

TriService Nursing Research Program Final Report Cover Page

Sponsoring Institution	TriService Nursing Research Program
Address of Sponsoring Institution	4301 Jones Bridge Road Bethesda MD 20814
USU Grant Number	HU0001-15-1-TS04
USU Project Number	N15-006.
Title of Research Study or Evidence-Based Practice (EBP) Project	Effectiveness of a Group Lifestyle Balance Class in an Active Duty Population
Period of Award	1 April 2015 – 31 March 2019
Applicant Organization	The Geneva Foundation
Address of Applicant Organization	917 Pacific Ave, Suite 600, Tacoma WA 98402

Signatures

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Date

28 JUN 2019

Mentor Signatures

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6/24/19

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6/24/19

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Abstract

Purpose: To examine and compare the effectiveness of three lifestyle intervention programs in an active duty population.

Design: Randomized control trial with three groups.

Methods: Participants were randomly assigned to one of three intervention groups: the Group Lifestyle Balance (GLB) program, the Better Body Better Life (BBBL) program and the Fitness Improvement Program (FIP). Primary outcome measures were: weight, abdominal circumference, minutes of physical activity, lipid and HbA1c levels, and well-being as measured by the RAND SF-36 questionnaire. Data were collected at three time points: baseline, 3 months and 6 months.

Sample: 122 active duty Air Force participants were enrolled. Eligibility criteria included: An active duty member of any U.S. armed service with one of the following conditions:

- Abdominal circumference over 35 in. for men/31.5 in. for women
- BMI over 25 kg/m²

Willing to commit to 12 weekly 1-hour classes followed by three monthly 1-hour classes

Analysis: Changes in measurements from baseline were analyzed using repeated measures ANOVAs, paired t-tests, and one-way ANOVAs as appropriate for each variable.

Findings: 83 participants completed the study with 23 in the BBBL group, 30 in the FIP group and 30 in the GLB group. No statistically significant differences in baseline demographics and measures were observed. The GLB participants had significant decreases in weight (-3.12 pounds, $p=.01$) and abdominal circumference (-0.90 inches; $p=.01$) over time. There were no significant changes in weight or abdominal circumference from baseline in the FIP or BBBL groups. No significant changes were observed in HbA1c or lipids in any group.

Implications for Military Nursing: Evidence from this study will be shared with Air Force and the Defense Health Agency leaders to inform future decisions on supported lifestyle interventions programs. Nurses can use this evidence to advise patients on the utility of lifestyle intervention programs.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

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

Secondary Priority

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

Progress Towards Achievement of Specific Aims of the Study or Project

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

Specific Aims:

1. Aim 1: To determine if the Group Lifestyle Balance (GLB) program provided to an at-risk active duty population is effective. Hypotheses: There will be a significant reduction in the primary endpoint (weight) and improvement in several secondary outcome measures (abdominal circumference, physical activity, fasting lipids, HbA1c, and self-perceived well-being) for participants in the GLB intervention delivery mode measured pre and post intervention, and as compared to those randomly assigned to usual care (Fitness Improvement Program [FIP]) or the Better Body Better Life (BBBL).
2. Aim 2: To determine the usefulness of the GLB, BBBL, and FIP interventions to active duty personnel through a qualitative content analysis of open-ended responses on a questionnaire, specifically the Intervention Feedback Questionnaire, administered after the interventions are completed.

Aim 1.

A total of 122 participants were enrolled and 83 participants completed the study – 30 in the GLB group, 30 in the FIP group, and 23 in the BBBL group. The original sample size estimate based the primary outcome of weight with an effect size of .30, power of 0.80 and alpha level of .05 indicated that 23 participants per group were needed. For the initial/baseline measurements, it was confirmed that there were no statistically significant differences among groups (BBBL, FIP, GLB) in age, gender, race/ethnicity, military rank, weight, abdominal circumference, HbA1c, nor fasting total cholesterol, HDL, LDL, or triglycerides (see Table 1).

