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Barrier reduction in individualized vs. macronutrient restricted hypocaloric diets

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**BARRIER REDUCTION IN INDIVIDUALIZED
VS. MACRONUTRIENT RESTRICTED
HYPOCALORIC DIETS**

A Thesis

Presented to

**The Faculty of the Department
of Nutrition and Food Science**

San Jose State University

In Partial Fulfillment

of the Requirements for the Degree

Master of Science

by

Marily Ann Oppezzo

August, 2003

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ABSTRACT

Barrier Reduction in Individualized vs. Macronutrient Restricted Hypocaloric Diets

M. Oppezzo, C.B. Hollenbeck, P. Schaaf, and L. McProud. San Jose State University, San Jose, CA, and Stanford University School of Medicine, Stanford, CA.

Obesity is implicated in the development of chronic disease. A major barrier to successful weight loss is overly restrictive diets. The present study investigates whether a population that failed on a restrictive hypocaloric diet (RHD) will be successful in achieving weight loss with a less restrictive individualized hypocaloric diet (IHD). Thirteen participants who failed on a previous RHD were studied. For three months, subjects followed individualized diets with the same caloric deficit as the previous RHD; seven completed the study. Analysis of the dietary records indicated that less restricted diets were not successful in lowering perceived barriers or achieving successful weight loss. The results of the study emphasize the complexity of achieving successful weight loss in individuals who have experienced difficulty in previous attempts at weight loss.

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PREFACE

The following is a publication style thesis. Chapters I and III are written according to guidelines outlined in the *Publication Manual of the American Psychological Association, 5th edition, 2001*. Chapter II is written in journal format for submission to *The Journal of The American Dietetic Association*.

Table of Contents

	<u>Page</u>
List of Tables	x
CHAPTER I: Introduction and Review of the Literature.....	1
Introduction	2
Review of Literature	4
Problems Associated with Obesity.....	4
Theoretical Perspective / Conceptual Framework for Weight Loss Studies..	6
General Barriers to Weight Loss.....	7
Estimating Portion Sizes	7
Difficulty Planning Meals	8
Emotional Barriers	8
Binge Eating	9
Lack of Social Support	9
Lack of Self-Efficacy	10
Economic Barriers	10
Highly Restrictive Diets.....	10
Caloric Restriction Alone is Physiologically Adequate to Induce	
Weight Loss.....	11
Individualized Hypocaloric Diet as a Less Restrictive Approach	12
CHAPTER II: Journal Article.....	15
Authors' Title Page.....	16

Abstract.....	18
Introduction.....	19
Subjects and Methods.....	20
Subjects	20
Study Design	21
Data Analysis.....	22
Results.....	22
Discussion.....	23
Acknowledgements	27
References	28
CHAPTER III: Summary and Recommendations, References.....	36
Summary and Recommendations	37
References.....	40
Appendices	46
Appendix A: Participant Number, Barrier Number, Pre-IHD Rating, Post-IHD Rating, Change in Ratings, Average Pre/Post Ratings, and Average Change For Completed and Non-Completed Program Participants.....	47
Appendix B: Barriers to Weight Loss Programs Ratings List	52
Appendix C: Stanford University Human Subjects Approval Form.....	54
Appendix D: Human Subjects Consent Form.....	55
Appendix E: San Jose State University Human Subjects Approval Form....	62

List of Tables

<u>Tables</u>	<u>Page</u>
1. Completed and Non-Completed Program Participants' Initial Weight, Subsequent Weights, Weight Change, Estimated Weight Change / Week, Mean, SEM, and p-Value.....	32
2. Completed Program Participants' Estimated Kcal/Day to Maintain Weight, Kcal/Day Prescription, Reported Kcal/Day, Estimated Kcal/Day Intake Given Weight Change, Mean, and p-Value.....	33
3. Completed Program Participants' Barrier Reduction: Mean, Standard Error of the Mean, and p-Value.....	34
4. Non-Completed Program Participants' Barrier Reduction: Mean, Standard Error of the Mean, and p-Value.....	35

CHAPTER I

INTRODUCTION AND REVIEW OF LITERATURE

Introduction

Obesity is a growing problem in the United States. Between 1991 and 2000 the rate of obesity grew 60%, and today it is estimated that 61% of the population are either overweight or obese (NCHS, 2001). Overweight is defined as a Body Mass Index of 25 to 29.9 kg/m², while obesity is defined as a BMI of 30 kg/m² or above (BMI is a ratio of weight in kg to height in meters squared; kg/m²) (NCHS, 2001). In a study on the effects of obesity, current or past smoking, and problem drinking on chronic health conditions, Sturm (2002) found that obesity had significantly larger negative effects than smoking and/or drinking. In fact, the effect of obesity on the body was shown to be similar to the effects of the body aging 20 years. It is estimated that obesity is responsible for approximately 300,000 adult deaths in the U.S. each year (Allison, Fontaine, Manson, Stevens, & VanItallie, 1999). Chronic diseases associated with obesity include hypertension, cardiovascular disease, dyslipidemia, diabetes, gallstones, respiratory dysfunction, joint and low back pain, and certain forms of cancer (Hubert, Feinleib, McNamara, & Castelli, 1983; Rimm et al., 1995). After studying over one million Americans, Calle, Thun, Petrelli, Rodriguez, and Heath (1999) found a link between obesity and premature death; the increased risk begins with moderately overweight individuals and increases proportionally through severe obesity. With regards to health care, obese people face significantly more disease and up to 44% greater health care costs than those who are not obese (Quesenberry, Caan, & Jacobson, 1998). Not only are obese people at increased risk for mortality, but their health care costs and incidence of comorbid diseases are also increased compared to those who are not obese.

Due to the problems associated with obesity, many individuals are repeatedly encouraged to, and attempt to, lose weight. Serdula et al. (1999) found that when men and women were assessed independently, 28.8% of men and 43.6% of women were trying to lose weight. Timperio, Cameron-Smith, Burns, and Crawford (2000) assessed 2500 people and found that the most common methods used were reducing the amount of food eaten (95.6%), reducing dietary fat intake (87.3%), and increasing physical activity (84.4%). In their attempts to lose weight, Americans spend \$33 billion a year on weight loss products and services (Wolf & Colditz, 1998).

Despite the numerous efforts and large amount of money being spent on weight loss programs, the success in reducing obesity in the American population has been very poor. Even those who manage to lose weight fail to maintain their weight loss (Blackburn, Wilson, & Kanders, 1989; French & Jeffery, 1994). The rate of recidivism among individuals losing weight is nearly 100% with fewer than 5% of individuals maintaining weight loss for a period of 5 years (National Institutes of Health, 1992). The National Institutes of Health (1992) reported that there is a strong tendency to regain weight, with as much as two thirds of the weight lost regained within one year of the program completion, and almost all of the weight regained within five years. Extensive research has been done to identify why weight loss is so difficult for those who attempt to lose weight.

There are many barriers that individuals attempting to lose weight must overcome. Among the major ones are difficulty in estimating proper portion sizes, inability to find time to plan and eat meals, emotional eating, comorbid depression, binge eating, stress and anxiety, lack of social support, lack of self-efficacy, and inadequate finances (French, Jeffery, Story, & Neumark-Sztainer, 1998; Jeffery et al., 1993; NIH, 1992; Robbins &

Fray, 1980; Sherwood, Jeffrey, and Wing, 1999; Urban, White, Anderson, Curry, & Kristal, 1992). One predominant barrier to succeeding in a weight loss program that has been identified is the diet plan is too restrictive and different from the individual's lifestyle (NIH, 1992). This renders long-term success highly unlikely (Foreyt & Poston, 1999). There is a need to develop a less restrictive program that is more tailored to an individual's lifestyle in order to minimize this barrier to achieving successful weight loss. A diet tailored more to an individual's lifestyle and limited only in the number of prescribed kilocalories (individualized hypocaloric diet; IHD) might be more successful in achieving and maintaining desired weight than a diet restricted not only in kilocalories, but also macronutrient composition and individual food choices (restrictive hypocaloric diet; RHD). Since the only change in a prescribed IHD diet is an energy deficit, participants may view weight loss as a new adaptation of their old lifestyle rather than a completely new way of living, and will perceive the task as more achievable.

