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ATTN: JANA L. WARDIAN

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval


2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

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4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

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1. The author must complete page two of this form:
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3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g., case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

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   "The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."
A Retrospective Analysis of Outcomes from the WHASC DCOE Group Lifestyle Balance Program 2009-2013


American Journal of Preventive Medicine

11b. PUBLISHED ABSTRACT (List intended publication/journal.)

11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

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Contact 252-7141 for email instructions

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☐ NO ☐ YES ☐ N/A

COMMENTS ☑ APPROVED ☐ DISAPPROVED
Presentation of IRB approved research with appropriate disclaimers. Approved

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APPROVED (In compliance with security and policy review directives.)

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Evaluation of the Group Lifestyle Balance Program in a Military Setting

According to the CDC, 89 million Americans have prediabetes (CDC, 2014). People with prediabetes are at higher risk of developing Type 2 diabetes mellitus (T2DM), but not all cases of prediabetes progress to diabetes. The Diabetes Prevention Program (DPP) demonstrated that lifestyle interventions, including diet and exercise, reduced the risk of prediabetes conversion to diabetes in individuals with elevated fasting glucose that did not meet the criteria for diabetes. The DPP cohort participated in a randomized intensive lifestyle intervention or metformin treatment that was designed to evaluate whether these modifications would either prevent or delay the diagnosis of diabetes. The incidence of diabetes in the intensive lifestyle management DPP group was reduced by 58% over 2.8 years when compared to the control group, and diabetes incidence in the metformin group was reduced by 31% when compared to the control group (CDC, 2014).

The success of the DPP led to modification of the program into a 12 session group-based intervention called the Group Lifestyle Balance™ (GLB) Program (University of Pittsburgh, 2011). Since then, the GLB program has consistently shown to be an effective model for decreasing diabetes and cardiovascular disease in those at high risk (Kramer et al., 2009). The translation of the DPP into successful GLB programs continues as the GLB has been adapted for implementation in a variety of populations and settings including, a poor urban community (Piatt et al., 2012); an underserved Latino population (Ruggerio et al., 2011); Native American youth (Brown et al., 2010); YMCA sites (Ackerman et al., 2008); and delivered by diabetes educators in urban, suburban, and rural outpatient-hospitals (Kramer et al., 2011).
Evidence from other studies demonstrate that self-directed and coach-led programs yield effective results in weight loss (Dunkley et al., 2014; Ma et al., 2013). Effectiveness and retention results of lifestyle intervention programs concentrated on dietary intervention, physical activity, or both. These lifestyle intervention programs examine outcomes including weight, BMI, waist circumference, fasting glucose, HbA1C, lipids, and blood pressure (Dunkley et al., 2014). Of the 22 studies in the review, more intensive programs demonstrated higher weight loss compared to less intensive programs (Dunkley et al., 2014). Programs considered more intensive utilized coach led and self-study programs. More effective programs included the use of group interventions to minimize cost and used specific behavior change strategies that are associated with increased effectiveness (Dunkley et al., 2014).

This retrospective analysis of the outcomes for patients participating in the GLB program at Wilford Hall Ambulatory Surgical Center (WHASC), Diabetes Center of Excellence (DCOE) will represent the first assessment of GLB program outcomes for military beneficiaries.

Method

The WHASC Internal Review Board approved this retrospective cohort study, which evaluated clinical data routinely collected for patients participating in the GLB program at WHASC DCOE from 01 January 2009 through 31 Dec 2013.
Participants

Patients at risk for diabetes were referred to the GLB program through their primary care physician or self-referral. Those deemed to be at risk for diabetes included one or more of the following: 1) overweight or obese defined as BMI $\geq 25 \text{ kg/m}^2$; 2) prediabetes defined as fasting glucose $\geq 100 \text{ mg/dL}$ and $\leq 125 \text{ mg/dL}$ or glycated hemoglobin (HbA1c) $\geq 5.7\%$ and $\leq 6.4\%$; or 3) metabolic syndrome (MetS). MetS was defined as three or more of the following: waist circumference $\geq 102 \text{ cm in males or } \geq 88 \text{ cm in females};$ triglyceride $\geq 150 \text{ mg/dL};$ high-density lipoprotein (HDL) $< 40 \text{ mg/dL in males or } < 50 \text{ mg/dL in females};$ blood pressure $\geq 130/85 \text{ mmHg};$ fasting blood sugar (FBS) $> 100 \text{ mg/dL and } < 126 \text{ mg/dL.}$ Approximately 90.3% of subjects were overweight or obese and 90.6% met the definition of prediabetes. Overall, 90.5% were overweight or obese and prediabetic.