To examine the effects of the different interventions on outcome measure changes from baseline, repeated measures ANOVAs were performed to look at weight (measured in pounds) and abdominal circumference (measured in inches) as a function of TIME (baseline, 3 months, 6 months). In the GLB group, TIME was found to have a statistically significant effect on weight ($F(2,57)=4.68$; $p=.013$) and abdominal circumference ($F(2, 57)=4.35$; $p=.018$). Specifically, subjects in the GLB group lost an average of 3.12 lbs of weight and 0.9 inches of abdominal circumference after 6 months in the study. In contrast, no statistically significant effect of TIME was found on weight ($F(2,44)=0.99$; $p=.38$) nor abdominal circumference ($F(2, 44)=2.47$; $p=.10$) in the BBBL group. There was also no statistically significant effect of TIME on weight ($F(2,58)=0.88$; $p=.42$) nor abdominal circumference ($F(2, 58)=3.11$; $p=.052$) in the FIP group.

Table 1. Baseline Measures by Group

	BBBL (n=40)		FIP (n=42)		GLB (n=40)		Total (n=122)		p value
	N	Mean (SD) or %	N	Mean (SD) or %	N	Mean (SD) or %	N	Mean (SD) or %	
Time during duty day to exercise?	26	65.00%	30	71.43%	27	67.50%	83	68.03%	NS
Exercise hours (for those who reported having)	25	3.06 (1.41)	26	3.21 (1.49)	24	2.80 (1.27)	75	3.03 (1.39)	NS
Deployed in the last 36 months?	10	25.00%	10	23.81%	9	22.50%	29	23.77%	NS
If deployed, did the subject report a change in	5	50.00%	8	80.00%	8	88.89%	21	72.41%	NS
If deployed, did the subject report a change in	7	70.00%	9	90.00%	7	77.78%	23	79.31%	NS
Age	40	30.58 (5.68)	42	32.52 (7.81)	40	33.7 (8.40)	122	32.27 (7.45)	NS
Gender									NS
Female	14	35%	17	40.48%	24	60.00%	55	45.08%	
Male	26	65%	25	59.52%	16	40.00%	67	54.92%	
Ethnicity									NS
White	18	45.00%	23	54.76%	19	47.50%	60	49.18%	
African American	8	20.00%	8	19.05%	10	25.00%	26	21.31%	
Hispanic/Latino	6	15.00%	4	9.52%	8	20.00%	18	14.75%	
Asian	5	12.50%	4	9.52%	2	5.00%	11	9.02%	
Multiple/Other	3	7.50%	3	7.14%	1	2.50%	7	5.74%	
Rank									NS
E1-E4	13	32.50%	10	23.81%	10	25.00%	33	27.05%	
E5-E6	20	50.00%	18	42.86%	14	35.00%	52	42.62%	
E7-E9	2	5.00%	8	19.05%	6	15.00%	16	13.11%	
O1-O3	3	7.50%	4	9.52%	6	15.00%	13	10.66%	
O4+	2	5.00%	2	4.76%	4	10.00%	8	6.56%	
Usual duty hours									NS
Day	36	90.00%	41	97.62%	38	95.00%	115	94.26%	
Night	2	5.00%	1	2.38%	1	2.50%	4	3.28%	
Swing/other	2	5.00%	0	0.00%	1	2.50%	3	2.46%	
Weight	40	200.29 (32.26)	42	204.46 (36.68)	40	190.95 (31.20)	122	199.66 (33.72)	NS
Abdominal circumference	40	36.49(4.17)	42	36.86 (4.02)	40	35.51 (3.63)	122	36.30 (3.96)	NS
HbA _{1c}	35	5.31 (.31)	33	5.28 (.47)	37	5.35 (.36)	105	5.31 (.38)	NS
Cardiovascular history	40	5 (12.5)	42	5 (11.9)	40	2 (5)	122	12 (9.84)	NS
Diabetes history	40	0 (0)	42	0 (0)	40	1 (2.5)	122	1 (2.5)	NS
Cancer history	40	0 (0)	42	0 (0)	40	3 (7.5)*	122	3 (2.46)	p=.043*
Mental health history	40	8 (20)	42	6 (14.29)	40	7 (17.5)	122	21 (17.21)	NS
Lipid lowering meds	40	2 (5)	42	2 (4.76)	40	2 (5)	122	6 (4.92)	NS
Glucose lowering meds	40	0 (0)	42	0 (0)	40	0 (0)	122	0 (0)	NS

* Note: Cancer status was resolved at baseline for 2 out of 3 of participants reporting a history of cancer.