Review of Literature

Problems Associated with Obesity

Obesity is a growing problem in the United States. Between 1991 and 2000 the rate of obesity increased dramatically, and today it is estimated that 61% of the population are either overweight or obese (NCHS, 2001). Overweight is defined as a Body Mass Index of 25 to 29.9 kg/m², while obesity is defined as a BMI of 30 kg/m² or above (BMI is a ratio of weight in kg to height in meters squared; kg/m²) (NCHS, 2001). In a study on the effects of obesity, current or past smoking, and problem drinking on chronic health conditions, Sturm (2002) found that obesity had significantly larger negative effects than smoking and/or drinking. In fact, the effect of obesity on the body was shown to be similar

to the effects of the body aging 20 years. It is estimated that obesity is responsible for approximately 300,000 adult deaths in the U.S. each year (Allison, Fontaine, Manson, Stevens, & VanItallie, 1999). Chronic diseases associated with obesity include hypertension, cardiovascular disease, dyslipidemia, diabetes, gallstones, respiratory dysfunction, joint and low back pain, and certain forms of cancer (Hubert, Feinleib, McNamara, & Castelli, 1983; Rimm et al., 1995). After studying over one million Americans, Calle, Thun, Petrelli, Rodriguez, and Heath (1999) found a link between obesity and premature death; the increased risk begins with moderately overweight individuals and increases proportionally through severe obesity. With regards to health care, obese people face significantly more disease and up to 44% greater health care costs than those who are not obese (Quesenberry, Caan, & Jacobson, 1998). Not only are obese people at increased risk for mortality, but their health care costs and incidence of comorbid diseases are also increased compared to those who are not obese.

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Theoretical Perspective / Conceptual Framework for Weight Loss Studies

The health belief model is a theoretical construct that can be used as a predictor of change. This model was constructed by Rosenstock (1974). The theory was derived using well-established psychological and behavioral theories primarily from Lewin, Dembo, & Festinger (1944). The health belief model assumes that a person's attitudes and beliefs are important determinants of one's actions, and it states that perceptions of barriers and benefits of certain health changes are important indicators of overall health promotion program success (Elder, Guadalupe, Ayala, & Harris, 1999; Sweeny & Gulino, 1987). The health belief model has been used to explain many different health actions of people who have specific conditions or diseases, and more research needs to be done due to the influence of health status, past health behavior, lifestyle, and social and personal motivations for health change (Sweeny and Gulino, 1987).

Pender (1982) has proposed a modified version of this health model to relate it to determining preventative behavior, rather than simply alteration of a current disease state. Individual perceptions and modifying factors, are at the beginning phase of health changes,

and perceived barriers, benefits, and cues to action are at the later phase, which is linked to the likelihood of action and success (Pender, 1982). Pender's modification of the health belief model may be used as a predictor of health behavior change outcomes (Pender, 1982). Sweeny and Gulino (1987) looked at the validity of the model's explanation for breast-feeding practices, and support the health belief model's clinical utility. Pender's model states that there is a balance between the perceived barriers to a change and the perceived benefits of the change; if the barriers are reduced, then a certain level of success may be predicted. This portion of the construct is used in the design of the current study.

General Barriers to Weight Loss

Past research has documented several common barriers to weight loss. Among the major ones are difficulty in estimating proper portion sizes, inability to find time to plan and eat meals, emotional eating, comorbid depression, stress and anxiety, lack of social support, lack of self-efficacy, inadequate finances, and dietary plans that are too restrictive in their nature (French, Jeffery, Story, & Neumark-Sztainer, 1998; Jeffery et al., 1993; NIH, 1992; Robbins & Fray, 1980; Urban, White, Anderson, Curry, & Kristal, 1992).

Estimating Portion Sizes

Jeffery et al. (1993) found that dieters who aren't provided with measured food had difficulty with estimating portion sizes. Specific food provision led to greater accuracy in estimating caloric values than did the procedure of having patients evaluate the nutritional content of their own diets using a reference guide or basic instruction. When dieters cannot accurately estimate the caloric intake given in a serving, it is more difficult for them to adhere to a caloric prescription. Sarlio-Lahteenkorva and Rissanen (1998) found that even with obese people who successfully lost weight in the study, there was lower than

expected intake of energy calculated from food records. This underreporting has been documented in several studies (Sarlio-Lahteenkorva & Rissanen, 1998; Black et al., 1993). Underreporting can indicate true difficulty in estimating portion size, or conscious underreporting of amounts known to be larger.

Difficulty Planning Meals

Jeffery et al. also identified that difficulty finding time to plan or eat meals according to the program stipulations was a barrier (1993). Although not specifically stated, it is reasonable to suggest that more calorically dense “convenience foods” are more apt to be chosen with little time for meal preparation and planning. Also, the presence of a meal plan in general appears to provide structure to the eating behavior (Wing et al., 1996). Another related identified barrier to weight loss success was having the appropriate or prescribed foods available to eat (Wing et al., 1996.). Urban et al. (1992) suggested that many dieters found weight loss difficult because of the inconvenience that the program imposes. This could be interpreted as inconvenience associated with lack of time for meal preparation and planning or not having the prescribed foods available.

Emotional Barriers

The NIH (1992) found that the inability to deal with a high risk emotional and social situation is a frequent downfall of most weight loss programs. Indeed, emotions and eating have been documented to have an interactive relationship (Robbins & Fray, 1980). Robbins and Fray (1980) stated that hunger, stress, and anxiety have common “interoceptive stimulus-changes,” and therefore can cause action from different stimuli due to overlapping pathways. As early as 1973, Bruch suggested that hunger cues can be confused with emotional states, and by not discriminating between the two, inappropriate

eating can occur. It is also possible that the diet itself is an anxiety-invoking situation, and the more it deviates from one's current lifestyle, the more anxiety may result.

The NIH (1992) also identified depression as a common co-morbid disorder or feeling associated with hunger and eating. The NIH asserts that not only could there be a mutual causal relationship between obesity and depression, but that the latter is a huge barrier to successful weight loss attempts.

Binge Eating

Often concomitant with depression is the barrier of binge eating (Sherwood, Jeffrey, and Wing, 1999; Marcus, et al., 1990). Binge eating is defined as episodic consumption of large amounts of food, accompanied by a feeling of loss of control (Stunkard, 1959). Women with binge eating tendencies reported a greater number of perceived barriers to weight loss (Sherwood, et al., 1999). Moreover, binge eating is correlated with an increased dropout rate for weight loss programs (Sherwood, et al., 1999; Yanovski, Gormally, Leser, Gwirtsman, & Yanovski, 1994). Polivy and Herman (1985) argued that restricted eating behavior is a direct precursor to binge eating. Therefore, it is reasonable to suggest that a less restrictive diet may lower this barrier to weight loss by reducing the tendency toward binge eating.

Lack of Social Support

The U.S. Department of Health and Human Services (USDHHS) (1996) and Urban et al. (1992) identified lack of family support as an important barrier to weight loss. Diets that are too restrictive and too different from one's normal life may conflict with the family's eating habits, especially if the dieter is the cook. The NIH (1992) linked unsuccessful weight loss attempts to lack of social and professional support.

Lack of Self-Efficacy

Self-efficacy, or belief that one has the ability to achieve something, is important in weight loss. NIH (1992) found that lack of self-efficacy impedes weight loss attempts and program adherence. Individuals who are unsatisfied with their weight loss progression are at risk of failure, especially if there is not enough weight loss early in the weight loss program (NIH, 1992).

Economic Barriers

Weight loss attempts are also viewed as costly events. Not only do many programs have high enrollment costs, but the foods that are required to be purchased for the diet can be expensive as well. The Women's Health Trial identified the cost of the diet as a potential barrier to weight loss program adherence (Urban, et al., 1992). French et al. (1998) found that when women of lower educational or economic status rate their perceived barriers to weight loss, program cost is one of the barriers most frequently viewed as important. It is reasonable to suggest that diets based on an individual's own dietary patterns will lower this barrier.

