DGIM Project Summary
Controlling Urgency with Relaxation Exercises (CURE)

Principal investigator:
Alison Huang, MD, ahuang@ucsfmed.org

Research question(s):
To determine whether a device-guided slow-breathing exercise program can reduce the frequency and severity of OAB symptoms in women, as well as improve associated autonomic nervous system imbalance and anxiety-related symptoms.

Brief Background/Significance:
Nearly one in five adult women suffer from overactive bladder, a syndrome characterized by recurrent, strong urges to void, increased frequency of daytime or nocturnal voiding, and in many cases involuntary leakage of urine when women are unable to get to the toilet in time. Among women in the community, OAB is associated with sleep disruption, social isolation, decreased work productivity, sexual dysfunction, and depression. When further complicated by involuntary urine leakage (i.e., urgency incontinence), OAB can also lead to falls and fractures, increased caregiver burden, and loss of ability to live independently, with potentially devastating consequences for quality of life.

Currently, the most widely used treatments for OAB are anticholinergic drugs that can decrease involuntary bladder contractions, but are associated with multiple problematic side effects such as dry mouth, constipation, and even cognitive impairment, especially in older women. As a result, many clinicians are reluctant to prescribe these drugs to older women, and at least half of women who start anticholinergic drugs for OAB discontinue them in less than a year. While behavioral treatments such as pelvic floor exercises can be effective in reducing OAB, these are only modestly effective in the absence of time-intensive, one-on-one training with physical therapists. At this time, there is an urgent need for alternate therapies for OAB that are more effective, better tolerated, and more widely generalizable.

To address this possibility, we propose to conduct a randomized trial of a mindfulness-based slow-breathing technique that has previously been shown to decrease anxiety and improve autonomic control. Women with OAB will practice slow-breathing exercises at home using a commercially-available guided-breathing device that requires limited individual instruction, is relatively inexpensive, and is FDA-approved for treatment of hypertension—another chronic condition associated with both autonomic dysfunction and anxiety. To enable rigorous evaluation of efficacy, women will be randomized to: 1) use a standard guided-breathing device to practice slowing their respiratory rate to 5 to 10 breaths per minute (BPM) for a minimum of 15 minutes per day (consistent with recommended use of the device to treat hypertension), or 2) use a visually-identical control device reprogrammed to promote breathing at a normal resting rate of 14 BPM. All women will also receive a pamphlet with information about behavioral self-management of OAB, consistent with usual care.

Inclusion Criteria:
- Women aged 21 years or older who are able to walk to the bathroom without assistance
- Report recurrent episodes of urgency (sudden or strong urges to urinate) beginning at least 3 months prior to screening
- Able to record all voiding and incontinence episodes on a screening 3-day voiding diary and rate the severity of urgency associated with each episode using a validated urgency severity scale
- Document at least 9 voiding or incontinence episodes on the above 3-day voiding diary that are associated with at least moderate sensation of urgency (using the above urgency severity scale)
- Willing to refrain from initiating other treatments that may affect voiding during the trial period

Exclusion Criteria:
- Use of anticholinergic OAB medications or other medications known to affect urinary function (i.e., diuretics, tricyclic antidepressants) within 1 month of screening
- Current urinary tract infection (detected via screening dipstick urinalysis or urine culture) or a history more than 3 urinary tract infections in the preceding 1 year
- Prior history of lower urinary tract surgery, pelvic cancer, or pelvic irradiation; or other pelvic or abdominal surgery within 6 months of screening
• History of interstitial cystitis, fistula in the bladder or rectum, or congenital or childhood defect leading to chronic urinary incontinence, retention, or other chronic urinary symptoms
• Known history of major neurologic conditions likely to have major or permanent effects on bladder function such as stroke, multiple sclerosis, spinal cord injury, or Parkinson's disease
• Use of bladder botulinum injections, electrostimulation, or other invasive therapies for OAB or incontinence within 3 months of screening
• Formal pelvic floor rehabilitation or other formal behavioral therapy for bladder symptoms involving a physical therapist or other certified practitioner within 3 months of screening
• Started, stopped, or changed dosage of a psychoactive medication likely to affect anxiety within 3 months of screening, or plans to start, stop, or change dosage during the trial
• Resting blood pressure (average of 2 measures) less than 100/60 at screening (women with baseline low blood pressure may theoretically be at increased risk of hypotension with use of RESPeRATE)
• Resting breathing rate already below 10 breaths/minute before treatment
• History of chronic pulmonary disease likely to interfere with breathing exercises (e.g., emphysema)
• Currently pregnant, gave birth within the past 3 months, or planning pregnancy during the study
• Unable or willing to sign an informed consent, fill out questionnaires, or undergo study procedures

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’ bladder symptoms and also offer benefits for anxiety and hypertension. The interventions pose minimal risks, 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):
9/2014-9/2017

Funding source:
National Institute on Aging (NIA)

Potential for DGIM collaborators?
We would welcome involvement by DGIM fellows or residents

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

Date form completed:
February 3, 2015