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Psychosocial and behavioral pre-treatment predictors of weight loss outcomes

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ABSTRACT. OBJECTIVE: *This study tested whether baseline behavioral and psychological variables predict weight and fat loss among overweight, non-obese individuals participating in a six-month calorie restriction trial. Participants (N=48) were randomly assigned to four groups, three of which included a calorie restriction program and one of which served as a healthy diet weight maintenance control. For the purposes of this study, data were analyzed only for participants assigned to the three calorie restriction groups (n=36). Ten psychological and behavioral measures were investigated through principal components factor analysis to examine whether these measures were assessing similar or distinct psychological and behavioral constructs. Based on the obtained six-factor solution, one measure from each domain was selected for inclusion in hierarchical regression analyses, which was used to test the relative importance of psychosocial and behavioral variables in predicting percent weight and fat loss over six months. After controlling for demographic and treatment variables, the behavioral and psychological measures of negative mood states, poor psychosocial functioning, and somatic symptoms were associated with less weight loss ($R^2=0.68$, $p<0.001$) and fat loss ($R^2=0.65$, $p<0.001$) over six months. Among overweight individuals, poor psychological adjustment, somatic symptoms, and negative mood states appear to form a psychosocial profile that is predictive of less weight and fat loss in calorie restriction programs.* (Eating Weight Disord. 13: 30-37, 2008). ©2008, Editrice Kurtis

INTRODUCTION

Prolonged calorie restriction (CR) has been found to increase longevity and delay the development of age-associated diseases in a wide variety of organisms (1). Preliminary reports suggest that CR may also reduce morbidity and mortality in primates (2, 3). The potential benefit of CR for humans is a topic of increasing scientific interest (4). Recently, some of the beneficial effects of CR were found to extend to humans since two biomarkers of aging (i.e., low fasting insulin and low core body temperature), as well as DNA damage, were improved in overweight individuals who underwent six months of CR (5). Additionally, a metabolic adaptation, or reduced RMR, was observed in these same participants (6). This metabolic adaptation is hypothesized to be important mechanistically in the beneficial effects of CR on longevity.

Based on these preliminary findings in primates and humans, as well as a large

body of evidence documenting the beneficial physiological changes associated with CR in other animals, advocates for the study of caloric restriction have made strong arguments that CR is a viable and potentially safe approach for improving health and longevity in non-obese humans (7). Some experts have suggested that public health policy initiatives are currently needed to assist humans in adopting a CR lifestyle in our obesogenic environment (8). Additionally, many popular press publications have recently advocated the benefits of CR based on recent human studies.

Others have argued, however, that the existing evidence is not sufficient to justify broad implementation of CR interventions and that further study of the effects of CR on emotional, behavioral, and cognitive function in humans is necessary (9). This argument is based in part from findings in the animal literature indicating that CR may have negative emotional and behavioral

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effects, such as increased abnormal food related behavior (10) and aggression (11; 12). In contrast to the extensive research literature documenting the physiological effects of CR, relatively little is known about the potential behavioral, cognitive, and psychological correlates of long-term CR in humans. Furthermore, it is unknown if CR interventions are equally effective for all humans. Given the current debate, there is value in identifying the psychological characteristics of people who respond most favorably to CR regimens.

This study was conducted as an ancillary project to a six-month randomized controlled trial that tested the effects of three calorie restriction approaches, as compared to a healthy diet (no-calorie restriction), on biomarkers of aging and metabolic adaptation in healthy, overweight individuals (5). The three-calorie restriction approaches were: 1) 25% calorie restriction, 2) 12.5% calorie restriction and 12.5% increased energy expenditure by structured exercise, and 3) low-calorie diet. The primary aim of the current study was to examine whether baseline psychological and behavioral factors (e.g., eating behavior, emotional states) were predictive of weight and fat loss over six months among individuals participating in the main study. For the purpose of the current study, data were analyzed only for participants assigned to CR groups.

MATERIALS AND METHODS

Screening procedures

As noted above, the current study represents an ancillary project of the main study entitled Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (CALERIE). An extensive screening process was employed in the CALERIE study to ensure participants were healthy and suitable to participate in this trial. All potential participants (aged <50 years for men and <45 years for women) completed three screening visits during which assessments of height, weight, and blood pressure were completed; blood tests were also conducted to ensure there were no physical contraindications to participation in this study. Due to the stringent inclusion/exclusion criteria used, a large number of individuals were excluded from the CALERIE study during the screening process. Thus, the number of individuals excluded in the present study is the result of the extensive screening process employed in the larger study. A total of 599 individuals were screened and 551 were excluded (460 were ineligible; 91 withdrew during screening). Potential participants were excluded for the following reasons: BMI out of

range or weight instability ($n=163$); medical condition or medication use ($n=71$); other medical exclusions (e.g., elevated blood pressure, $n=147$); age out of range ($n=58$); smoker ($n=11$); psychological reasons ($n=8$); and exercise regularly ($n=2$). Of the 65 individuals who completed all three screening visits, eight were excluded because they reported significant obstacles for participation (e.g., scheduling problems).