Highly Restrictive Diets

The main barrier to weight loss success is that the programs are too restrictive in composition and are too different from one's regular lifestyle (NIH, 1992). Rozin (1980) showed that what individuals eat is correlated with what they like. Urban et al. (1992) found that dieters perceived the program as difficult when they were deprived of favorite foods and therefore tended to fail. Therefore, diets that allow individuals to choose among their favorite foods, and are restricted only in the amounts may be more successful in terms of the dieter's adherence to the weight loss program. Weight loss programs often

label sweet and high-fat foods as "bad" and prohibited. Polivy and Herman (1985) postulated that this restriction of certain foods prevents most individuals from succeeding in weight loss and sets them up for overeating. When certain foods are prohibited, the dieter's hunger signals may not be adequately appeased by "good" or non-prohibited foods and may increase the likelihood of bingeing on those prohibited foods (Polivy & Herman). If individuals are allowed to eat the prohibited foods, occasional indulgences will not lead to feelings of failure (Orbach, 1978). Polivy and Herman (1985) concluded that it is possible that not prohibiting certain foods and allowing the selection of a diet more to an individual's food preferences can lower this barrier of overly restrictive dieting.

Caloric Restriction Alone is Physiologically Adequate to Induce Weight Loss

Several commercial weight loss programs claim that a caloric restriction is not enough to lose weight. They tout that certain foods are more "metabolically costly" than others, and that these foods need to be limited in order to ensure weight loss (Council on Scientific Affairs, 1988). For example, some low-fat diets are based on the premise that carbohydrates and protein require more kilocalories to convert to fat than fat alone. While certain other benefits may be derived from this type of eating pattern, the Council on Scientific Affairs (1988) stated that there is no evidence that altering the content of the diet, in terms of fat, protein, and carbohydrates, has metabolic effects that either accelerate or inhibit weight loss. Alford, Blankenship, and Hagen (1990) reported that the variation in macronutrient composition is not the cause of the weight loss; the crucial issue is the total kilocalories consumed. Hill et al. (1991) found similar results when they compared high-fat to high-carbohydrate isocaloric diets; they concluded that energy intake, not the percentages of different food constituents, is the main determinant in maintaining

individual weights. Macronutrient restrictions, therefore, are not necessary to induce adequate weight loss. Although they may be successful in inducing a temporary decline in body weight, this success is attributable only to caloric deficit rather than the macronutrient composition. Alford et al. (1990) concluded that since percentages of macronutrients are not a determinant of weight loss, selection of a weight loss diet could be designed around existing dietary patterns.

Individualized Hypocaloric Diet as a Less Restrictive Approach

The majority of weight loss programs impose too many restrictions: restrictions of macronutrients, kilocalories, food choices, and even the time of day one eats. Numerous and radical changes from the individual's lifestyle are not only overwhelming for a short period of time, but also difficult to permanently incorporate into the individual's regular dietary patterns. There is little or no evidence that such radical changes in eating habits are successful in being maintained in the long run. Research has shown that one or two small changes are more successful than numerous radical changes and/or restrictions (Abusabha, Hsieh, & Acterberg, 2001; Foreyt & Poston, 1999; Blair & Connelly, 1996). Foreyt and Poston suggested that treatment regimens should be modified so that they are easily incorporated in the participant's current lifestyle. Blair and Connelly suggested that by placing an emphasis on small, moderate lifestyle changes obese patients are more likely to increase their physical activity. In a retrospective study on success in long-term weight loss, Abusabha et al. (2001) found that most dietary changes were made very gradually and took a number of years to be fully incorporated into people's lifestyles. Therefore, it is reasonable to suggest that a diet that incorporates one simple change, namely a caloric restriction, would have a high likelihood of being incorporated into an individual's

lifestyle. This allows the dieters to maintain their general dietary patterns, and the program would be viewed as a small change in their current lifestyle, rather than a temporary and radical break from their normal lifestyle.

Individualized hypocaloric diets (IHD) have been suggested to be an adequate and superior weight loss method (Coulston & Rock, 1994). Coulston and Rock state that using a moderate reduction in caloric intake as a weight loss method is rarely associated with severe discomfort and deprivation, and therefore changes are more likely to become a permanent, healthful pattern. This holds true even if only modest weight loss, rather than the person's ideal weight, is achieved. In their review of popular diets, Coulston and Rock stated that simply a reduction in caloric intake which is large enough to promote weight loss but not so restrictive that it compromises nutritional adequacy is the best weight loss method. Coulston and Rock assert that it has few, if any, medical risks and it also teaches the participants modification in their current lifestyle, which may prevent relapse.

In summary, there are many barriers to weight loss, the most prominent one being that diets are too restrictive and impose too many drastic changes. Since restrictive weight loss programs have not proven to be successful, there is a need to investigate whether or not a less restrictive program will facilitate individuals in achieving successful weight loss. It can be argued that reordered eating with only a caloric restriction in the context of existing dietary patterns, an IHD, may be more successful than an RHD. Though Coulston and Rock (1994) have suggested that it is an adequate weight loss method, no research has been done to test the success of an IHD. For this reason, the proposed IHD is an innovative weight loss method that has a need to be tested for success. The purpose of this study was to test the hypothesis of whether or not people who have not succeeded on

past weight loss studies are more likely to succeed in less restrictive diets.

CHAPTER II

JOURNAL ARTICLE

Title: Barrier reduction in individualized versus macronutrient restricted hypocaloric diets.

Key Words: Hypocaloric diet, Barrier reduction, Individualized, Non-restrictive diets

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ABSTRACT

Barrier Reduction in Individualized vs Macronutrient Restricted Hypocaloric Diets
M. Oppezzo, C.B. Hollenbeck, P. Schaaf, L. McProud. San Jose State University, San Jose, CA, and Stanford University School of Medicine, Stanford, CA.

Objective: Obesity is implicated in the development of chronic disease, and most people who try to lose weight are unsuccessful. A major barrier to success is overly restrictive weight loss diets. The present study investigated whether a population that failed at a restrictive hypocaloric diet (RHD) weight loss program will be more successful in achieving weight loss with a less restrictive individualized hypocaloric diet (IHD).

Design: This was a weight-loss intervention study, which lasted for 3 months.

Subjects: Thirteen healthy participants who did not succeed at a previous RHD at the Stanford University General Clinical Research Center, were recruited for the study.

Intervention: Subjects were prescribed an individualized diet with the same caloric deficit as the previous RHD, ($BEE \times 1.5 - 750$ kcal), and were instructed to follow the program for 3 months. Weekly weights and food record evaluations were collected. Barriers to weight loss were rated using a Likert scale and were assessed at the beginning, in regards to the recent RHD they completed, and at the termination of the IHD weight loss program for all participants.

Main Outcome Measures: Weight, ratings of barriers to weight loss, and daily food records reporting estimated daily caloric consumption were measured.

Statistical analyses performed: Paired t-tests were used for data analyses of changes in weight, perceived barriers to weight loss between the RHD to the IHD, and reported kcal intake compared to estimated kcal intake given weight loss.

Results: Of the thirteen subjects, seven completed, and six terminated the program early. There was no significant weight loss or differences in the perceived barriers in the 7 participants who completed the study. In the participants who did not complete the study, two barriers were significantly changed from the RHD to the IHD. These individuals reported a decrease in the restricted nature of the diet and an increase in binge eating behavior. Analysis of the dietary records indicated that many of the participants were unsuccessful in estimating portion size and calories consumed.

Applications/Conclusions: These results indicate that less restricted diets were not successful in lowering perceived barriers or achieving successful weight loss in this population. The results of the present study emphasize the complexity of achieving successful weight loss in individuals who have experienced difficulty in previous attempts at weight loss.

Introduction

Obesity is a growing problem in the United States. Between 1991 and 2000 the rate of obesity increased dramatically and today it is estimated that 61% of the population are either overweight or obese (1). It is estimated that obesity is responsible for approximately 300,000 adult deaths in the U.S. each year (2). Chronic diseases associated with obesity include hypertension, cardiovascular disease, dyslipidemia, diabetes, gallstones, respiratory dysfunction, joint and low back pain, and certain forms of cancer (3,4). Obese people are at increased risk for morbidity and mortality compared to those who are not obese.

