



Abstract

Grant Number: 5U01DK057136-03

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PI Title: PROFESSOR

Project Title: HEALTH OUTCOMES OF WEIGHT-LOSS: DATA COORDINATING CENTER

Abstract: *This proposal describes plans by an experienced group of investigators and staff at the Wake Forest University School of Medicine (WFU) to serve as the Coordinating Center (CoC) for the Study of Health Outcomes of Weight-Loss (SHOW). SHOW is a multicenter randomized trial designed to test whether weight loss interventions can reduce the progression of carotid atherosclerosis and other health outcomes in a cohort of 6000 obese type 2 diabetics. Participants will be randomized to one of 3 intervention arms: intensive lifestyle intervention (diet and exercise), intensive lifestyle intervention plus pharmacotherapy, or community control. The primary outcome is carotid intimal medial thickness. Secondary outcomes include cardiovascular (CV) and cerebrovascular events and death, CV risk factors, and glycemic control. Participants will be recruited over a 3-year period with 4-7 years of intervention and follow-up. WFU plans to operate the CoC for the SHOW trial. In that role, we will provide expert statistical support for sample size, data analyses and interpretation; collaborate in the design of SHOW and provide all supporting study documents including manuals and data collection forms; design and implement a web-based data management system; plan and support recruitment, retention, the implementation of the intervention, and adherence; subcontract with all Core Facilities (e.g., central laboratory); train and certify staff; perform study administrative duties; and participate in paper-writing.*

Thesaurus Terms:

human therapy evaluation, noninsulin dependent diabetes mellitus, obesity, weight loss atherosclerosis, carotid artery, chemotherapy, clinical trial, cooperative study, diet,

*disease /disorder proneness /risk, exercise, outcomes research
clinical research, human subject, nutrition related tag*

Institution: WAKE FOREST UNIVERSITY
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Fiscal Year: 2001

Department: PUBLIC HEALTH SCIENCES

Project Start: 30-SEP-1999

Project End: 31-AUG-2006

ICD: NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND
KIDNEY DISEASES

IRG: ZDK1

