

ARIC Manuscript Proposal # 828

PC Reviewed: 09/18/01
SC Reviewed: 09/18/01

Status: A
Status: A

Priority: 2
Priority: 2

1.a. Full Title: Beneficial Effects of 5 -15% Weight Loss on Metabolic Risk Factors for Type 2 Diabetes and Cardiovascular Disease

b. Abbreviated Title (Length 26 characters): Modest Weight Loss

2. Writing Group (list individual with lead responsibility first):

Lead: Kimberly P. Truesdale
Address: UNC-CH School of Public Health
McGavran-Greenberg Hall CB # 7435
Chapel Hill, NC 27599
Phone: 919-966-0117 Fax: 919-966-8392
E-mail: Kim_Truesdale@unc.edu

Writing group members: Kimberly Truesdale, June Stevens, and Jianwen Cai

3. Timeline: Dataset preparation and analysis will start immediately upon approval. We plan to complete the analysis and manuscript in one year.

4. Rationale:

In the United States, the prevalence of obesity increased dramatically from NHANES II (1976-1980) to NHANES III (1988 –1991) [Flegal, 1998]. Based on the estimates from NHANES III, 22.5% of the adults (20 – 74 years of age) were obese (BMI \geq 30.0 kg/m²) and an additional 32.0% were pre-obese (BMI 25.0 – 29.9 kg/m²) [Flegal, 1998]. The prevalence of obesity varies by ethnicity and gender where African American women, at 37.4%, had the highest prevalence compared to White women, White men and African American men. In general, both men and women tend to gain weight until around the age of 55, then they tend to lose weight [Williamson, 1993]. Stevens et al (1998) have shown that among African American men and White men and women in the ARIC cohort, average weight gain was approximately 8 pounds per decade over a period of 3 decades following age 25. For African American women, weight gain was approximately double that amount. The rate of weight gain is generally highest during early adulthood [Williamson, 1990]. The NHEFS found that 27.3% of women and 33.3% of men 45 to 64 years of age lost 5 – 14.9% of their body weight during a 10-year period (1971-1975 to 1982-1984) [Williamson, 1993].

Obesity increases the risk of type 2 diabetes and cardiovascular disease. It is also associated with high blood pressure, high levels of total- and LDL-cholesterol, triglycerides and fasting serum glucose and low levels of HDL-cholesterol [NHLBI, 1998]. Several prominent researchers and clinicians have advocated an initial goal of a 10% weight loss for overweight and obese individuals [NHLBI, 1998; Wadden, 1999; Goldstein, 1992; Blackburn,

1995; de Leiva, 1998]. This goal is based on evidence from weight loss trials that have shown that risk factors for diabetes and CVD are significantly reduced by a relatively small amount of weight loss [Goldstein, 1992; Blackburn, 1995; NHLBI, 1998; de Leiva, 1998].

The focus of this research will be to determine if over a 3-year period individuals with this modest weight loss (5-15%) attain risk factor profiles equivalent to levels of individuals who maintained the lower body weight over the same 3-year period. In other words, can a physician tell a patient that if you lose weight, you will have the same risk of developing type 2 diabetes or CVD as an individual who maintained their body weight? This concept is analogous to the issue of whether individuals who quit smoking acquire the same risk profile as never-smokers. Our question is also related to, but different from, research on weight cycling. Weight cycling research has examined whether individuals who have lost and gained weight several times are at higher risk of developing chronic disease compared to weight stable individuals with the same BMI [NTFPTO, 1994]. Our interest is to compare the levels of risk in individuals who have lost weight to those who were at that weight (the acquired weight after weight loss) over a period of time. We know of no other studies that have focused on this issue.

5. Main Hypothesis/Study Questions:

The objective of this study is to determine if a person who loses weight attains the same metabolic risk levels as a weight stable person with the same BMI. The metabolic risk factors that we will examine are systolic and diastolic blood pressure, total-, LDL- and HDL-cholesterol, triglycerides and fasting serum glucose. We will use mixed models for the analysis [Littell, 1996].

Study Questions

1. Determine whether individuals who lose weight over a 3-year interval attain the same mean levels of risk factors for diabetes and CVD as individuals with the same BMI who have maintained their weight over the interval.
2. Determine the odds of individuals with modest weight loss after 3 years having the metabolic risk factor level above the normal limit compared to weight stable individuals with the same BMI?

Hypothesis

After 3 years of follow-up subjects with the same BMI will have similar mean levels of metabolic risk factors for diabetes and CVD regardless of whether they maintained their weight during the interval or attained the current BMI after a 5 – 15% weight reduction.

6. Data (variables, time window, source, inclusions/exclusions):

OUTCOME:

The outcome variables of interest for the proposed study are systolic and diastolic blood pressure, total-, LDL- and HDL-cholesterol, triglycerides and fasting serum glucose. For the analysis of the first study question the outcome variables will be continuous. For the analysis of the second study question the outcome variables will be dichotomized (normal vs. high risk).

EXPOSURE:

The exposure variable of interest for the proposed study is percent weight change between examinations. This will be calculated as follows:

$$\% \text{ wt} \Delta_{j,j+1} = ((\text{weight}_j - \text{weight}_{j+1}) / (\text{weight}_j)) * 100$$

where, j = visit number (1st, 2nd, or 3rd)

% wt $\Delta_{j,j+1}$ = percent weight change between the jth and (j+1)th visits
weight_j = participants weight at the jth visit

We will create three percent weight change categories: small weight losers (5 – 9.9% weight reduction between visits); ideal weight losers (10.0 - 15.0% weight reduction between visits) and weight maintainers (less than or equal to 2.0% difference in weight between visits).

COVARIATES:

The following variables will be examined: BMI, age, ethnicity, gender, center, education, smoking status, drinking status, physical activity, and dietary intakes.

EXCLUSIONS:

- Non-African American or White participants
- African American participants from the Minnesota or Maryland centers
- Participants who died within 1 year of follow-up
- Participants missing weight

7.a. Will the data be used for non-CVD analysis in this manuscript? ___ Yes X No

b. If Yes, is the author aware that the file ICTDER02 must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used? ___ Yes ___ No
(This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? ___ Yes X No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = “No use/storage DNA”? ___ Yes ___ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: <http://bios.unc.edu/units/csc/ARIC/stdy/studymem.html>

X Yes ___ No

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