Due to the problems associated with obesity, many individuals repeatedly attempt to lose weight (5). Despite attempts, the success in reducing obesity in the American population has been very poor. Even those who manage to lose weight fail to maintain their weight loss (6,7). The rate of recidivism among individuals losing weight is nearly 100% with fewer than 5% of individuals maintaining weight loss for a period of 5 years (8). Extensive research has been done to identify why weight loss is so difficult for those who attempt to lose weight.

There are many barriers that individuals attempting to lose weight must overcome. Among the major ones are difficulty in estimating portion sizes, inability to find time to plan and eat meals, emotional eating, co-morbid depression, binge eating, stress and anxiety, lack of social support, lack of self-efficacy, and inadequate finances (8-13).

One predominant barrier to succeeding in a weight loss program, however, is that the diet plan is too restrictive and different from the individual's lifestyle (8). The majority of weight loss programs impose too many restrictions; restrictions of macronutrients, kilocalories, food choices, and even the time of day one eats. Research has shown that

small, moderate lifestyle changes that are gradually introduced are more likely to become part of one's permanent lifestyle and are more successful than radical changes in eating habits (14-16). It is, therefore, reasonable to suggest that a diet that makes one simple change, namely a caloric restriction, would have a higher likelihood of being incorporated into an individual's lifestyle successfully than a diet which has more restrictions. It can be argued that reordered eating with only a caloric restriction in the context of existing dietary patterns, or an individualized hypocaloric diet (IHD), may be more successful than a macronutrient restricted hypocaloric diet (RHD), which restricts not only the calories, but also the percentages of each macronutrient for each meal. Since the only change in the prescribed IHD diet is energy deficit, participants may view weight loss as a new adaptation of their old lifestyle, rather than a completely new restrictive way of living, and may perceive the task as more achievable. Though Coulston and Rock (17) have suggested that it is an adequate weight loss method, no research has been done to test the success of an IHD. The purpose of this study was to test the hypothesis of whether or not people who have not succeeded on past weight loss studies are more likely to succeed in less restrictive diets.

Subjects And Methods

Subjects

Healthy, insulin resistant males and females who were non-compliant on a previous protocol in the General Clinical Research Center at Stanford University Medical Center were recruited for this study (Protocol 650). Non-compliant participants were defined as those who were unsuccessful in achieving weight loss or those who withdrew from the study prior to completion of the protocol. None of the study participants had a prior

history of eating disorders. Inclusion criteria were good general health without clinical or biochemical evidence of diabetes, hepatic or renal disease, body mass index (BMI) between 29 and 36 kg / m², and between 30 and 70 years of age.

Study Design

Individuals who failed a previous GCRC protocol (RHD) were recruited to complete a second dietary protocol using individualized hypocaloric diets (IHD). The RHD was restricted not only in kilocalories, but also macronutrient composition and individual food choices. Basal energy expenditures (BEEs) were initially determined using the Harris-Benedict Equation and a 1.5 activity factor to estimate total energy requirement and hypocaloric diets were developed using a 750 kcal deficit. (18,19). Before being enrolled on the IHD, all participants received an initial dietary evaluation and interview to determine barriers experienced in the previous protocol (RHD). Ten common barriers to weight loss were assessed using a Likert rating scale(8-13). Individualized hypocaloric diets (IHD), were then developed for each of the participants. Individuals were instructed on how to count calories to adhere to the caloric prescription using their own individual dietary macronutrient patterns and food choices consistent with their individual lifestyle. BMI was calculated using a height meter tape and a digital scale. Participants kept daily food records of the caloric value and amounts of the foods consumed. Weekly meetings were held to monitor progress by obtaining body weight and evaluating food records. The duration of the study was 3 months, with an expected weight loss of 0.6 to 0.8 kg per week. At the completion of the study participants were scheduled for an exit visit and interview, which included a final weight and assessment of barriers experienced on the diet.

The study was approved by the Administrative Panel on Human Subjects at Stanford University School of Medicine, and all subjects gave written informed consent before participating in the study.

Data Analysis

The individual's change in body weight on the IHD intervention was evaluated as the difference from the initial visit to the final visit. Comparative statistics and paired t-tests were used to evaluate the change in body weight and caloric intakes. In addition, five samples of each participant's daily food records were randomly selected and analyzed for accuracy of caloric estimation and compliance with the prescribed caloric number (Food Processor, Nutrition and Fitness Software, ESHA Research, Inc., Version 7.9). The individual's assessment of the barriers on the RHD versus the IHD interventions were compared using paired t-tests.

Results

Thirteen individuals were enrolled in the study (Table 1). Seven completed and six failed to complete the three-month program. There were no significant differences in body weight in either of the groups. Of the seven subjects who completed the study the average wt loss was 2.3 kg over the three-month period. Only one participant succeeded in achieving the prescribed weight loss of 8.2 kg, while one person gained 1.6 kg. Of the participants who did not complete the study, four lost weight and two gained weight. Since the time each was on the study varied for the participants who did not complete the study, the means are given as kg/week. On the average those who lost weight, lost 0.24 kg / week, while those who gained weight, gained an average of 0.435 kg/week.

The participants' estimated maintenance caloric needs, kcal/day prescribed, reported daily kcal intake, computed daily kcal intake (using food records), and estimated daily kcal intake given the weight loss or gain are shown in Table 2. Since the average difference between the reported and computed daily intake were quantitatively small, only the reported data were used for comparison. The mean reported daily energy intake in those individuals who completed the study was 1551 kcal/day, while the estimated energy intake to achieve the observed weight loss was 2161 kcal/day. Thus, the estimated daily kcal intake of these individuals exceeded the reported intake by approximately 610 kcal ($p = 0.004$)

The results of the perceived changes in the ten common barriers experienced to weight loss are shown in Table 3. Among the seven individuals who completed the study, there were no significant differences noted in any of the barriers, although barrier 1 (difficulty estimating portion size) showed a marginally significant reduction ($p = 0.08$). Among the non-completed program participants, there were significant changes in two of the barriers, marginal changes in an additional barrier and no significant changes in the remaining seven barriers. In the barriers that were significantly changed, barrier 3 (diet and nutrition composition was too restrictive) was significantly reduced ($p = 0.025$), while barrier 5 (exceeded prescribed caloric intake due to binge eating) increased significantly ($p = 0.034$); barrier 2 (difficulty finding time to plan or eat meals) showed a marginal increase ($p = 0.076$).

Discussion

The hypothesis to be tested in the present study was that the individuals who were unsuccessful on the RHD would be more adherent and therefore more successful in

achieving the prescribed outcome weight loss on the IHD intervention. The results of the present study clearly indicate that the hypothesis was not supported. There were no significant reductions in overall weight for either the completed or non-completed program participants. Indeed, only one individual was successful in achieving the prescribed weight loss, while the remaining subjects experienced either small, non-clinically significant reductions, or gained weight over the duration of their participation.

For the participants who completed the study, none of the barriers to weight loss were significantly changed from the RHD to the IHD. Thus, individualizing their diet prescriptions failed to show significant reductions in any of the currently identified barriers. On the other hand, barrier 1, difficulty estimating portion sizes, was marginally reduced ($p = 0.08$) following the IHD. Because the participants were given individualized instruction on calorie estimation for the IHD, they may have perceived a reduction in this barrier. However, it would appear that the changes in this barrier were more perceived than real, given the significant differences between the reported kcal intake and the estimated kcal intake based on actual weight loss. The mean difference in the reported kcal intake and that estimated by actual weight loss suggest that difficulty estimating portion size still existed in these individuals as a barrier to weight loss.