In addition to the screening process described above, a number of psychological questionnaires were also used to provide an initial screen of potential participants. For each of these measures, alert scores were used to inform staff members if participants' scores were elevated based on the following criteria: >20 on the Beck Depression Inventory (BDI) (13), >14 on the Restraint subscale of the Eating Inventory (EI), >12 on the Disinhibition subscale of the Eating Inventory (EI) (14), >100 on the Body Shape Questionnaire (BSQ) (15), and >70 on three or more subscales of the Multiaxial Assessment of Eating Disorder Symptoms (MAEDS) (16). Weekly staff meetings involving clinical psychologists were conducted to determine if participants who scored above any of these alert scores should continue in the screening process.

In addition to completing the initial screening questionnaires, potential participants were interviewed by psychology staff members using the Structured Clinical Interview for the Diagnostic and Statistical Manual (DSM-IV) (SCID-IV) (18) and Interview for the Diagnosis of Eating Disorders, 4th version (IDED-IV) to identify individuals who had a history of psychosis, major depression, eating disorders, or another psychiatric problem that might adversely impact participation in the study. Potential participants who reported symptoms sufficient to meet criteria for a psychological disorder were excluded. Potential volunteers were administered an adaptation of the Motivation and Readiness Scale to measure intention to adhere to various aspects of the intervention. Additionally, all participants were interviewed regarding potential obstacles to participation in the study, e.g., work schedule, family responsibilities, travel schedule, and driving distance to the Pennington Biomedical Research Center (PBRC). Participants were also asked to complete a fourteen-day food diary during the screening process. Further details of the screening process have been previously reported (5).

Participants

Thirty-six male (25-50 years) and female (25-45 years), overweight individuals ($25 \leq \text{BMI} < 30$)

participated in the present study. These 36 study participants represent a subset of the 48 participants who participated in the larger study examining the effects of calorie restriction on biomarkers of aging and metabolic adaptation (5). Of the 36 participants who enrolled in this study, 35 completed the entire program. The sample was predominantly Caucasian ($n=22$; 61.1%); twelve participants were African-American, one was Asian, and one was Latino.

Participants were randomized into one of three groups for six-months: 1) 25% CR of baseline energy requirements, 2) 12.5% CR +12.5% increase in total energy expenditure by structured exercise (CR+EX), and 3) very low calorie diet (LCD) until a 15% reduction in body weight, followed by maintenance of new lower body weight. Participants were provided with all of their food from baseline to week 12 and from weeks 22-24, and self-selected their diets based on individual calorie prescriptions from weeks 13-21. Descriptions of the procedures for calculating individual caloric requirements are described elsewhere (5).

Participants were provided with monthly incentives up to \$100 based on their adherence to their assigned treatment condition. Each participant received a monthly adherence score which consisted of the following components: attendance at weekly group sessions, attendance at weekly clinic visits, completion and accuracy of self-monitoring, and compliance with CR or CR+EX assignment. In addition, participants were provided with compensation for the time involved in completing three five-day inpatient stays (baseline, month 3, and month 6).

Procedures

Participants who were determined to be suitable to participate in this study completed a 5-day inpatient stay (baseline), during which extensive metabolic tests were performed and all psychological questionnaires were completed. The psychological questionnaires were administered by a trained professional, and participants completed these questionnaires in a quiet environment free from distraction. Participants also completed inpatient stays at months 3 and 6. The same procedures were completed at all three time points.

Outcome measures

Weight

Weight was measured each week in a hospital gown, after the participant had voided and fasted for twelve hours. At baseline, weight was calculated from the mean of five weights

measured over a four-week baseline period (i.e., day 0, 7, 14, 21, and 28). Weight loss was calculated by determining the difference between the participant's baseline weight and the participant's weight at the end of the six-month study (i.e., week 24) and is expressed as percent of weight loss.

Body composition

Percent body fat was measured using dual energy x-ray absorptiometry (Hologic QDR 4500A, Bedford, MA). Change in fat mass was determined by subtracting the difference between fat mass at baseline and fat mass at the end of the study (i.e. week 24) and is expressed as a percent of fat mass at baseline.

