DGIM Project Summary
Lessening Incontinence through Low-impact Activity (LILA)

Principal investigator(s):
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Research question(s):
1) To examine the feasibility of recruiting and retaining ambulatory women aged 50 years and older into a randomized trial of a yoga therapy versus physical conditioning program for treatment of incontinence.
2) Explore whether a clinically meaningful reduction in incontinence frequency could be detected in a full-scale trial of yoga versus physical conditioning.
3) Explore potential effects of yoga versus physical conditioning on other symptom and quality-of-life outcomes associated with incontinence.

Brief Background/Significance:
Approximately one in four middle-aged and older women suffer from urinary incontinence, a condition associated with depression, social isolation, functional decline, falls and fractures, and admission to long-term care facilities. Current first-line treatment for both stress- and urgency-type incontinence includes behavioral management strategies such as bladder re-training and pelvic floor exercises to increase bladder capacity, strengthen the muscles supporting the bladder neck, and suppress involuntary bladder contractions. Unfortunately, many patients who attempt to practice these techniques after routine teaching by general practitioners are not able to do so effectively. Although the efficacy of these techniques can be improved by in-depth, one-on-one training and biofeedback with pelvic physical therapists or other specialized medical practitioners, this type of intensive pelvic floor rehabilitation therapy is costly, and access to trained pelvic physical therapists is limited.

Second-line treatment for urgency-type incontinence (i.e., leakage caused by a sudden urge to void) consists primarily of anticholinergic drugs that are modestly effective in reducing incontinence, but have multiple side effects such as dry mouth, stomach upset, constipation, and cognitive impairment. As a result, over half of patients who initiate anticholinergic therapy discontinue it within a year. For stress-type incontinence (i.e., leakage with activities that increase abdominal pressure), surgery and other invasive procedures can be effective, but are inappropriate or poorly tolerated by many patients, especially older women who are at greatest risk of incontinence. There is a need for alternate therapies that that are not only effective, but also more accessible and better tolerated.

Yoga is a complementary behavioral intervention with the potential to improve incontinence through multiple mechanisms, while avoiding the shortcomings of existing therapies. When taught in a way that emphasizes mindful awareness of specific bodily structures, yoga can be used to help women control and strengthen their pelvic floor muscles through group instruction and home practice. As a result, a group-based yoga program that incorporates practice of specific yoga postures to promote awareness and engagement of the pelvic floor may provide a more accessible alternative to traditional, one-on-one pelvic floor rehabilitation therapy, provided that it can be taught in a standardized way that is appropriate for patients’ clinical and safety needs.

Inclusion Criteria:
• Women aged 50 years or older who report urinary incontinence starting at least 3 months prior to screening
• Self-report at least required frequency of urinary incontinence episodes on a screening 3-day voiding diary
• Self-report urgency-predominant, stress-predominant, or mixed-type incontinence on a voiding diary
• Willing to refrain from initiating treatments that may affect their incontinence during the study

Exclusion Criteria:
• Participation in formal or organized yoga classes or instruction within the past 3 months; or any prior yoga therapy directed specifically at improving urinary incontinence
• Participation in at least weekly organized physical conditioning classes or instruction in the past 3 months involving muscle stretching and strengthening exercises
• Currently pregnant (by self-report or screening urine pregnancy test), gave birth within the past 6 months, or planning pregnancy during the study period (approximately 2 to 6 months)
• Current urinary tract infection (screening dipstick urinalysis with leukocyte estrace, nitrites or blood) or a history or 3 or more urinary tract infections in the preceding year
• Report history of neurologic conditions such as stroke, multiple sclerosis, spinal cord injury, or Parkinson's disease, or a lumbosacral spine condition associated with neurological symptoms
• Unable to walk up a flight of stairs or at least 2 blocks on level ground (i.e., functional capacity < 4 METs), or unable to get up from a supine to a standing position in 10 seconds or less
• Morbid obesity defined by a measured body mass index of >40 kg/m² at the screening evaluation.
• Report any history of prior anti-incontinence or urethral surgery (not including urethral dilation), pelvic cancer, or pelvic irradiation for any reason
• Report use of bladder botox, electrostimulation, bladder training, or pelvic floor exercise training (with certified practitioners) in the past 3 months
• Report other surgery to the pelvis (hysterectomy, oophorectomy, vaginal surgery, bladder surgery, colon surgery) within the past 3 months
• Report use of medications with the potential to affect incontinence (e.g., anticholinergic bladder medications, tricyclic antidepressants, mirabegron, loop diuretics) within the past month
• Report starting stopping, or changing the dose of a medication with the potential to affect anxiety or stress symptoms within the past 1 month
• Report use of medical devices (i.e. pessary) for incontinence within the previous month (participants may stop use of device and re-present for study)
• Report history of interstitial cystitis, fistula or hole in bladder or rectum, or birth defect leading to urine leakage
• Report symptomatic pelvic organ prolapse, vulvodynia, chronic pelvic pain, or pain when practicing pelvic floor exercises
• Participation in another research study that involves investigational drugs or devices that could potentially confound the results of this study
• Unable to understand study procedures, complete study interviews, or and provide informed consent in English

Method of contact/recruitment (for this DGIM proposal):
Posting of recruitment fliers and postcards in the practice waiting room

Benefits/burden for participants (clearly identify potential for harm):
Participation may improve participants’ incontinence and general health. The intervention programs involve low-risk behavioral interventions, and all study procedures are non-invasive.

Any benefits or burden to DGIM practitioners?
We do not anticipate any direct benefits, nor any direct burdens.

Timeline for recruitment (projected start and stop dates):
2/2015-6/2016

Funding source:
National Center for Complementary and Integrative Health (NCCIH)

Potential for DGIM collaborators:
Yes, please speak to principal investigator

Do you agree to notify us when recruitment is completed?
Yes

Date form completed:
February 3, 2015