There were greater changes in the barriers to weight loss perceived in those individuals who did not complete the study. For the participants who did not complete the study, there was a significant decrease in barrier 3, diet and nutrient composition was too restricted, and a significant increase in barrier 5, presence of binge eating behavior. The changes in these barriers, to a large extent, are contradictory. A less restrictive diet that is

more tailored to the lifestyle of the participant was hypothesized to be perceived as less restrictive and to lower the likelihood of a binge eating, since no foods were deemed “forbidden” or restricted. The changes in barrier 3 would have been predicted since the IHD, by definition, is less restrictive, and in that sense could be viewed as a self-fulfilling prophecy (why this was not also identified by the participants who completed the study is not apparent). On the other hand, the fact that there was a significant increase in perceived binge eating behavior does not support this notion. Perhaps this barrier may have increased in the IHD because the participants were allowed to consume the foods they liked, and could not exert sufficient control over their portions. It is also conceivable that these participants who dropped out of the study projected the fault of non-compliance on binge eating. Finally, in the group of non-completed program participants, difficulty in finding time to plan or eat meals (barrier 2) was marginally increased ($p = 0.08$). Perceived differences in this barrier is somewhat confusing, since this diet was structured around their current dietary pattern and lifestyle. It is possible that at least part of the reason that these individuals did not complete the study was due to these perceptions.

The data indicate that there was a significant difference between the recorded caloric intake, and the estimated daily caloric intake given the weight loss. This is indicative of underreporting, which has been shown to be a common problem in weight loss protocols (20, 21). This is also consistent with the marginal changes noted in the present study in regard to the perceived difficulty in estimating portion sizes. Although suggestive, it is not possible to determine from the present study if the underreporting was a reflection of the difficulty in estimating portion sizes.

In conclusion, the present study suggests that less restrictive individualized hypocaloric diets were not successful in facilitating weight loss in a population of individuals who were previously unsuccessful on more restricted hypocaloric diets. It could be argued that every population studied for weight loss has failed at least one previous weight loss attempt, and too many see weight loss as a set time period apart from their daily lives. Changing views of weight loss to one of adapting a slightly different lifestyle for life, rather than completely changing one's daily pattern only for a short period of time, is important. Cognitive restructuring, accompanying an IHD, may then be more successful in achieving weight loss than IHD alone. Further research is needed to determine additional strategies that would accompany a less-restricted, individualized, hypocaloric diet to achieve successful and lasting weight loss.

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Table 1

Completed and Non-Completed Program Participants' Initial Weight, Subsequent Weights, Weight Change, Estimated Weight Change / Week, Mean, SEM, and p-Value.

Participant	Initial Wt (kg)	Weight 1 mo (kg)	Wt: 2 mo (kg)	Wt: 3 mo (kg)	Wt. Change (kg)
COMPLETED					
1	88.3	87.2	86.7	87.4	- 0.9
2	111.1	107.3	106.0	102.9	-8.2
3	74.0	71.9	70.8	69.6	- 4.4
4	94.0	92.5	91.0	95.6	+1.6
5	99.1	98.3	96.7	96.1	- 3.0
6	81.0	79.5	80.8	79.5	- 1.5
7	88.2	86.8	87.3	87.3	- 0.9
Mean ± SEM	90.8 ± 4.6			88.5 ± 4.2 ^{NS*}	
NON COMPLETED					
					Est. wt change kg / wk
8	69.4	68.1	Dropped wk 6: Final wt 67.6		- 0.3
9	90.5	95.0	Dropped wk 6: Final wt: 95.1		+ 0.77
10	84.4	Dropped wk 4: Final wt: 83.7			- 0.175
11	82.5	Dropped wk 4: Final wt: 82.2			- 0.075
12	86.0	Dropped wk 4: Final wt: 86.4			+ 0.1
13	91.8	Dropped wk 4: Final wt: 90.1			- 0.425

* Significant p-value set at 0.05

Table 2

Completed Program Participants Estimated Kcal/Day to Maintain Weight, Kcal/Day Prescription, Reported Kcal/Day, Estimated Kcal/Day Intake Given Weight Change, Mean, and p-Value.

Participant	Estimated Kcal/Day to Maintain Wt	Kcal/Day Prescription (750 kcal deficit)	Participant Kcal/Day Reported (mean *)	Estimated Kcal/Day given wt. change	Difference btwn reported mean kcal/day and estimated kcal/day	p-value **
1	2331	1580 - 1600	1606	2248.5	642.5	
2	3163.5	2400 - 2420	1782.2	2413.5	631.3	
3	2289	1700	1470	1885.7	415.7	
4	2376	1650	1855.6	2522.7	667.1	
5	2089	1350	1058	1814	756.0	
6	2211	1460 - 1480	1505	2073.5	568.5	
7	2250	1500	1582.6	2167.5	584.9	
Mean ± SEM			1551.4 ± 97.9	2161.1 ± 98.4	610.1	0.004

* For each participant, n = 5 food records

** Difference between reported and estimated kcal intakes; significant p-value set at 0.05

Table 3

Completed Program Participants' Barrier Reduction: Mean, Standard Error of The Mean, and p-Value

Barrier	Pre-Test Mean $\pm$ SEM	Post-Test Mean $\pm$ SEM	p-value*
1. Difficulty estimating portion size	3.0 $\pm$ 0.4	2.1 $\pm$ 0.3	0.078
2. Difficulty finding time to plan or eat meals	2.9 $\pm$ 0.6	2.4 $\pm$ 0.4	0.559
3. Diet and nutrition composition too restrictive	2.4 $\pm$ 0.5	1.4 $\pm$ 0.3	0.156
4. Depression, stress, or anxiety lead to overeating	2.1 $\pm$ 0.5	2.6 $\pm$ 0.6	0.555
5. Exceeded prescribed daily caloric intake due to uncontrolled eating binges	2.4 $\pm$ 0.6	2.1 $\pm$ 0.3	0.766
6. Lack of support from spouse or friends	1.9 $\pm$ 0.5	1.5 $\pm$ 0.4	0.356
7. Lack of self-efficacy	2.2 $\pm$ 0.6	1.7 $\pm$ 0.4	0.427
8. Unsatisfied with weight loss progression and gave up	2.1 $\pm$ 0.6	2.0 $\pm$ 0.4	0.919
9. Did not feel satiated enough to maintain caloric restriction	2.0 $\pm$ 0.5	1.9 $\pm$ 0.3	0.895
10. The program was economically difficult to maintain	1.0 $\pm$ 0.0	1.0 $\pm$ 0.0	**

* Significant p-value set at 0.05

** p-value not calculated because there was no difference between the pre and post test

Table 4

Non-Completed Program Participants' Barrier Reduction: Mean, Standard Error of the Mean, and p-Value

Barrier	Pre-Test Mean $\pm$ SEM	Post-Test Mean $\pm$ SEM	p-value*
1. Difficulty est. portion size	2.1 $\pm$ 0.6	1.8 $\pm$ 0.5	0.665
2. Difficulty finding time to plan/eat meals	2.3 $\pm$ 0.5	3.3 $\pm$ 0.7	0.076
3. Diet and nutrition composition too restrictive	3.3 $\pm$ 0.4	2.0 $\pm$ 0.4	0.025
4. Depression, stress, or anxiety lead to overeating	3.6 $\pm$ 0.7	3.5 $\pm$ 0.7	0.363
5. Exceeded prescribed daily caloric intake due to uncontrolled eating binges	2.6 $\pm$ 0.5	3.2 $\pm$ 0.6	0.034
6. Lack of support from spouse or friends	1.7 $\pm$ 0.3	1.8 $\pm$ 0.4	0.897
7. Lack of self-efficacy	2.2 $\pm$ 0.5	2.8 $\pm$ 0.8	0.484
8. Unsatisfied with weight loss progression and gave up	3.0 $\pm$ 0.3	4.0 $\pm$ 0.4	0.111
9. Did not feel satiated enough to maintain caloric restriction	2.3 $\pm$ 0.3	2.3 $\pm$ 0.4	1.000
10. The program was economically difficult to maintain	1.0 $\pm$ 0.0	1.0 $\pm$ 0.0	**

* Significant p-value set at 0.05

** p-value not calculated because there was no difference between the pre and post test

CHAPTER III

SUMMARY AND RECOMMENDATIONS

REFERENCES

Summary and Recommendations

Obesity is implicated in the development of chronic disease, and most people who try to lose weight are unsuccessful. A major barrier to success is overly restrictive weight loss diets. The present study investigated whether a population that failed at a restrictive hypocaloric diet (RHD) weight loss program would be more successful in achieving weight loss with a less restrictive individualized hypocaloric diet (IHD). The results of the present study clearly indicate that the hypothesis was not supported. There were no significant reductions in overall weight for either the completed or non-completed program participants. Only one individual was successful in achieving the prescribed weight loss, while the remaining subjects experienced either small, non-clinically significant reductions, or gained weight over the duration of their participation. For the participants who completed the study, none of the barriers to weight loss were significantly changed, except difficulty estimating portion sizes was marginally significantly reduced. This may be reflected in the underreporting that occurred in the participants' food records. The data indicate that there was a significant difference between the recorded caloric intake, and the estimated daily caloric intake given the weight loss. However the present study's data was not conclusive enough to conclude that the underreporting and difficulty estimating portion sizes were related.