Predictor variables

Beck Depression Inventory-II (BDI-II)

The BDI-II is a 21-item self report screening instrument for measuring symptoms of depression in adults. The BDI-II has established reliability and validity (19).

Body Shape Questionnaire

The Body Shape Questionnaire (BSQ) is a self-report instrument that assesses concerns about body size and shape, specifically the experience of "feeling fat" (20).

Current dieting questionnaire

This three-item self-report questionnaire was developed in a pilot investigation to assess current dieting, as described by Lowe (21). In the pilot investigation, these questions were found to have a high level of internal consistency ($\alpha=0.85$).

Dutch Eating Behavior Questionnaire (DEBQ)

The DEBQ (22) is a self-report inventory that measures restrained eating, emotional eating, and external eating. For the purposes of this study, only the Restrained Eating scale was administered. The reliability and validity of this measure has been established in a series of studies (23).

Eating Inventory (EI)

The constructs measured by the EI include dietary restraint, disinhibition, and perceived hunger (14). The EI is commonly utilized in studies of eating attitudes or behaviors, and it has established reliability and validity (14, 24).

General Health Questionnaire

The 28-item General Health Questionnaire (25) measures the following psychological constructs: psychological adjustment (i.e., self-

reported stress), somatic symptoms (i.e., bodily complaints and illness), and negative mood states (i.e., anxiety and depression). The validity of this questionnaire has been demonstrated in numerous studies (26).

Motivation and Readiness Scale- Weight Loss (MARS-WL)

The MARS-WL (27) scale is based on the transtheoretical model of behavior change (28) and consists of 10 questions designed to assess motivation and confidence for behavior change necessary to promote weight loss. Participants respond on a 5-point scale, varying in the degree of likelihood they would use a particular weight management strategy. Possible responses are based upon the definitions of the stages of change from the transtheoretical model. This questionnaire has been used in a previous study (27), which found participants' self-reported motivation to be highly correlated with participation in the optional aspects of a weight loss treatment program.

Multiaxial Assessment of Eating Disorder Symptoms (MAEDS)

The MAEDS is a self-report inventory that measures six symptom domains related to eating disorders: binge eating, restrictive eating, purgative behavior, fear of fatness, avoidance of forbidden foods, and depression. The MAEDS has satisfactory reliability and validity (16, 17).

RAND 36-item Health Survey (SF-36)

The RAND 36-item Health Survey (SF-36) is a validated measure of health-related quality of life (29). The SF-36 measures eight domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, vitality (energy/fatigue), emotional well being, bodily pain, social functioning, and general health perceptions.

Restraint scale

The Restraint Scale (30) is a 10-item self-report inventory with established reliability and validity (23). The Restraint Scale contains two subscales: concern for dieting and weight fluctuations (23).

Statistical analyses

A data reduction method (i.e., principal components factor analysis) was used to reduce the number of variables used in prediction models¹. Hierarchical regression analyses were then used to test if psychological and behavioral variables were predictive of weight and fat loss, as well as change in energy balance after six months of intervention taking into account treatment effects and demographic variables (age, sex, race, and baseline BMI). All analyses were performed using SAS version 8.2.

RESULTS

Baseline characteristics of participants are presented in Table 1. Weight loss by group for the current study sample was as follows: Body weight was significantly reduced in all groups: CR (-10.4±3.2%); CR+EX (-10.0±2.9%), and LCD (-13.9±2.4%). Each intervention group had significant losses of fat mass (CR:24±3%, CR+EX: 25±3%, LCD: 32±3%) and fat free mass (CR:5±1%, CR+EX:3 ±1%, LCD 6±1%).

Hierarchical regression analyses

Based on data reduction results, one variable was selected from six different domains to be included in hierarchical regression models, which were conducted to evaluate the relative importance of psychosocial and behavioral variables in predicting weight and fat loss over six months, after accounting for demographic variables (age, BMI, race, and sex) and treatment effects (three intervention groups). The following psychological and behavioral measures, collected at baseline, were entered into hierarchical regression models: BDI-II, EI - Restraint subscale, MAEDS questionnaire - Binge Eating and Purgative Behavior subscales, General Health Questionnaire (GHQ), and the MARS motivation subscale. For each hierarchical regression model, the demographic variables were entered in the first step, treatment variables were entered in the second step, and psychological and behavioral variables were entered in the third and final step.