Paired t tests (or the nonparametric equivalent, the Wilcoxon matched-pairs signed-ranks test) were performed to look at HbA1c, as well as fasting total cholesterol, HDL, LDL and triglycerides as a function of TIME (baseline vs. 6 months) in each group (BBBL, FIP, GLB). However, there was no statistically significant difference between the baseline and 6 months measures of HbA1c, total cholesterol, HDL, LDL nor triglycerides in any of the groups.

Physical activity in each group, as measured by the number of self-reported minutes/exercise per week at baseline, 3 months, and 6 months, was analyzed using the Skillings Mack test. There were no significant differences in this measure from baseline, 3 months, to 6 months in the BBBL ($p=.53$), FIP ($p=.96$), nor GLB ($p=.61$) groups. Physical activity in each group as measured by the Modified Activity Questionnaire (MAQ) (reported hours/week as well as metabolic hours/week) from baseline to 6 months, was analyzed using the Wilcoxon matched pairs signed-ranks test. The GLB group reported a statistically higher number of leisure activity hours/week at 6 months relative to baseline ($p=.04$) although there was no significant change in total activity hours/week in this group. No other statistically significant differences were noted in physical activity for any groups as measured by the MAQ.

Aim 2.

Of the 122 participants enrolled, 83 also completed the Intervention Feedback Questionnaire. A content analysis was performed on the responses to the 8 questions on the Intervention Feedback Questionnaire. Responses were coded according to key constructs described by the participants and as agreed upon by the study team members. For example, in response to the first question “Please tell us what you liked best about the program” many participants stated that they liked the information that was presented. In this case, any response related to ‘good information’ was coded by the same number. This coding process was accomplished for each of the 8 questions. The responses were then described for each group but no quantitative statistical analysis was performed since the data were qualitative in nature. A summary of the most common responses to questions can be seen in Table 2. Note that responses to question 8 (“Please write any other comments you have about the program”) are not reported in the table because many participants made no comment and comments that were made were too disparate.

Table 2. Most Common Responses on the Intervention Feedback Questionnaire by Group

Group	Q1 Liked Best N (%)	Q2 Liked Least	Q3 Useful	Q4 Difficult	Q5 Beneficial	Q6 Recommend to others	Q7 Changes improve
BBBL N=23	Good Info 10 (43%)	Schedule 10 (43%)	Yes – 15 (65%) No – 5 (22%)	Yes – 13 (57%) No – 9 (39%)	Yes – 18 (78%) No – 4 (17%)	Yes – 19 (83%) No – 4 (17%)	More flexible schedule- 7 (30%)
FIP N=30	Schedule- 9 (30%)	No facilitator- 14 (47%)	Yes – 20 (67%) No – 7 (23%)	Yes – 3 (10%) No – 27 (90%)	Yes – 21 (70%) No – 9 (30%)	Yes – 23 (77%) No - 7 (23%)	No response – 9 (30%) No CBT – 7 (23%)
GLB N=30	Good Info- 16 (53%)	Nothing – 8 (27%) Schedule- 6 (20%)	Yes – 28 (93%) Blank – 2 (7%)	Yes – 11 (37%) No – 19 (63%)	Yes – 29 (97%) Blank – 1 (3%)	Yes – 29 (97%) Blank – 1 (3%)	Physical activity – 8 (27%)

Relationship of current findings to previous findings:

The results of this study indicated that the GLB program was effective for reducing weight in an active duty population. This is consistent with findings from studies in non-active duty populations that demonstrated that the GLB program was effective in promoting weight loss and decreasing factors for type 2 diabetes and coronary vascular disease (Seidel, et al., 2008; Kramer et al., 2009; McTigue, et al., 2009; Kramer, et al., 2010; Kramer, McWilliams, Chen, & Siminerio, 2011; Kramer, et al., 2012; Ma et al., 2013; Kramer, Perez-Cepak, Venditti, Semler & Kriska, 2013; Piatt, Seidl, Chen, Powell, & Zgibor, 2012). However, weight changes on average were relatively small in this study compared to other studies involving the GLB program and no significant differences were noted in HbA1c and lipids. One possible explanation for these differences is that the active duty population may be a more healthy population compared to other at-risk populations studied.

No other studies have been found in the literature on the BBBL or the FIP. However, the BE WELL program, which was the predecessor of the on-line FIP, was found to be effective for decreasing weight in active duty members who had failed a prior fitness assessment (Webber, Nelson & Gildengorin, 2012). The BE WELL program that was studied was a 1-day in-person class with a facilitator. However, Air Force policy changed that class to the FIP which is an on-line self-directed course without a facilitator. No studies were found that looked at the FIP or BBBL specifically. Therefore, this was the first study to demonstrate that neither the FIP nor the

BBBL was shown to be effective in decreasing weight and abdominal circumference, increasing physical activity, or improving well-being.

