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Health-related Quality of Life among participants in the SMART Weight Loss Trial

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1. Introduction and Background

Obesity is a global pandemic that increases the risk of many health conditions including heart disease, type 2 diabetes, some cancers, hypertension, dyslipidemia, stroke, liver and gall bladder disease, sleep apnea, osteoarthritis, and gynecological problems (Centers for Disease Control and Prevention, 2011). In addition to physical health consequences, obesity

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has been reported to be associated with social stigmatization and depression (National Heart Lung and Blood Institute, 1998). Thus, the treatment of obesity has the potential to greatly impact public health and health-related quality of life (HRQoL). Indeed, one of the overarching goals of obesity treatment is the improvement of an individual's quality of life.

Nurses, especially those who work in primary care settings, are in a strategic position to address obesity both as a preventable disease through health promotion across the lifespan and as a chronic disease that negatively affects physical and psychological well-being. However, only two studies have examined interventions delivered in primary care settings by nurses and general practitioners (Hudson, 2004; ter Bogt et al., 2011). Moreover, results of a large study of registered nurses in the United States (4,980) found that while almost all nurses acknowledged that obesity is a significant health risk, the majority (76%) did not discuss weight loss with their patients (Miller, Alpert, & Cross, 2008). A recent literature review shows that, in general, health care professionals have negative attitudes towards obese patients. Although a recent study has shown that nurses' attitudes towards obese patients have improved, several studies have shown that nurses believe that obesity can be prevented with self-control. (Budd, Mariotti, Graff, & Falkenstein, 2011)

Studies suggest that HRQoL and weight are related, but relationships between HRQoL and weight change among weight loss study participants remain unclear. Hence, we examined these relationships using secondary data analyses from the SMART Trial, a randomized clinical trial of a 24-month behavioral weight loss intervention. Our primary hypothesis was that during the 24-month trial as weight decreased, HRQoL would increase. A secondary hypothesis was that low baseline HRQoL would inhibit weight loss.

Background

Several reports link obesity to decreased HRQoL and weight loss to increased HRQoL (Fontaine & Barofsky, 2001); however, the association between weight loss and improvements in HRQoL has not been unequivocally established. A recent study of participants in a bariatric support group found that a majority (86.1%) had high HRQoL ratings; however, the cross-sectional design did not allow for comparisons to be made with pre-weight loss HRQoL (Sutton & Raines, 2010). A meta-analysis of 34 randomized clinical trials of weight loss treatment reported that HRQoL does not consistently improve with weight loss (Maciejewski, Patrick, & Williamson, 2005); only 9 of 34 trials showed HRQoL improvements in one or more domains. Moreover, the details of the association between weight loss and HRQoL, such as whether both physical and mental HRQoL are affected by weight loss and the magnitude of the association across HRQoL domains, are not clear.

A low HRQoL may affect weight loss outcomes. As previously stated, obesity is associated with osteoarthritis; Fontaine and Barofsky (2001) found that 56% of obese adults seeking weight loss treatment reported chronic bodily pain. This pain could interfere with exercise recommendations associated with behavioral treatment of obesity. Bish et al. (2006) reported complex, body mass index (BMI) and gender-specific relationships between HRQoL and weight loss efforts. A low HRQoL increased the odds of attempting weight loss among men while a high HRQoL increased the odds of attempting weight loss among women. Among both men and women, lower HRQoL was associated with a reduced likelihood of meeting physical activity recommendations across most domains of HRQoL and BMI categories (Overweight, Class I Obesity, Class II/III Obesity). For individuals in the highest BMI category (Class II/III Obesity) lower HRQoL was associated with an increased likelihood of calorie restriction (Bish et al., 2006).

2.0 Methods

2.1 Parent Study Design and Participants

The design, recruitment and randomization procedures for the SMART Trial have been described in detail elsewhere (L. E. Burke et al., 2009). In brief, the study population included adults between 18 and 59 years of age with a BMI between 27 and 43 kg/m². The study excluded individuals who had conditions that required medical supervision of diet or exercise, participated in a weight-loss program in the 6 months prior to recruitment, or planned an extended vacation or relocation during the study period. The study protocol was approved by the University of Pittsburgh Institutional Review Board. All participants provided written informed consent.