No significant variable by treatment interac-

¹A principal component factor analysis with orthogonal rotation was performed to test whether the various measures were assessing similar versus distinct psychological and behavioral constructs. Factors were retained if they had eigenvalues greater than 1.0 and accounted for 5% or more of the variance. This resulted in a six factor solution which accounted for 75% of the total variance in the constructs measured by the psychological questionnaires. The following factors were identified: Dieting/Restrained Eating, Body Image Concerns and Binge Eating, Depression, Dieting Motivation and Confidence, Well Being, and Extreme Weight Control Behaviors. All measures significantly loaded (≥ 0.40) on at least one of the factors, and the vast majority of measures loaded on a single domain, suggesting they were assessing distinct psychological and behavioral constructs.

TABLE 1
Baseline characteristics of participants in the three calorie restricted groups (n=36).

| | M | Men (n=16) (SEM) | Range | M | Women (n=20) (SEM) | Range |
|----------------------------|------|---------------------|------------|------|-----------------------|-----------|
| Age (yr) | 37.3 | (1.8) | 26-49 | 37.6 | (1.2) | 27-45 |
| Weight (kg) | 89.1 | (2.3) | 76.7-103.2 | 75.8 | (1.7) | 61.7-91.6 |
| BMI (kg/m ²) | 27.9 | (0.3) | 25.5-30.6 | 27.6 | (0.4) | 24.8-30.1 |
| Body fat percentage | 24.5 | (0.8) | 16.9-31.4 | 37.9 | (0.9) | 28.9-45.4 |
| Systolic BP (mmHg) | 116 | (2.5) | 96-136 | 108 | (2.0) | 89-122 |
| Diastolic BP (mmHg) | 76 | (2.7) | 58-90 | 72 | (1.8) | 58-88 |
| Six-month follow-up | | Men (n=15) | | | Women (n=20) | |
| Weight loss (%) | 10.7 | (1.0) | 4.1-17.0 | 11.9 | (0.7) | 7.0-16.7 |
| Fat mass loss (%) | 29.6 | (3.3) | 8-52 | 24.3 | (1.6) | 11.3-39.6 |

tions was found; thus, we collapsed the three groups in the prediction model. We then tested for main effects of the psychological and behavioral variables when all three CR groups were combined. In the initial prediction model, the demographic variables (age, BMI,

race, and sex) and treatment effects (three intervention groups) accounted for a significant amount of the variance in weight loss over six months ($R^2=0.37$; $p<0.001$) (Table 2). When the behavioral and psychological variables were added to this model, they con-

TABLE 2
Relation between baseline demographic, treatment, and psychological variables with weight loss following six months of caloric restriction.

| Variables Entered | B | F | df | R ² | ΔR^2 |
|------------------------------------|---------|-------|-------|----------------|--------------|
| Demographic | | 1.7 | 4,30 | 0.18 | |
| Age | 0.24 | | | | |
| Sex | -0.22 | | | | |
| Race | 0.34 | | | | |
| BMI | -0.10 | | | | |
| Treatment | | 2.75* | 6,28 | 0.37* | 0.19* |
| CR vs. LCD | -0.45* | | | | |
| CR+EX vs. LCD | -0.46* | | | | |
| Behavioral and Psychological | | 3.9** | 12,22 | 0.68** | 0.31*** |
| Beck Depression Inventory | -0.29 | | | | |
| Binge Eating Scale (MAEDs) | 0.01 | | | | |
| General Health Questionnaire (GHQ) | -0.37** | | | | |
| Motivation (MARS) | -0.31 | | | | |
| Purgative Behavior (MAEDs) | -0.25 | | | | |
| Restraint Scale (EI) | 0.01 | | | | |

F-values are for the entire model, inclusive of previous steps. β -weights (and their significance) are taken from the final step of each model. For each hierarchical regression model, the demographic variables were entered in the first step, treatment variables were entered in the second step, and psychological and behavioral variables were entered in the third and final step.

* $p<0.05$. ** $p<0.01$. *** $p<0.001$.

tributed a significant amount of additional variance ($\Delta R^2=0.31$) which resulted in the final model accounting for 68% of the variance in weight loss over six months ($p<0.001$) (Table 2). Specifically, higher scores on the GHQ, which assessed negative mood states, poor psychosocial functioning, and somatic symptoms, were associated with less weight loss over six months. Although the GHQ was the only psychological/behavioral variable that had a statistically significant association ($p<0.05$) with percent weight loss, the overall pattern of results suggested that participants with lower levels of psychological adjustment lost less weight in comparison to participants with higher levels of psychological adjustment. Specifically, participants who reported higher levels of depression (measured by the BDI and subscale of GHQ), purgative behavior (subscale of the MAEDs), and somatic complaints (subscale of GHQ), and lower levels of psychosocial functioning (subscale of GHQ) lost less weight.