Effect of problems or obstacles on the results: The primary problems encountered in this study were recruiting and retaining subjects despite a large known population. We believe that this in part was due to challenges that are inherent to studying interventions in active duty personnel including lack of stability and consistency of the population from frequent moves and deployments and regulations that restrict the use of incentives. The research team brainstormed and initiated several measures to provide personnel with information about the study including email blasts through Unit Fitness Monitors, handing out flyers in primary care clinics, and posting flyers in dining facilities. Unfortunately, these measures did not yield an enrollment that was adequate to meet original milestones. Therefore, the Principal Investigator requested approval from the sponsor to provide a cash gift card incentive to participants for completing the first and last blood samples. This type of incentive is allowable by federal regulation for active duty personnel and recruitment and retention rates were noted to improve after this incentive was introduced. In addition, a no cost extension was requested (and subsequently approved) in order to obtain enough data to adequately address the aims. Data collection and analyses were accomplished by the end of the extended period of performance.

Limitations: This study was conducted at only one location and with only one active duty component which may limit the generalizability to other locations and military services. For instance, it is possible that the BBBL program could be implemented differently at other Air Force bases. Furthermore, the initial sample size estimate was powered on the primary outcome of weight and may have been underpowered to detect differences in secondary outcome measures of HbA1c, lipids, and well-being. In addition, the sample size was not large enough to do secondary analyses on other variables that may impact outcomes such as occupation, dietary habits, and deployments.

Conclusion: Results from this study indicate that the GLB program is effective in improving weight and abdominal circumference in this at-risk active duty population. Results also indicate that neither the currently available BBBL or FIP programs are effective in improving weight or abdominal circumference in an active duty population. Furthermore, given that in the GLB group in which a significant change in weight and abdominal circumference were found despite no significant change in overall physical activity, suggests that some other component of lifestyle intervention such as dietary changes, may be more significant in affecting the outcome of weight. Further study on dietary interventions in active duty populations may be warranted.

Significance of Study or Project Results to Military Nursing

Nurses can use the evidence from this study when advising active duty members about effective interventions for weight loss. This new evidence is particularly pertinent to nurses who practice as primary care providers and case managers for active duty Airmen and nurses who work in preventive and occupational health. Nurses can also use this evidence when advising Air Force leaders about which type of interventions to make available to active duty personnel. These results will be shared with subject matter experts at the Air Force Medical Readiness Agency and the Defense Health Agency for consideration when determining which lifestyle interventions to endorse. Future research on the GLB program at other sites and with other active duty services should be considered. In addition, modeling studies with larger active duty populations could be considered to determine which variables are most predictive in positive responses to lifestyle interventions.

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

None to date.

References Cited

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Webber, B.J., Nelson, M.S., Gildengorin, V. (2012) Indicators of sequential fitness assessment failures for Travis Air Force Base Airmen who attend the Be Well course, *Military Medicine*, 177, 302-307.

Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Podium Presentations	Armitage, N., Kramer, K., Hopkins, D., Nelson, M., Thornton, J., Langeslay, R., Stout, A., & Buthker, K. Effectiveness of lifestyle interventions in an active duty population TSNRP Research and EBP Dissemination Course, San Diego, CA, 30 Apr – 2 May 2019.	12 April 2019 60 AMW/PA Travis AFB, CA
Poster Presentations	Armitage, N.H, Nelson, M., Kramer, K. Comparison of lifestyle interventions in an active duty population. TSNRP Research and EBP Dissemination Course, Ellicott City, MD, 25 Apr 2017.	27 January 2017 60 AMW/PA Travis AFB, CA
	Armitage, N., Kramer, K., Hopkins, D., Nelson, M., Thornton, J., Langeslay, R., Stout, A., & Buthker, K. Effectiveness of lifestyle interventions in an active duty population. AMSUS Annual Meeting, National Harbor, MD, 27-30 November 2018	13 November 2018 60 AMW/PA Travis AFB, CA
	Armitage, N., Kramer, K., Hopkins, D., Nelson, M., Thornton, J., Langeslay, R., Stout, A., & Buthker, K. Effectiveness of lifestyle interventions in an active duty population TSNRP Research and EBP Dissemination Course, San Diego, CA, 30 Apr – 2 May 2019.	13 November 2018 60 AMW/PA Travis AFB, CA
Media Reports	TSNRP Newsletter Fall/Winter 2016 Research Spotlight	TSNRP

