Tufts UNIVERSITY | Jean Mayer United States Department of Agriculture Human Nutrition Research Center on Aging

HealthyWeight FOR LIVING

International Obesity and Health Consortium
Concept Brief

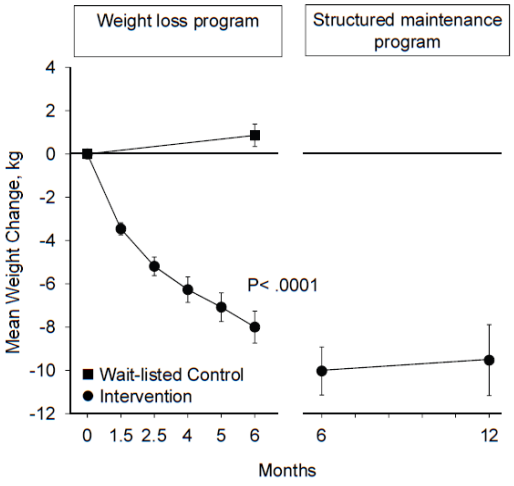
Summary: An International Obesity Consortium is being formed to identify common and unique factors that contribute to obesity and related diseases including diabetes and cardiovascular disease in different countries. This information will be used to develop country-specific interventions for effective, sustainable weight loss and improved health.

Background

The obesity epidemic is the major public health crises of our time. The detrimental impact of excess weight is now seen in almost every country worldwide, and the effects are far reaching—including increased rates of chronic diseases including diabetes and cardiovascular disease, impaired cognitive performance, and, in employees, high medical costs and increased absenteeism and presenteeism [1, 2].

The Jean Mayer USDA Human Nutrition Center on Aging at Tufts University has an internationally recognized group of research scientists and physicians specializing in adult weight control for prevention of obesity-related diseases. The team is committed to helping resolve the obesity crisis by leading a scientific breakthrough in sustainable, scalable weight control programs in high-risk countries, and is forming an *International Obesity Consortium* to achieve this goal. Benefits of being part of the consortium will include collaborating with an international team on a topic of great importance and access to standardized methodology and expert training for the research.

Preliminary Work



The Energy Metabolism Laboratory at Tufts University has just completed a highly successful randomized trial demonstrating the most effective weight management program to date in worksites [3-5] and the program has also recently been used in community groups with equivalent success. Average net weight loss over a 6 month period in overweight and obese worksite employees was 20 lbs when using the new Healthy Weight for Living (HWL) intervention, an amount *which was three times greater than the typical weight loss in previous equivalent studies.* There were also substantial reductions in the cardiovascular risk factors assessed: fasting blood glucose, total and LDL cholesterol and blood pressure in parallel to weight changes. Moreover, weight loss of this magnitude has the potential to reverse recent diagnoses of diabetes and prevent the development of numerous diseases associated with excess weight. Of particular significance, there were substantial documented changes in *food preferences*, which are expected to facilitate sustainability of results over time. Participants lost weight even during the most challenging U.S. Holiday season encompassing Thanksgiving, Christmas and New Year. The program was well received and popular. A low intensity maintenance program was provided on a monthly basis for 6 months

after the weight loss phase and, as demonstrated in the figure, it was highly successful in preventing weight regain. These results demonstrate a substantial advance in weight management that, when adapted to the specific issues of other countries can potentially make a major contribution to reducing the obesity epidemic worldwide.

Additional highlights of the Tufts Healthy Weight for Living program:

- There was an enormous *interest* in the program: ≈50% of eligible (i.e. overweight and obese) individuals offered the program signed up.
- 89% of subjects in this study were active participants throughout 6 months of sustained weight loss, demonstrating its *acceptability* to participants.
- There were numerous reports of *reduced comorbidities and medication use*, improving health and transformed quality of life that will be formally captured as outcomes in our next studies.
- Two different interventionists delivered the HWL program and obtained comparable rates of success, indicating that the existing *training program is effective*.

International Healthy Weight for Living Overview

We will start this initiative with a cross-sectional study of predictors of obesity in three countries, and will use this information to develop and test scalable weight control programs specifically adapted for effectiveness in each country. Leadership for cross-sectional studies and method development will be provided by Dr Sai Das, and the intervention component of the study will be led by Dr Susan Roberts. Dr Edward Saltzman will provide leadership in medical aspects of healthy weight control. As described above, the team has already completed a highly successful study of a science-based program for long-term weight control in U.S. adults that will provide an important available resource for accelerating progress in the International Obesity Consortium projects.