A similar pattern of results was found when examining the association of behavioral and psychological measures with percent change in fat mass over six-months. In the initial prediction model, the demographic variables (age, BMI, race, and sex) and treatment effects (three intervention groups) again accounted for a significant amount of the variance in fat loss over six months ($R^2=0.32$; $p<0.001$). The behavioral and psychological variables again contributed a significant amount of additional variance to this model ($\Delta R^2=0.33$) which resulted in the final model accounting for 65% of the variance in fat loss over six months ($p<0.001$). Specifically, higher scores on the GHQ, which assessed negative mood states, poor psychosocial functioning, and somatic symptoms, were associated with less fat loss over six months.

DISCUSSION

The purpose of this study was to identify psychosocial and behavioral variables that predict weight loss outcomes following six months of calorie restriction. Participants who reported lower levels of psychological adjustment (i.e., self-reported stress) and higher levels of somatic symptoms (i.e., bodily complaints and illness), and negative mood states (i.e., anxiety and depression) lost less body weight and body fat during a six-month calorie restriction program. These results were statistically significant after taking into account the effects of demographic and treatment variables. As illustrated in Table 2, the psychological questionnaires contributed an additional 31% to the

regression model. Thus, the variance accounted for by variability among individuals regarding psychological and behavioral factors was large and at least as great as the variance accounted for by the treatment. Also, these effects were based on examination of participants in the three treatment groups and did not include a comparison with the healthy diet, weight maintenance control group.

All participants were carefully screened for abnormal psychological or eating behavior conditions prior to being accepted in the study. The overall effect that psychological and behavioral pre-treatment predictors have on weight loss outcomes would have likely been greater than if we did not extensively screen participants. Nevertheless, the present study provides an initial answer to the important question of whether all humans respond equally to CR. Our findings indicate that even with careful screening, individuals who reported greater symptoms of anxiety and depression, as well as more somatic symptoms, had less successful weight loss outcomes than individuals who reported fewer symptoms.

By providing information regarding the acceptability of CR among healthy, overweight participants, this study contributes to the debate regarding the ethics and feasibility of broad-scale recommendations of CR (9). Although the present analysis did not examine the issue of safety (medical and psychological) of CR, two recent analyses from the same study population have examined this issue. In the first analysis, Williamson et al. found that caloric restriction was not associated with increased eating or mood disturbances (31). Since caloric restriction was verified through objective changes in energy balance, this finding extends previous randomized controlled trials that made similar conclusions (32, 33). In the second analysis, Martin et al. examined the effects of CR on cognitive function and found that CR was not associated with cognitive impairment (34). Since CR was again objectively measured through changes in energy balance, the authors concluded that previous reports of cognitive impairment associated with dieting may reflect sampling and information processing biases.

The results of the present study should be interpreted in the context of its limitations. First, the generalizability of the findings is limited by our small sample size, as well as restricted body mass index (BMI) range. Thus, these findings need to be replicated in future studies that utilize larger sample sizes and more diverse populations. As previously mentioned, participants were provided with all of

their food for the first three months of this study, and participants in the LCD group were instructed to remain weight stable after achieving a 15% reduction in body weight. This may represent an additional limitation in that the study was designed to promote maximal compliance to the intervention during the first three months, which would directly impact weight loss during this time. However, in-feeding programs do not ensure compliance since it is impossible to control the foods participants eat outside of the center. Therefore, compliance can still be a problem, as indicated by the variability even in this tightly controlled study.

The present study also had a number of strengths. First, this is the first study to test the effects of psychological predictors among a non-obese population receiving three different types of caloric restriction programs. Second, the variance accounted for by psychological and behavioral factors was large and was at least as great as the variance accounted for by the treatment. Third, large weight losses of approximately 10%-13% of initial body weight were achieved by participants in all three CR programs at six months. This weight loss compares favorably to reported weight loss outcomes for most programs, which typically ranges from 7% to 10% of initial body weight (35). Moreover, dietary intake and energy expenditure were closely monitored in this study, which provides confidence that the weight loss achieved was due to behavioral compliance with the three different CR programs.

In conclusion, the present study indicates that all humans do not respond equally to CR. Rather, participants with lower psychological adjustment (i.e., self-reported stress), somatic symptoms (i.e., bodily complaints and illness), and negative mood states (i.e., anxiety and depression), lost less body weight and body fat in CR programs. Clinicians and researchers should therefore pay close attention to these variables when working with overweight individuals participating in CR programs.

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