At the time of the data collection, the GLB program consisted of 4 monthly group sessions, weekly self-study modules, and weekly interaction with the lifestyle coach via telephone or a secure messaging system. At each group session, the self-study modules to be completed prior to the next group session were distributed. The self-study modules included a DVD/CD that provided video instruction for each week’s topics, supplemental information, and printed course materials.

Goals for patients participating in the GLB program included intensive lifestyle modification resulting in weight loss of 7% by 12 week session, weekly moderate physical activity to reach 150 minutes per week by the 12 week session, completion of food and activity logs for 12 weeks,
review of educational materials between face-to-face sessions, and participation in group
sessions.

Participants were expected to complete the self-study module each week prior to the scheduled
phone call/message so they could discuss any questions regarding the material and the status of
their personal goals. Participants with a smartphone or computer were encouraged to track their
activity on the MyFitness Pal app and share the account with the lifestyle coach to facilitate
activity and food log reviews.

Group sessions were offered during weekdays at various times; however, no classes were offered
in the evening or on weekends. Participants could choose the time and day that was most
convenient for them. Demographic information (e.g. gender, race, ethnicity, employment status,
highest education level completed) was collected upon enrollment. Participant weight, height,
and blood pressure were collected at each group appointment. Waist circumference was collected
at baseline and upon completion (week 12). Lab work drawn prior to beginning the program and
upon completion included hemoglobin A1c (HbA1c), FBS, cholesterol, triglycerides, LDL, and
HDL.

Data Collection

Patients who participated in GLB at the DCOE were monitored throughout the program.
Baseline data were collected including standard demographic information (e.g. gender, race,
ethnicity, employment status, military status, highest education level completed, family history
of diabetes). Participant weight, height, waist circumference, and blood pressure were collected at baseline and upon completion of the 12 week GLB program. Furthermore, laboratory tests at baseline and completion of the GLB program included HbA1c, FBS, cholesterol (CHOL), triglycerides (TG), low-density lipoprotein (LDL), and HDL.

Data were analyzed using SPSS version 19. Descriptives compared baseline participants’ demographics with completers overall and by gender. Outcomes of the GLB program were examined using paired t-tests to compare observed clinical measures at baseline to the same measures at completion of the 12-week program.

**Results**

Institutional Review Board approval was obtained prior to retrospective data collection. There were 704 baseline attendees (Table 1). Baseline participants were primarily female (61%), about 52 years old, mostly Caucasian (61%) and non-Hispanic (66%). Many baseline participants were college graduates (39%); half were employed full time and 22% were retired. Approximately half of participants (52%) had a family history of diabetes.

Both men and women were retained at similar rates from baseline to completion. Those who were employed full time experienced higher dropout rates. In addition, those who were active duty (AD) were less likely to complete the program than those who were retired, especially for women, as 55 AD women began the GLB program and only 10 completed.
The participants who were retained throughout the program were older with mean age of 55.51 at session 12 compared with 52.36 at baseline. Consistent with older age, the percentage of retired military increased from baseline (33%) to completion (43%). Moreover, college graduates (23% to 28%) and those with graduate degrees (16% to 18%) were retained at higher rates from baseline to completion.

Figure 1 shows the number of participants in each of the four in-person sessions. The greatest decline in participation occurred from baseline to session 5 with a decrease of 212 participants (30%). From session 5 to session 9, an additional 107 participants (22%) were lost. Few participants were lost from session 9 to session 12 (5%). Thus, 51.7% completed the 12 week program.

Independent samples t-tests were conducted to determine significant differences in baseline clinical measures between those who completed the program (n=364) and those who did not complete (n=340). No clinically significant differences were observed in weight, BMI, waist circumference, blood pressure, HbA1c, FBS, or lipids between the two groups. Therefore, attention was given to clinical outcomes for those who completed the GLB program.

Paired t-tests compared observed clinical measures at baseline to the same measures at completion of the program (Table 2). While only about a 4% weight loss was observed in participants who completed the 12-week program, it was significant ($p < 0.01$). Corresponding BMI significantly decreased from 31.67 at baseline to 30.41 at completion ($p < 0.01$). Additional
benefits for those who completed were realized. Average weight loss was 3.36 kg and 37.9% achieved at least 5.0% reduction in weight; 19.4% achieved 7.0% or greater weight loss. Waist circumference significantly decreased \( (p < 0.01) \). However, no significant differences in blood pressure were observed. FBS significantly improved \( (p < 0.01) \) and there was a significant improvement in HbA1c \( (p < 0.01) \). Cholesterol markers significantly improved for both men and women, with significant improvements in total CHOL, TG, and LDL measures \( (p < 0.01) \) and negligible differences in HDL.