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 Table

Recruitment and Retention Aspect	Number		
Subjects Projected in Grant Application	131		
Subjects Available	1800		
Subjects Contacted or Reached by Approved Recruitment Method	Unknown		
Subjects Screened	185		
Subjects Ineligible	63		
Subjects Refused	0		
Human Subjects Consented	122		
Subjects GLB / BBBL / FIP	40	40	42
Intervention Group 1 / Intervention Group 2 / Control or Sham Group Subjects Who Withdrew	10	17	12
Intervention Group 1 / Intervention Group 2 / Control or Sham Group Subjects Who Completed Study	30	23	30
Intervention Group 1 / Intervention Group 2 / Control Group Subjects With Complete Data	30	23	30
Intervention Group 1 / Intervention Group 2 / Control Group Subjects With Incomplete Data	0	0	0

Demographic Characteristics of the Sample

Characteristic	
Age (yrs)	32.8 ± 7.5
Women, n (%)	55 (45%)
Race	
White, n (%)	60 (49%)
African American, n (%)	26 (21%)
Hispanic or Latino, n (%)	18 (15%)
Asian, n (%)	11 (9%)
Other, n (%)	7 (6%)
Military Service or Civilian	
Air Force, n (%)	122 (100%)
Service Component	
Active Duty, n (%)	122 (100%)
Rank	
E1-E4	33 (27%)
E5-E6	52 (43%)
E7-E9	16 (13%)
O1-O3	13 (11%)
O4+	8 (7%)

Program Budget Summary Report

Company: The Geneva Foundation
User: Tappero, Elyssa

Period Start Date: 4/1/2015
Period End Date: 3/31/2019

Current Fringe Rate: 35.50%
Current G&A Rate: 19.80%



Contract: 10393 - Effectiveness of a Group Lifestyle Balance CI
 Award Amount: 292,427.00
 Total Estimated: 292,427.00
 Total Funded: 292,427.00

Contract PoP: 4/1/2015 - 3/31/2019
 Customer: TRISERVICE NURSING RESEARCH PROGRAM
 Customer Contract ID: HU0001-15-1-TS04
 Contract Manager: Robinson, Kathleen

Category	Budget	Period	Cumulative	Commitments	Cumul. + Commit.	Remaining Balance
Direct Expenditures						
Personnel						
Personnel Salary & Wages	188,764.02	148,459.13	148,459.13	0.00	148,459.13	40,304.89
Fringe Benefits (Burden)	0.00	40,304.89	40,304.89	0.00	40,304.89	-40,304.89
Total Personnel	188,764.02	188,764.02	188,764.02	0.00	188,764.02	0.00
Non-Personnel						
Equipment	0.00	0.00	0.00	0.00	0.00	0.00
Travel	4,823.25	4,823.25	4,823.25	0.00	4,823.25	0.00
Supplies	2,045.27	2,045.27	2,045.27	0.00	2,045.27	0.00
Other	4,676.95	4,676.95	4,676.95	0.00	4,676.95	0.00
Consultant	27,108.69	27,000.00	27,000.00	0.00	27,000.00	108.69
Subcontractor	16,526.82	16,526.82	16,526.82	0.00	16,526.82	0.00
Total Non-Personnel	55,180.98	55,072.29	55,072.29	0.00	55,072.29	108.69
Total Direct Expenditures	243,945.00	243,836.31	243,836.31	0.00	243,836.31	108.69
Indirect Expenditures						
G&A Burden	48,569.00	48,023.55	48,023.55	0.00	48,023.55	545.90
Other Indirect Costs	-87.00	0.00	0.00	0.00	0.00	-87.00
Total Indirect Expenditures	48,482.00	48,023.55	48,023.55	0.00	48,023.55	458.90
Total Dir. + Indir. Expenditures	292,427.00	291,859.86	291,859.86	0.00	291,859.86	567.59
Fee Amount	0.00	0.00	0.00	0.00	0.00	0.00
Total Expenditures + Fee	292,427.00	291,859.86	291,859.86	0.00	291,859.86	567.59