DGIM Project Summary
(1 page preferred, 2 pages maximum)

Name of Project: Menopausal Treatment Using Relaxation Exercises (MaTURE) Study

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
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Research question(s):
1) determine the efficacy of slow-paced respiration using the relaxation device to reduce the frequency of hot flashes.
2) determine the efficacy of slow-paced respiration on other symptom and quality-of-life outcomes associated with hot flashes.
3) determine if improvement in frequency of hot flashes with paced respiration is mediated by reduction in sympathetic nervous system activity, relative increase in parasympathetic activity, or parameters of slow-paced respiration.

Brief Background/Significance:
Hot flashes occur in as many as two thirds of U.S. women during menopause and are severe enough to require treatment in 20%. Although postmenopausal hormone therapy is an effective treatment, it is associated with increased risk for a variety of serious adverse effects. There is currently an urgent need for alternative treatments that are effective, safe, and easy to use.

Inclusion/exclusion criteria (list)

Inclusion criteria
• Women aged 40 through 59 years at the time of their screening visit
• Peri- or postmenopausal, as defined by one of the following:
  1) Self-reported history of bilateral oophorectomy (complete removal of both ovaries), with or without history of hysterectomy
  2) Serum FSH levels ≥ 30 mU/mL (must be checked if women have a history of hysterectomy without bilateral oophorectomy)
  3) No history of hysterectomy or bilateral oophorectomy, but fewer than 10 menstrual periods in the past year
• Adequate adherence to study interventions and procedures during a 1-week run-in period using the RESPeRATE control device, including:
  o ambulatory hot flash monitor showing at least 72 hours of total recording time during run-in
  o hot flash diary successfully completed on at least 6 days during run-in
  o RESPeRATE device documenting at least 6 separate days of use during run-in
  o RESPeRATE device showing at least 12 minutes of use on each of at least 6 days during run-in
• Documentation of an average of at least 4 hot flashes per 24 hours as recorded by both the hot flash monitor and the hot flash diary
• Capable of understanding study procedures and giving informed consent
• Willing to refrain from using other treatments for hot flashes during the study period

Exclusion criteria
• Currently pregnant or breastfeeding, or have been pregnant or breastfeeding in the past year
• Use of medications known to affect the frequency or severity of hot flashes within 3 months of screening (estrogens, progestins, testosterone, clonidine, methyldopa, selective serotonin reuptake inhibitors, gabapentin, raloxifene, tamoxifen, aromatase inhibitors).
• Resting blood pressure (average of 2 measures) less than 100/60 (women with pre-existing low blood pressure may be at increased risk for symptomatic hypotension with use of the RESPeRATE device) at the screening or baseline visit
• Baseline spontaneous resting breathing rate less than 10 BPM (average of 2 measures obtained over 30 seconds at the screening visit)
• Requiring chronic medical therapy for pulmonary disease such as emphysema, chronic bronchitis, asthma, or chronic obstructive pulmonary disease.
• Known sensitivity to adhesives such as band-aids or surgical tape (which may generalize to the hot flash monitor electrodes)
• Cardiac pacemaker or implanted defibrillator (which may be disrupted by ambulatory hot flash monitor sensing of these devices)
• No access to a telephone (given the need to participate in follow-up telephone calls)
• Plans to travel via airplane during the period of wearing the ambulatory hot flash monitor (the monitor would need to be removed before passing through airport security)
• Plans to move out of the area in the 3 months following the screening visit
• Inability to sign an informed consent, participate in screening interviews, or understand and complete questionnaires in English during screening visits
• Report conditions that, in the judgment of the investigators, render potential participants unlikely to follow the protocol, including plans to move, substance abuse, significant psychiatric problems, or dementia

Participation in another research study that involves investigational drugs or devices that could potentially confound the results of this study

Method of contact/recruitment (be specific)
• Mailing letters to a database of women with hot flashes who have given permission to be contacted about future research opportunities
• direct community-based media efforts (newspaper notices, radio advertising, brochures in local clinics, talks to local community groups, notices in churches)
• social media/networking sites and direct recruitment from physician offices (specifically in gynecology, primary care, and alternative medicine clinics).

Benefits/burden for participants (clearly identify potential for harm)
The relaxation device is a commercially-available guided-breathing device (Costco, Amazon) that is FDA-approved for treatment of mild hypertension and widely used without a prescription. Risk to participants from use of the device is minimal; in clinical trials that included over 492 participants, no side effects were reported. Additionally, our research team observed no side effects in our previous feasibility trial of 12 women treated with slow paced respiration. The effect of RESPeRATE on blood pressure decreases with lower baseline blood pressure such that it does not lower blood pressure in persons with baseline less than about 120 mmHg systolic.

Any benefits or burden to DGIM practitioners? Minimal, flyers in clinic space

Timeline for recruitment (projected start and stop dates) : January 2012 -July 2013

Funding source? NIH

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular) Possible.

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

Date form completed: 02/27/2012