In addition, conditions of interest for the 364 completers were examined including prediabetes, obesity, and MetS (Table 3). Prediabetes incidence fell by 2.0% \( (p < 0.001) \). Obesity was reduced by 8.7% \( (p < 0.001) \) and MetS decreased by 6.8% overall \( (p < 0.01) \). Furthermore, Table 3 displays the change in MetS risk factors from baseline to completion. Significant differences were found for central obesity, TG, and FBS \( (p < 0.001) \).

Discussion

The primary purpose of this study was to determine the efficacy of the GLB program in our population. We found that the GLB program was overwhelmingly successful in reducing several measures of clinical interest. Completers of the 12-week program lost an average 4% of their baseline body weight (3.36 kg), with 37.9% of completers achieving a 5% or greater weight loss, and 19.4% exceeding 7% weight loss. As a direct result, markers of glucose and cholesterol metabolism improved as did the numbers of those classified as having prediabetes, obesity and MetS. It is clear that there is clinical benefit to patients who complete this program. As such, it
is worthwhile to consider investment in this type of program on a larger scale in the Military Health System.

Our results are similar to those reported in other lifestyle change programs published in the literature. A recent meta-analysis of 11 randomized controlled trials of intensive lifestyle change programs for prediabetes found a mean weight loss of 2.30 kg compared to the DCOE GLB program’s 3.36 kg (Dunkley et al., 2014). Participants that completed programs and lost weight were more successful in decreasing risk factors for developing diabetes (citation). Thus, developing effective strategies on adhering to program guidelines and increasing graduation rates could lead to weight loss, and reduce or delay development of T2DM.

Although we are only reporting weight changes through 12 weeks, the weight loss observed in our subjects exceeded the mean weight loss observed in other studies by over 1 kg. It is unclear whether our participants maintained this degree of weight loss over a longer period of time. Even so, we should note that our GLB program was similarly structured to many of these programs, and it is reasonable to presume that long-term performance would likewise be similar. The meta-analysis also found that diabetes prevention programs that adhered to specific principles tended to be more successful. These principles were obtained from the Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention (IMAGE project) (Greaves et al., 2011) and the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) (Chatterton et al., 2012). Currently, our GLB program utilizes about half of these strategies. We may see even greater success with our program completers if we incorporated more of these principles. We are currently expanding the program to include
additional core classes over nine months after program completion, which incorporates several
additional strategies related to prolonged engagement.

While it is clear that completers receive significant clinical benefits, we experienced a
high attrition rate. Nearly half (48.3%) of the patients who started our program dropped out prior
to 12 weeks, losing some of the potential benefit they may have otherwise achieved. Therefore,
improving retention must be a focus of the GLB program as we move forward. In April 2016, the
DCOE GLB program included an orientation to help participants make a better choice on
deciding if the GLB program would be right for them. Participants learned about the history of
the program, goals and requirements, covered a timeline syllabus for each week of the program,
and reviewed materials. Participants were allowed to choose their start date, and had a greater
sense of benefits of the program. It remains to be seen if retention will improve as a result.

Since retired individuals were more likely to complete the GLB, holding sessions when
convenient for working individuals (e.g. evenings, weekends) may improve retention. AD
participants were more likely to discontinue with nearly ¾ not completing the program. Efforts
are underway to gain support from supervisors for AD at risk for diabetes to attend the GLB
program.

Future Studies

Future studies should examine longitudinal benefits for completers who were able to achieve 5-
7% weight loss. In addition, determining strategies utilized by GLB participants who were able
to achieve significant weight loss may assist other GLB participants achieve similar results.
Moreover, a longitudinal study should be conducted to see how many completers were able to maintain lifestyle changes that resulted in significant clinical benefits. In addition, longitudinal studies could identify what percentage of GLB completers converted to diabetes within five years versus those who were able to delay or prevent conversion to diabetes.

Limitations

There was no formal longitudinal follow up with GLB program completers; therefore, our results only reflect outcomes at the time of program completion.

Conclusions

The GLB program is a valuable diabetes prevention program and was effective at improving clinical outcomes and reducing the incidence of prediabetes, obesity, and MetS for participants who completed the program. Therefore, every effort should be made to support and encourage GLB participants to complete the program.

Disclaimer:

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References