For the participants who did not complete the study, there was a significant decrease in barrier #3, diet and nutrient composition was too restricted, and a significant increase in barrier #5, presence of binge eating behavior. This contradicts the notion that a less restrictive diet that is more tailored to the lifestyle of the participant would lower the

likelihood of binge eating, since no foods were deemed “forbidden” or restricted. Perhaps this barrier may have increased in the IHD because the participants were allowed to consume the foods they liked, and could not exert sufficient control over their portions. It is also conceivable that these participants who dropped out of the study projected the fault of non-compliance on binge eating.

In conclusion, the present study suggests that less restrictive individualized hypocaloric diets were not successful in facilitating weight loss in a population of individuals who were previously unsuccessful on more restricted hypocaloric diets. It could be argued that every population studied for weight loss has failed at least one previous weight loss attempt, and too many see weight loss as a set time period apart from their daily lives. Changing views of weight loss to one of adapting a slightly different lifestyle for life, rather than completely changing one’s daily pattern only for a short period of time, is important. This type of cognitive restructuring, accompanying an IHD, may then be more successful in achieving weight loss than IHD alone. Additionally, as many of the common barriers to weight loss are of psychological origin, measures to resolve abnormal psychological relationships with food may need to be addressed for the success of any weight loss attempt. Using an IHD, but providing structure, such as giving specific amounts of the participant’s selected food choices, may be more successful in achieving weight loss. Furthermore, it is general clinical practice to use a rate of 1 – 1.5 pounds of weight loss per week for minimal loss of metabolically active tissue. However, this standard may be set too high. By spanning weight loss across a longer period of time, there will be less daily caloric restriction, and a possible higher success rate. When participants view their

more attainable weekly weight loss goal as achievable, their self-efficacy may subsequently increase. Further research is needed to determine additional strategies that would accompany a less-restricted, individualized, hypocaloric diet to achieve successful and lasting weight loss.

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APPENDICES

Appendix A

Participant Number, Barrier Number*, Pre-IHD Rating, Post-IHD Rating, Change in Ratings, Average Pre/Post Ratings, and Average Change For Completed and Non-Completed Program Participants.

Participant	Barrier #	Pre	Post	Change
Completed				
1	1	3	2	- 1
	2	4	1.5	- 2.5
	3	4	1	- 3
	4	1	3	+ 2
	5	1.5	2	+ 0.5
	6	4	3.5	- 0.5
	7	3.5	4	+ 0.5
	8	3.5	4	+ 0.5
	9	2	2.5	+ 0.5
	10	1	1	0
2	1	4	3	- 1
	2	5	2	- 3
	3	1	2	+ 1
	4	4	5	+ 1
	5	5	1	- 4
	6	3	1	- 2
	7	1	1	0
	8	1	1	0
	9	1	2	+ 1
	10	1	1	0
3	1	2	2	0
	2	2	2	0
	3	1	1	0
	4	1	2	+ 1
	5	1	1	0

* Specific barriers provided in Appendix B

	6	1	1	0
	7	1	1	0
	8	1	1	0
	9	1	1	0
	10	1	1	0
4	1	2	1	-1
	2	2	5	+3
	3	3	3	0
	4	2	1	-1
	5	2	3	+1
	6	1	1	0
	7	1	1	0
	8	2	3	+1
	9	2	3	+1
	10	1	1	0
5	1	3	3	0
	2	2	2	0
	3	3	1	-2
	4	2	4	+2
	5	2	3	+1
	6	1	2	+1
	7	2	2	0
	8	1	2	+1
	9	2	2	0
	10	1	2	+1
6	1	5	2	-3
	2	4	2	-2
	3	4	1	-3
	4	4	1	-3
	5	4	3	-1
	6	2	1	-1
	7	5	1	-4
	8	5	1	-4
	9	5	2	-3

	10	1	1	0
7	1	2	2	0
	2	1	2	+ 1
	3	1	1	0
	4	1	2	+ 1
	5	1	1	0
	6	1	1	0
	7	2	2	0
	8	1	2	+ 1
	9	1	1	0
	10	1	1	0
Mean (n=7)	1	3.00	2.14	- 1.14
	2	2.86	2.35	- 0.51
	3	2.43	1.43	- 1.00
	4	2.14	2.57	+ 0.43
	5	2.36	2.14	- 0.22
	6	1.86	1.50	- 0.36
	7	2.21	1.71	- 0.50
	8	2.07	2.00	- 0.07
	9	2.00	1.93	- 0.07
	10	1.00	1.00	0.00
Non-Completed				
8	1	1	1	0
	2	3	4	+ 1
	3	3	3	0
	4	5	5	0
	5	3	4	+ 1
	6	2	1	- 1
	7	2	4	+ 2
	8	3	4	+ 1
	9	3	3	0
	10	1	1	0
9	1	4.5	2	- 2.5

	2	2	5	+3
	3	2	1	-1
	4	3.5	3	-0.5
	5	4.5	5	+0.5
	6	1	2.5	+1.5
	7	4	1	-3
	8	4	4	0
	9	2	1	-1
	10	1	1	0
10	1	1	1	0
	2	2	2	0
	3	3	2	-1
	4	5	5	0
	5	3	4	+1
	6	1	1	0
	7	1	1	0
	8	3	3	0
	9	3	3	0
	10	1	1	0
11	1	3	4	+1
	2	2	3	+1
	3	5	3	-2
	4	5	5	0
	5	2	2	0
	6	2	2	0
	7	2	5	+3
	8	2	5	+3
	9	3	3	0
	10	1	1	0
12	1	1	2	+1
	2	4	5	+1
	3	3	2	-1
	4	2	2	0
	5	2	3	+1

	6	1	3	+ 2
	7	3	5	+ 2
	8	3	5	+ 2
	9	2	3	+ 1
	10	1	1	0
13	1	2	1	- 1
	2	1	1	0
	3	4	1	- 3
	4	1	1	0
	5	1	1	0
	6	3	1	- 2
	7	1	1	0
	8	3	3	0
	9	1	1	0
	10	1	1	0
Mean (n=6)	1	2.08	1.83	- 0.25
	2	2.33	3.33	+ 1.00
	3	3.33	2.00	- 1.33
	4	3.58	3.50	- 0.08
	5	2.58	3.17	+ 0.59
	6	1.67	1.75	+ 0.08
	7	2.16	2.83	+ 0.67
	8	3.00	4.00	+ 1.00
	9	2.33	2.33	0
	10	1.00	1.00	0

Appendix B

Barriers to Weight Loss Programs Ratings List

Rate on a 5 point Likert scale the extent to which each act as a barrier to your recent weight loss effort. (1= not at all a problem; 5 = a very big problem)

1. Difficulty estimating portion size:

1	2	3	4	5
---	---	---	---	---

2. Difficulty finding time to plan or eat meals:

1	2	3	4	5
---	---	---	---	---

3. Diet and nutrition composition was too restrictive:

1	2	3	4	5
---	---	---	---	---

4. Depression, stress, or anxiety leads to overeating:

1	2	3	4	5
---	---	---	---	---

5. Exceed prescribed daily caloric intake due to uncontrolled eating or experienced binge eating, an episodic consumption of large amounts of food accompanied by feeling a loss of control

