Military Health System Research Symposium, Ft. Lauderdale, FL. 17-21 Aug 2015	7/20/2015 MAMC PAO

	Impact of Weekly Brief Coaching and Weight at Time of Enlistment on Soldier Weight Loss. Food and Nutrition Conference and Expo, Nashville, TN. 4 October 2015	8/16/15 MAMC PAO
	The Relationship Between Body Composition, Vitamin D Levels, and Bone Health in Overweight Service Members. Madigan Research Day, Tacoma, WA. 24 April 2015	NA – Madigan AMC only
	The Relationship Between Body Composition, Vitamin D Levels, and Bone Health in a Cohort of Service Members. Seattle Nursing Research Consortium, Lynnwood, WA. 25 January 2015	11/5/14 MAMC PAO
Media Reports	Research Aims to Help Soldiers Stay Fit, Stay Ready…Stay Army! Research Spotlight. TSNRP Newsletter Spring/Summer 2014. Also TSNRP Facebook post.	2/20/14 MAMC PAO
Selected for presentation but unable to attend	An RCT of Nurse Coaching vs. Herbal CAM for Soldier Weight Reduction, TSNRP Research & EBP Dissemination Course, San Antonio, TX (Poster & Podium). September 2015.	7/20/15 MAMC PAO

Reportable Outcomes

Reportable Outcome	**Detailed Description**
Applied for Patent	none
Issued a Patent	none
Developed a cell line	none
Developed a tissue or serum repository	none
Developed a data registry	none

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	500
Subjects Available	
Subjects Contacted or Reached by Approved Recruitment Method	1533
Subjects Screened	643
Subjects Ineligible	100
Subjects Refused	108
Human Subjects Consented	435
Subjects Consented Control/ Nurse Coaching / Coaching + supplement/Coaching + placebo/Unit Based Self-refer	86/81/83/85/100
Subjects Who Withdrew Control/ Nurse Coaching / Coaching + supplement/Coaching + placebo/Unit Based Self-refer	28/30/44/40/25
Subjects Who Completed Study Control/ Nurse Coaching / Coaching + supplement/Coaching + placebo/Unit Based Self-refer	58/51/39/45/75
Subjects With Complete Data Control/ Nurse Coaching / Coaching + supplement/Coaching + placebo/Unit Based Self-refer	48/40/28/38/64
Subjects With Incomplete Data Control/ Nurse Coaching / Coaching + supplement/Coaching + placebo/Unit Based Self-refer	10/11/11/7/11

Demographic Characteristics of the Sample

Characteristic	
Age (yrs)	30 ±8.2
Women, n (%)	116 (26.6)
Race	
White, n (%)	305 (70.1)
Black, n (%)	83(19)
Hispanic or Latino, n (%)	87 (20)
Other, n (%)	47 (10.8)
Married, n(%)	309 (71)
Married with children, n(%)	178 (41)
Military Service or Civilian	
Army, n (%)	435 (100)
Enlisted, n(%)	396 (91)
Service Component	
Active Duty, n (%)	435 (100)
History overweight, n (%)	263 (61)
Lost weight to enter Army, n (%)	166 (38)