After screening 704 individuals for eligibility, we enrolled 210 participants in the trial. The participants were randomly assigned to one of three self-monitoring groups: paper record (PR), personal digital assistant (PDA), or PDA with tailored feedback (PDA+FB). All three groups received the same standard cognitive-behavioral intervention in a group format; the only difference among the groups was in the self-monitoring method they were assigned to use. The intervention team was led by a nurse-behavioral scientist and included a nurse-psychologist, exercise physiologist and nutrition scientist. Details of the intervention have been reported elsewhere (L. E. Burke et al., 2009). All participants received nutritional and behavioral counseling and were provided with practical hands-on experience to develop skills to implement a healthy lifestyle. They also received a daily calorie and fat gram goal based on gender and baseline body weight. For participants weighing less than 200 lbs, the prescribed daily total calorie intake was 1200 kcal for women and 1500 kcal for men. For those weighing more than or equal to 200 lbs, the goal was 1500 kcal for women and 1800 kcal for men. The daily fat gram goal was 25% of the total daily calories for everyone. Participants were instructed to reach a weekly goal of 150 minutes of moderate intensity exercise by the 3rd month and 180 minutes by the 6th month. All participants were instructed to self-monitor their daily energy and fat intake, as well as physical activity (type and duration) during the study period.

2.2 Measures

Demographics—Baseline demographic characteristics were collected via a self-administered, standardized questionnaire. Information obtained included age, gender, race, marital status, education and income.

Body weight—Change in weight was the primary outcome for the study. At baseline, 6, 12, 18 and 24 months, we measured weight (lb) on a digital scale (Tanita Corporation of America, Inc., IL) with participants wearing light clothing and no shoes.

HRQoL assessment—HRQoL was measured with the SF-36 Version 2 at baseline and repeated at each semi-annual assessment through 24-months. This 36-item questionnaire measures general health-related quality of life, with scores ranging from 0 to 100; a higher score indicates a better health state (McHorney, Ware, Lu, & Sherbourne, 1994). Two component scores, Mental Component Score and Physical Component Score, are derived from 8 domain scores. The 8 domains are: 1) Physical Functioning, 2) Role-physical (role limitations due to physical problems), 3) Bodily Pain, 4) General Health (perceptions of overall health), 5) Vitality, 6) Social Functioning, 7) Role-emotional (role limitations due to emotional problems), and 8) Mental Health. The two ordinally scaled component scores and eight domain scores of the instrument have shown good internal consistency reliability, with Cronbach's alphas exceeding .90 for physical and mental component scores; and ranging from .84 for general health perceptions to .95 for physical functioning for the eight domain

scores in the 1998 general U.S. population (Ware, Kosinski, & Dewey, 2000). In the present study Chronbach's alphas range from .78 to .91.

2.3 Statistical Analysis

Analyses were conducted using SAS version 9.1 (SAS Institute, Cary, NC). The significance level was set at 0.05 for two-sided hypothesis testing. Summary statistics were reported as mean (SD), median (inter-quartile range, IQR) or frequency count (%). The primary analyses for this paper examined changes in HRQoL with changes in weight from baseline to 24 months. The self-monitoring group assignment was not hypothesized to influence the relationship between weight and HRQoL. The current sample excluded individuals who did not provide any weight measurements after the baseline assessment ($n=14$) and individuals who refused to provide information regarding income ($n=5$) which was included as a confounder. Thus, the sample was limited to 191 participants. Comparisons between the study sample and participants who were excluded ($n=19$) were made using the ANOVA or the Kruskal-Wallis test for continuous variables and chi-square test of independence or Fisher's exact test for categorical variables.

For the primary analysis, linear mixed modeling was applied to assess the effects of percent weight change on percent HRQoL change, controlling for time (6th month, 12th month, 18th month and 24th month), treatment groups (PR, PDA, PDA+FB), income, marital status, education (years) and their interactions. Sensitivity analyses were conducted for influential cases identified through graphical methods. When the potentially influential cases were omitted via sensitivity analysis, the conclusions did not change, supporting the robustness of our findings.