1	2	3	4	5
---	---	---	---	---

6. Lack of support from spouse or friends:

1	2	3	4	5
---	---	---	---	---

7. Lack of self-efficacy:

1	2	3	4	5
---	---	---	---	---

8. Unsatisfied with weight loss progression and gave up:

1	2	3	4	5
---	---	---	---	---

9. Did not feel satiated enough to maintain caloric restriction:

10. The program was economically difficult to maintain:

Appendix C

Stanford University Human Subjects Approval Form

STANFORD UNIVERSITY
Stanford, California 94305-5401

David D. Oakes, M.D.
 CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS
 c/o Administrative Panels Office

(650) 724-8943
 (650) 725-8013 (fax)

Certification of Human Subjects Approval

Date: October 2, 2001

To: T. McLaughlin M.D.
 G. Reaven M.D.
 Department of

From: David D. Oakes, M.D., Chairman, Administrative Panel on Human Subjects in Medical Research

Protocol Title: Research title: Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk. (Grant title: GCRC Cap - Tracey McLaughlin.) (Supplement to GCRC Grant) (Includes Substudy: Simvastatin and Its Effect on Cholesterol and VLDL Receptors and Receptor Sites) Approval includes informed consents

Protocol Id: 73495 **Panel:** 1

The Panel approved human subjects involvement in your research project on October 2, 2001. If there is a contract involved, it must be signed before subject recruitment and enrollment.

The expiration date of this approval is October 1, 2002. If this project is to continue beyond that date, please submit an updated proposal in advance for the Panel's re-approval. If this proposal is used in conjunction with any other human experimentation or if it is modified in any way, it must be re-approved for these special circumstances. Note that all adverse events, occurring here and at other institutions, should be reported to the Panel regardless of whether or not the events are thought to be study related. You should also promptly report to the Panel any injuries to subjects.

All continuing projects and activities must be reviewed and re-approved at least annually by the Panel. Panel approval of any project is for a maximum period of one year. It is the responsibility of the investigator to resubmit the project to the Panel for continuing review.

Please remember that all data including all signed consent form documents must be retained for a minimum of three years past the completion of this research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, www.stanford.edu/dept/DoR/rph/2-10.html).

This institution is in compliance with requirements of protection of human subjects (45 CFR 46 and 21 CFR 56).

 David D. Oakes, M.D., Chairman

Approval Period: 10/02/2001 through 10/01/2002
Review Type: Regular - RENEWAL
Funding: - Supplement to RR00070: GCRC Cap - SPO: 23687
Assurance Number: FWA00000935
IRB Number: 1

Appendix D

Human Subjects Consent Form

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk
 Protocol 23687
 Division of Endocrinology, Stanford University
 Principle Investigator: Tracey Mc Laughlin
 October 2, 2001

CONSENT FORM**Insulin Resistance, Hyperinsulinemia, and Weight Loss****Experimental Subject's Bill of Rights:**

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to: be informed of the nature and purpose of the experiments; be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized; to be given a description of any attendant discomforts and risks reasonably to be expected; to be given an explanation of any benefits to the subject reasonably to be expected, if applicable; be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks and benefits; be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise; be given the opportunity to ask any questions concerning the experiment or the procedures involved; be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice; be given a copy of the signed and dated consent form; and be given the opportunity to decide to consent or not consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Informed Consent:

While participating in this study you should not take part in any other research project without approval from all the investigators. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

Are you participating in any other research studies? YES _____ NO _____

If you have donated blood within the last 6 weeks please let us know.

You have been asked to participate in a research project under the direction of Dr. Gerald Reaven and associates, which is designed to examine the response to weight loss with regard to insulin levels as determined by 1) inherited metabolic profile, 2) dietary composition, 3) diabetic medications. Insulin is a natural hormone that will cause your cells to remove glucose (sugar) from your blood. Individuals who are insulin sensitive are efficient at removing glucose (sugar) from the blood. Those individuals who are insulin resistant require more insulin to remove glucose (sugar) from the blood. One hundred and eighty participants will be enrolled in this study.

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk
 Protocol 23687
 Division of Endocrinology, Stanford University
 Principle Investigator: Tracey Mc Laughlin
 October 2, 2001

You will consume a low calorie diet as part of this study, and you will likely lose weight. We do not guarantee that you will lose weight, however. Your participation in this study may require admission to the Clinical Research Center for 3-4 days total. However, you may be out of the hospital on pass during times that tests are not being performed.

If you are on a lipid (cholesterol) lowering medication you may be asked to discontinue this for the duration of the study. We would ask you to discontinue the medication once it is determined that you qualify for this study.

Multiple blood samples will be taken throughout the duration of the study for measurement of blood sugar (glucose) and insulin concentrations and other laboratory test. Blood sampling is done by withdrawing blood from a vein/or placing an I.V. catheter (plastic tubing in your vein). This may cause some discomfort and carries a slight risk of infection, or bruising.

Insulin Sensitivity Test:

Prior to beginning the study, you must have your insulin sensitivity tested. Insulin resistance is related to both inherited and lifestyle factors, and is associated with obesity, diabetes, and coronary heart disease. The insulin sensitivity test is designed to measure how well your cells remove glucose (a type of sugar) from your blood in response to insulin. This test will involve the infusion of sugar, insulin and Octreotide (Sandostatin) by vein for three hours. You understand that during this test you have two small catheters (tubing) placed in your veins (I.V. lines). One of these will be used for blood drawing and the other for giving substances. Blood samples will be taken before, during and at the end of the infusion study. The total amount of blood that will be drawn from you during this study will not exceed 150 ml of blood (approximately 10 tablespoons). You have been informed that insulin is a natural hormone, and that sandostatin (a synthetic hormone) is a drug that temporarily blocks the secretion of insulin from your pancreas. This drug appears to be safe and has FDA approval for specific medical therapies. Dr. Reaven and his associates have received permission from the Food and Drug Administration to use sandostatin as an investigational drug in the procedure described above.

There are no serious adverse effects from the brief use of sandostatin in this study. However, there may be a transient (temporary) decrease in the pulse, and occasionally nausea and abdominal cramping can occur. On rare occasions episodes of diarrhea or loose stools have occurred several hours after the completion of the study.

You understand that insulin will cause your cells to remove glucose from your blood. It is possible that your blood glucose levels could become too low (hypoglycemia) during and immediately after the end of the study. In order to avoid this from occurring, your blood glucose levels will be measured during and after the study, and glucose will be given as needed to prevent hypoglycemia from occurring.

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk

Protocol 23687

Division of Endocrinology, Stanford University

Principle Investigator: Tracey Mc Laughlin

October 2, 2001

There is the risk of fever and sudden fall in blood pressure if the infusate solutions (substances given in your vein) are contaminated. However, you understand that the solutions are made from sterile components or substances tested for sterility before used in the preparation of the solutions, and the risk of contamination is very slight.

Comparison of Metabolic Response to Changes in the Type and Amount of Dietary Carbohydrate:

If you decide to participate, Dr. Gerald M. Reaven and associates will assign you to a low calorie research diet, individually tailored to your own metabolic rate. The composition of the test diets will contain either 40 or 60% of total calories as carbohydrates, 40 to 20% as fat and the remainder of total calories as protein. You will receive dietary counseling and advice from our research dietitians, and will prepare your own meals. Before and after six months of the research diet, you will be asked to participate in a meal profile study. You will be admitted to Stanford University Medical Center in the General Clinical Research Unit (GCRC). You may come in the evening before or the day of testing. You will be asked to fast for 12 hours prior to the study. On the day of the study a small catheter (plastic tubing) will be placed in your vein, and blood samples will be drawn before breakfast and then hourly for up to 8 HRS. You will be given lunch four hours after breakfast. You may go home when the study is completed. A history and physical exam will be done each time you are admitted to the GCRC for the meal profile study. The purpose of this diet phase of the study will be to examine the effects of variations in the composition of the diet on control of blood sugar and fats. The meal profile test will be done three times during this study, at the beginning of the study, immediately after the end of the diet period and after maintenance of weight loss (approximately two weeks after the end of the weight loss period).