In pursuit of our mission, the program is planned in three distinct phases:

Phase One 2013	Conduct a pilot feasibility cross-sectional study of predictors of obesity in 3 countries with high rates of obesity, including validating methodology for parameters being measured in the study. This work has previously been demonstrated to be feasible in China and will now be conducted in 3 additional international sites with appropriate levels of expertise to conduct a high-quality study. As additional sites sign on to participate in the program they will be provided with the methodology for the pilot so they can be included in the Phase One research that will determine eligibility for Phase Two.
Phase Two 2014-2015	Secure funding to conduct powered cross-sectional study in each participating country that has demonstrated method feasibility in the pilot study. Data will be analyzed to inform adaptation of the HWL intervention in each country.
Phase Three 2015-2017	Secure funding to test International HWL adaptations for weight loss and health risk reduction in a 12-month randomized trial in each country.

Phase One (2013)

A pilot cross-sectional study of predictors of BMI will be conducted in each new site to determine feasibility of examining predictors of obesity. While some of the key variables to be measured in this study have been included in previous investigations, no study has focused exclusively on obesity and included the necessary range of parameters needed in a focus on

obesity. Moreover, since self-reported data is an essential component of the work, we need to demonstrate that we can accurately collect this data in each different population.

Diet, physical activity, eating behavior, attitudes to weight and eating and relevant environmental factors will all be measured with common methodology across sites, and validation studies will be conducted for key measurements to ensure that accurate measurements are being obtained. For example, dietary records are critically important because they will tell us not just about calorie and macronutrient intakes, but other important dietary variables such as dietary variety and also meal patterns. We will therefore validate dietary records against physical activity and measured metabolic rate in each country during Phase One.

40 adult women aged 40-60 years will be recruited in each site for Phase One. Half the subjects will be lean (BMI 20-25 kg/m2) and half will be obese (BMI 30-40 kg/m2). All will be literate and able to complete study requirements, and will not have any diagnosed unstable chronic diseases (e.g. cardiovascular disease, diabetes). Examination of the validity of the different methods will be determined by comparison of relationships between different parameters with relationships reported in the literature. Power calculations will be performed to determine the number of subjects that will be needed for a powered trial demonstrating significant predictors of BMI in a larger study.

Resources provided by Tufts University Team: Tufts University will provide a common protocol, manual of procedures for methods, and training for each method in Boston. In addition Tufts will set up a website for data entry and will visit each site to trouble shoot methodology while the study is in progress. Tufts will also analyze food samples by bomb calorimetry for each site so that we have a second check on the dietary records of obese and lean subjects in each site. Tufts will additionally provide statistical direction and SAS codes for common analyses, advice with writing country-specific papers from the pilot, and provide page charges for a manuscript that combine data from all sites. One Tufts investigator with expertise for each region has been identified, ensuring that each site receives specific expert collaboration from Tufts.

Resources provided by International Sites: Each participating site will provide funding for Phase One so that we can obtain the preliminary data needed for being competitive for Phase Two funding. It may be possible to have a graduate student use this project for an MS or PhD thesis at relatively low cost, or to add measurements onto an existing study. On top of personnel resources, the sites will need to fund stipends for subjects (if used), pedometers, weight scale and height measurements, shipping charges for samples to Tufts, and additional miscellaneous needs such as a visit to Boston for the Investigator Training meeting in April 2013 and page charges for site-specific manuscript publication. A formal invitation to give a talk at Tufts will be provided to each site Principal Investigator to facilitate local support for the study and attending the meeting.

Study oversight: A Steering Committee will be formed including the Principle Investigators for each site and the Tufts investigator liaison for each site. The Steering Committee will meet by teleconference once per month during Phase One to ensure progress and to help resolve problems that arise.

Phase Two (2014-2016)

Following successful completion of Phase One, the team will seek international funding to conduct a powered cross-sectional study in each site, including all sites that have demonstrated

method validity in the pilot. Potential sources of funding for this work include governments in each site, NIH and WHO.

Phase Three (2016-2019)

Following successful completion of Phase Two that informs us on the specific obesity challenges in each country, the team will adapt the HWL intervention for each site and will seek funding to test the adapted versions for effectiveness and sustainability. Potential sources of funding for this work include governments in each site, NIH and WHO.

Summary

Resolving the worldwide obesity epidemic is one of the central challenges of our time. By using results from research on successful approaches to weight loss in the U.S., this study will bring advanced research capabilities to bear on resolution of the epidemic in other countries that also need urgent help.

International Healthy Weight for Living Team at Tufts University

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