For the secondary analysis, linear regression modeling was applied to assess the effects of baseline HRQoL, and treatment groups on the percent weight change from baseline to 24 months. In addition to the 19 participants excluded from the primary analyses, individuals who had any missing weight data ($n=16$) were excluded from these secondary analyses. One participant did not provide information for the baseline mental health subscale and another did not provide information for the baseline role emotional subscale. They were excluded from their respective analyses.

3. Results

Overall, our sample ($N=191$) was predominantly White (78.0%), female (84.3%), employed full time (82.2%), and currently married (68.6%), with an average age of 46.9 years and education of 15.8 years. The average BMI was 34.1 kg/m². A majority of participants (59.7%) had a household income that was greater than \$50,000 per year. On average, participants weighed 93.9±15.4 kg at baseline, 87.3±16.9 kg at 12 months, and 90.3±17.0 kg at 24 months. Participants excluded from the analysis ($n=19$) did not differ in any of the baseline characteristics from the current study sample.

The percent changes in weight during the 24 month study were significantly associated with percent changes in the Physical and Mental Component scores of the SF-36 (Table 1). For every 5% decrease in weight, the Mental Component score increased by 3.21% ($p=.003$), while Physical Component score increased by 1.43% ($p=.003$). For every 5% decrease in weight the Physical Functioning subscale score increased 2.30% ($p=.002$), the Role-physical subscale score increased 4.55% ($p<.001$), the General Health subscale score increased 3.38% ($p<.001$), the Vitality subscale score increased 9.38% ($p<.001$), the Role-emotional subscale score increased 2.83% ($p=.024$), and the Mental Health subscale score increased 2.78% ($p=.009$). No statistically significant associations were found between

changes in weight and the Bodily Pain or Social Functioning subscale scores. Baseline HRQoL was not associated with weight change at 24 months ($p > .05$).

4. Conclusion

This report provides further evidence of a link between weight loss and improved HRQoL among overweight and obese adults who participated in a behavioral weight loss intervention. The longitudinal design of this study allows us to observe the relationship between weight change and HRQoL over time, rather than simple cross-sectional associations. Thus, in this large sample of overweight and obese men and women, we can confirm that weight loss leads to improved HRQoL and weight gain leads to reductions in HRQoL. Nurses can utilize this information to educate their patients that even a modest weight loss can have significant impact on improving HRQoL.

Surprisingly, baseline HRQoL did not appear to affect weight loss success. We presumed that individuals with better physical health would be more inclined to exercise and individuals with better mental health would be more capable to make positive changes in their behavior. This suggests that baseline HRQoL should not be seen as an impediment to weight loss success. However, it is possible that the lack of an overall association between baseline HRQoL and subsequent weight loss is due to the way in which HRQoL was measured. A review conducted by Teixeira *et al.* which indicates that general measures of HRQoL, such as the SF-36, are not likely predictors of weight loss success, but weight-specific measures may have some predictive value (Teixeira, Going, Sardinha, & Lohman, 2005).

Based on these findings and other available data, nurses can counsel patients about multiple benefits of weight loss, including the potential for improved HRQoL. Moreover, they should not see low HRQoL as an impediment to weight loss treatment. Nurses need to take a more active role in treating individuals with obesity, preferably in collaboration with other health care professionals. Reviews of evidence-based treatment strategies for overweight and obesity that can be implemented by nurses are good sources of information (Burke, Tuite, & Turk, 2009; Warziski, Choo, Novak, & Burke, 2008). Nurses who encounter overweight or obese patients with low HRQoL in their practice can educate their patients about the relationship between weight and HRQoL and provide encouragement and reinforcement to engage in weight loss treatment providing support and assistance as appropriate for their practice.

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Table 1

Associations between weight loss and change in SF-36 scores from baseline to 24 months among 191 adults participating in a behavioral weight loss intervention.

	Score change associated with 5% weight loss	P- value
Component Scores		
Physical Component	1.43%	.008
Mental Component	3.21%	.003
Subscale Scores		
Physical Functioning	2.30%	.002
Role-physical	4.55%	<.001
Bodily pain	No association	.677
General Health	3.38%	<.001
Vitality	9.38%	<.001
Social Functioning	No association	.099
Role-emotional	2.83%	.024
Mental Health	2.78%	.009