At the discretion of the research dietitian, upon the completion of the study you may be asked to be followed for an additional 3 months by a dietetic intern under the supervision of our GCRC research dietitian for a continued weight loss program. No laboratory testing or other invasive testing will be done during this extended follow-up. This extended study will entail weekly visits at the GCRC for body weight measurement and to review food records. To participate in this additional program you will need to be, non-diabetic and in overall good health. If you were asked to go off any lipid lowering medications you can resume these medications.

Diabetic Medications:

If you are diabetic, you will be randomized to one of two diabetes medications: Rosiglitazone, an insulin sensitizer, or a sulfonylurea compound (e.g. Glipizide), an insulin secretagogue. Both of these medications help control blood glucose levels. Troglitazone, a drug of the same class as Rosiglitazone was associated with hepatitis, and in rare cases hepatic failure. So far, no liver problems have been reported with Rosiglitazone. However, because this drug is relatively new (on the market for about one year) we will be monitoring your liver enzymes monthly, and will

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk

Protocol 23687

Division of Endocrinology, Stanford University

Principle Investigator: Tracey Mc Laughlin

October 2, 2001

discontinue the drug if the liver enzymes are elevated. In addition, if your liver enzymes are elevated prior to beginning the study, you will be excluded from participating due to safety concerns. Sulfonylurea compounds can cause hypoglycemia. We will carefully monitor your dose so that the chance of this occurring is minimized. Symptoms of hypoglycemia include dizziness, hunger, shakiness, sweating and anxiety.

Adhesiveness of Monocytes to Endothelial Cells:

If you decide to participate, a fasting blood sample of 40 ml (approximately two and one half tablespoons) will be drawn from your arm for blood cell preparation. We will study the interaction of your monocytes (blood cells) with endothelial cells (lining of the blood vessel wall) in order to evaluate the early signs of atherosclerosis (hardening of blood vessels).

Brachial Artery Vasodilation Measurement – All participants will have this test

This is a test to evaluate the ability of your blood vessel to relax. This is a non-invasive test and takes approximately forty five minutes to perform. This test will be schedule on a separate day. An ultrasound (a-high-frequency sound-wave) probe will be used to take a picture of the blood vessel in your forearm. After a baseline picture is obtained, a blood pressure cuff will be inflated to 200mmHg on the arm for 5 min, just like having someone taking your blood pressure except it would be longer. The blood pressure cuff will then be released and pictures will be taken for the first 2 min after the cuff is released. Repeat pictures will be taken again 5 minutes later on the same arm. Then we will give you one tablet of sublingual nitroglycerin (0.4mg) which goes under your tongue. The blood vessel will then be imaged again for 4 minutes. Blood pressure and heart rate will be recorded during the test. Sometimes nitroglycerin can cause a headache (that usually only last a short while) or a drop in blood pressure that could cause you to feel faint. Because you will be lying down during the test this will probably not be a problem. If this does occur, let us know and we will elevate your legs and give you extra fluids if necessary. You will be monitored for 20 min post test to ensure there is no adverse affects such as low blood pressure.

Sub Study to Measure LDL Receptors

If you agree to participate in this study, you may be asked to participate in a sub study for three consecutive days. This will be described to you in a separate consent form. Choosing not to participate in the sub study will not effect your participation in this study.

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk
 Protocol 23687
 Division of Endocrinology, Stanford University
 Principle Investigator: Tracey Mc Laughlin
 October 2, 2001

Other:

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or breast feeding you may not participate in this drug study.

You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk. To confirm to the extent medically possible that you are not pregnant, you agree to begin the study after the onset of your next menstrual period. You must avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

ALTERNATIVES TO STUDY PARTICIPATION

Alternative treatments besides those mentioned above, for either weight loss or diabetes, will not be offered in this study.

You understand there are five different categories of oral (pills) medications available to treat diabetes. There are only two categories of oral medications available for treatment in this study. You understand you are free to ask any questions regarding available treatments and may choose not to participate after receiving information on other therapies without any prejudice to you or effect on your medical care. If you choose not to participate you will still be followed by your personal medical doctor for management of your diabetes.

In return for your participation in the study, you will receive a thorough medical evaluation, and, upon your request, this information will be forwarded to your personal physician. However, WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFIT FROM THIS STUDY.

This NIH (National Institutes of Health) is providing financial support for this study.

Any data that may be published in scientific journals will not reveal the identity of the subjects. Patient information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction. Any data under the investigator's control will be disclosed in a manner that does not reveal the identity of the subjects.

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk

Protocol 23687

Division of Endocrinology, Stanford University

Principle Investigator: Tracey Mc Laughlin

October 2, 2001

No payment will be provided for this project. There will be no additional cost to you for participating in this study.

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care. You will be told if any new information is learned which may affect your condition or influence your willingness to continue participation in this study. At the discretion of the protocol director you may be taken out of this study due to unanticipated circumstances. This may be: failure to follow instructions, you need treatment not allowed in this study, or for administrative reasons. If you have any questions, we expect you to ask us. Your decision whether or not to participate will not prejudice you or your medical care. If you have any additional questions later, please call Dr. Reaven or his associates at 650-723-7024 and they will gladly answer them.

All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury. In spite of all precautions, you may develop medical complications from participating in this study. If such complications arise, the researchers will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other cost. You do not waive any liability rights for personal injury by signing this form. For further information, please call (650) 723-5244 or write the Administrative Panel on Human Subjects in Medical Research, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401. In addition, if you are not satisfied with the manner in which this study is being conducted, or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same address and telephone number.

In the event of a research related injury call Dr. Mc Laughlin at 650-723-6661.

Insulin Resistance: Its Role in Weight Loss and Cardiovascular Risk
Protocol 23687
Division of Endocrinology, Stanford University
Principle Investigator: Tracey Mc Laughlin
October 2, 2001

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

Signature of Participant

Date

I attest that the requirements for informed consent or the medical research project described in this form have been satisfied-that the participant has been provided with the experimental subject Bill of Rights; if appropriate, that I have discussed the research project with the participant and explained to him or her in non technical terms all of the information contained in this informed consent form, including any risks or adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent

Date

Approval Date: October 02, 2001

Expiration Date: October 01, 2002

Appendix E

San Jose State University Human Subjects Approval Form

San José State
UNIVERSITY

**Office of the Academic
Vice President**

**Academic Vice President
Graduate Studies and Research**

One Washington Square
San José, CA 95192-0025
Voice: 408-283-7500
Fax: 408-924-2477
E-mail: gradstudies@sjsu.edu
<http://www.sjsu.edu>

To: Dr. Clarie Hollenbeck
Department of Nutrition & Food Science
San José State University
One Washington Square, CCB-107
San José, CA 95192-0058

From: Nabil Ibrahim
AVP, Graduate Studies & Research

Date: December 4, 2002

The Human Subjects-Institutional Review Board has approved your request to use human subjects in the study entitled:

"Barrier Reduction in Individualized vs Restricted Diets."

This approval is contingent upon the subjects participating in your research project being appropriately protected from risk. This includes the protection of the anonymity or confidentiality of the subjects' identity when they participate in your research project, and with regard to any and all data that may be collected from the subjects. The approval includes continued monitoring of your research by the Board to assure that the subjects are being adequately and properly protected from such risks. If at any time a subject becomes injured or complains of injury, you must notify Nabil Ibrahim, Ph.D. immediately. Injury includes but is not limited to bodily harm, psychological trauma, and release of potentially damaging personal information. This approval for the human subjects portion of your project is in effect for one year, and data collection beyond December 4, 2003 requires an extension request.

Please also be advised that all subjects need to be fully informed and aware that their participation in your research project is voluntary, and that he or she may withdraw from the project at any time. Further, a subject's participation, refusal to participate, or withdrawal will not affect any services that the subject is receiving or will receive at the institution in which the research is being conducted.

If you have any questions, please contact me at (408) 924-2480.

The California State University:
Chancellor's Office
Bakersfield, Channel Islands, Chico,
Dominguez Hills, Fresno, Fullerton,
Hayward, Humboldt, Long Beach,
Los Angeles, Maritime Academy,
Monterey Bay, Northridge, Pomona,
Sacramento, San Bernardino, San Diego,
San Francisco, San José, San Luis Obispo,
San Marcos, Sonoma, Stanislaus