

Notice of Opportunity for Collaboration
The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
For Urinary Incontinence Exercise Programs

The National Institute of Diabetes and Digestive and Kidney Disease of the National Institutes of Health (NIH) seeks collaboration with industry or non-profit organizations to provide exercise programs to be used in a NIH-sponsored multi-center clinical trial in women with urinary incontinence undergoing fitness, exercise, and education training program in their communities.

INTRODUCTION: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks collaborations with Industry, Corporations, and Non-Profit Organizations to provide exercise teaching programs and fitness educational material in both general fitness and pelvic floor specific exercises for women with stress urinary incontinence. The trial will be a prospective, randomized, controlled trial of community-dwelling women with urinary incontinence who agree to participate in one of 2, 11-12 week community based fitness programs: (1) one aimed at general health and fitness; and (2) one which incorporates exercises and behavior training for the pelvic floor and bladder in addition to general health and fitness.

STUDY GOALS: Primary study goal is to identify if differences exist in resolution of urinary incontinence symptoms in women participating in an 11-12 week, fitness and education program directed at pelvic health when compared to women participating in a similar program directed at general fitness and health. This study is within the UITN's primary mission of conducting clinical trials to forward research in urinary incontinence.

SUPPLEMENTAL INFORMATION: In 2000, the NIDDK established the Urinary Incontinence Treatment Network (UITN). The purpose of the UITN is to conduct high quality randomized controlled clinical trials of urinary incontinence. The UITN has completed three trials, the first comparing two surgical procedures for women with stress urinary incontinence, "A Randomized Clinical Trial of the Burch Modified Tanagho and Autologous Fascia Sling Procedures." The second trial compared adding behavioral therapy to patients on pharmaceutical drugs to test if patients can discontinue drugs sooner and have a sustained effect, the "Behavior Enhanced Drug Reduction of Incontinence Trial (BE-DRI). The third trial is a surgical trial, comparing two different approaches for mid-urethral slings, "Retropubic Mid-urethral Sling (RMUS) vs. Transobturator Mid-Urethral Sling (TOMUS)".

This proposed protocol for comparing exercises has been recently approved by the UITN Steering committee and reviewed by an independent NIDDK-appointed Data and Safety Monitoring Board.

The two-armed study will enroll approximately 230 women with 135 women randomized into each arm. Follow up will occur at the end of class and at one year. Enrollment will occur at nine participating clinical centers (William Beaumont Hospital, Loyola University, University of Alabama at Birmingham, University of California at San Diego; University of Maryland, University of Pittsburgh, University of Texas at Dallas; University of Texas at San Antonio, and the University of Utah). Central data collection and analysis will occur at the NIDDK funded Data Coordinating Center at the New England Research Institutes. Although the patient recruitment is anticipated to

begin in the spring to summer 2009, the collaborator(s) will, nonetheless, have the opportunity to comment on the study protocol. It is anticipated that the duration of this trial will be at least one year, with a three-six month recruitment period. The collaborator(s) will need to provide exercise programs, training for their exercise program for fitness trainers, and educational programs as needed. The Collaborator(s) is (are) expected to provide the products and training for free without charge. The Collaborator(s) may have access to information about the outcome of the study at the same time as the participating investigators. A Collaborative Agreement between the NIDDK and the Collaborator(s) will need to be executed prior to shipment of the products or placement kits or surgical instruments.

CAPABILITY STATEMENTS: The UITN Steering Committee will utilize the information provided in the “Collaborator Capability Statements” to aid in their selection of collaborator(s). It is the intention of the NIDDK that qualified applicants will have the opportunity to provide information to the UITN Steering Committee through their capability statements. Organizations can apply to provide either exercise program or both. The Capability Statement should not exceed 10 pages of narrative (not including appendices) and should address the following selection criteria:

- (1) Details on the type and goals of the exercise program to be offered.
- (2) Detailed plan demonstrating the ability to provide sufficient quantity of exercise program and for providing adequate training on use of the exercise program.
- (3) Detailed methodology of the fitness program, duration, and effectiveness of the exercise program with the intended goals of either general fitness or pelvic floor specific exercise.
- (4) Detailed plan of commitment to collaborate in the trial for the duration of the trial and willingness to promptly publish research results.
- (5) Detailed listing of the educational materials available and fitness accessories (if applicable) to accompany the fitness program.
- (6) Detailed plan to train fitness instructors at all the multi-clinical sites of this network to teach the exercise program. Plan can include instructional videos or a multi-day in-person instruction at the beginning, followed by up to 4 follow up in-person visit.
- (7) A description of the methods that would be used to assure patient privacy and maintain confidentiality of data.
- (8) The statement may include outcome measures of interest to the Collaborator. The specifics of the proposed outcome measured and the proposed support should include but not be limited to treatment of stress urinary incontinence.

SUBMISSION DATES: Only written capability statements received by the NIDDK on or before April 10, 2009 will be considered. Applicants meeting the criteria as set forth in this announcement will be invited at the Applicants own expense to discuss with the UITN Steering Committee their plans and capabilities pertinent to the study either with a teleconference or at a in-person meeting of the UITN Steering Committee to be held in the Spring of 2009 in the Baltimore-Washington, DC area.

TERMS: The selected Collaborator(s) will be expected to execute a collaborative agreement. No funding from the government is available.

CONTACT INFORMATION: Submit statements of interest and Capability Statements to:

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A formatted version of the Notice of Opportunity will be posted at:
http://techdev.niddk.nih.gov/_PDFs/UITN.Exercise.NOO.pdf.