SHAPE Study Results

One in three women will die from cardiovascular disease (CVD), making CVD the number one cause of death in women. After menopause, women have a higher risk for heart disease, possibly due to the loss of the female hormone estrogen. One potential reason for this is that decreasing levels of estrogen have been shown to cause the cells that line the arteries to become damaged and the arteries surrounding the heart to “stiffen.” These changes in artery health can lead to the development of CVD.

The purpose of the SHAPE (Sex Hormones and Atherosclerosis Prevention in Perimenopausal Women) study was to find out how decreases in the female sex hormone estrogen with the menopause transition cause arteries to become unhealthy. We used ultrasound imaging to assess the health of the carotid (in the neck) and brachial (in the arm) arteries in women who were premenopausal (normal menstrual cycles), perimenopausal (irregular menstrual cycles), or postmenopausal (no menstrual cycles in over a year). SHAPE found that carotid and brachial artery health was progressively impaired across the menopause transition groups, with premenopausal women having the healthiest arteries and postmenopausal the least healthy. SHAPE also found that artery health became impaired in premenopausal and perimenopausal women when estrogen levels were lowered with a medication, suggesting that estrogen has a beneficial effect on artery health. To understand how estrogen benefits artery health, SHAPE examined whether giving the antioxidant vitamin C improved vascular health. Vitamin C improved vascular health in late perimenopausal and postmenopausal women, meaning that the decline in vascular health with decline in estrogen was related in part to oxidative stress. Oxidative stress occurs when the production of molecules that can damage cells in the body outpaces the body’s ability to neutralize them.

NEW STAFF ANNOUNCEMENT

Kelly Downing earned her PhD in Nutritional Sciences from the University of Kentucky and completed a one-year postdoctoral fellowship at Stanford University before moving to Colorado to continue her postdoctoral work under the mentorship of Dr. Kerrie Moreau. Dr. Downing has previously used mouse models to study risk factors for cardiovascular disease and is excited to join the IMAGE group to gain valuable translational and clinical research experience. Drs. Downing and Moreau will work together on the SHAPE-2 study to investigate the effects of estrogen and oxidative stress on vascular function.

SHAPE 2

The results from SHAPE have led to a new study called SHAPE-2. SHAPE-2 will test whether low levels of tetrahydrobiopterin (BH4), a natural substance in the body that can cause the arteries to expand, explain how oxidative stress damages arteries in women with low levels of estrogen. To answer this question, SHAPE-2 will examine whether giving a medication that increases BH4 level improves vascular health in perimenopausal and postmenopausal women. These studies will contribute to the understanding of how decreases in estrogen levels as women go through menopause may contribute to the development of CVD. SHAPE-2 is currently enrolling healthy women aged 18 to 70 years of age. For more details and contact information, please see SHAPE-2 under “Studies for Women” on page 2.

IMAGE Summer Party

Tuesday, June 17, 2014
4:00-6:00 PM

Keep an eye out for the invitations. The Summer party is at the same location as last year’s party (Trivisible room in RC2). Reserve the Date !!!

Directions and parking details can be found at www.medschool.ucdenver.edu/image

(...and, yes, the chocolate fountain will be in attendance)
**NEW STUDIES FOR WOMEN & MEN:**

**SPARX** is a study to determine whether individuals recently diagnosed with Parkinson’s disease, and have not yet started drug treatment, can successfully take part in an aerobic exercise program. Individuals with PD are randomized to a control group that does not exercise, or to a group that exercises on a treadmill at a moderate or high intensity. Participants will exercise 4 days a week, for 30 minutes a day, for 6 months. If you or someone you know has been diagnosed with Parkinson’s disease and is interested in participating in this clinical research, please contact Drew Hepler at 720-848-6480, or Andrew.Hepler@ucdenver.edu. (COMIRB# 11-1237)

The Determination of Pain Phenotypes in Older Adults with Knee Osteoarthritis study is exploring what causes pain with knee osteoarthritis. We are looking for people aged 50 to 85 years old and with knee pain to attend a single testing session at the Anschutz Medical Campus (~2 hours) to explore factors that contribute to knee pain. Monetary compensation provided. To learn more, please email KNEEPain@ucdenver.edu or call 303-724-9590. (COMIRB# 11-1237)

**Sita Study** is a study to determine whether individuals recently diagnosed with Parkinson’s disease, and have not yet started drug treatment, can successfully take part in an aerobic exercise program. Individuals with PD are randomized to a control group that does not exercise, or to a group that exercises on a treadmill at a moderate or high intensity. Participants will exercise 4 days a week, for 30 minutes a day, for 6 months. If you or someone you know has been diagnosed with Parkinson’s disease and is interested in participating in this clinical research, please contact Drew Hepler at 720-848-6480, or Andrew.Hepler@ucdenver.edu. (COMIRB# 11-1237)

Leg Blood Flow Study: This is a study evaluating men and women with or without type 2 diabetes during single leg calf exercise. We are evaluating the function of heart and blood vessels during exercise. Eligible participants are healthy men and women with type 2 diabetes (not using insulin) between the ages 30-70 years who are non-smokers and currently exercise no more than once per week. To learn more, please call Drew Hepler at 720-848-6480, or email Drew.Hepler@ucdenver.edu. (COMIRB# 11-1237)

The AcT2 study is looking at a medication called acipimox and its effects on type 2 diabetes and exercise capacity. Study participants will be financially compensated and receive no-cost lab screenings, physical exams, exercise testing and more. Participants will be asked to take the investigational drug or placebo for 2 weeks on two separate occasions. If you are a non-smoker, age 30-60 with type 2 diabetes that does not require insulin, and you exercise less than 1 hour per week, then this study could be for you! If interested, contact Shawna McMullin at Shawna.mcmullin@ucdenver.edu or call 303-724-2255 or (PT: Regensteiner, COMIRB# 10-1393).

**The TEMPSU study** will examine whether one week of estrogen has different effects on insulin metabolism in women who are only a few years past menopause compared to women who are many years past menopause. Eligible participants are healthy women between the ages of 45 and 70 years who are not using hormone therapy and who are either within 6 years of menopause or more than 10 years past menopause. Volunteers will be asked to wear estrogen patches for one week prior to one of two study visits, and then to participate in a study designed to measure insulin metabolism. Up to $400 in compensation will be provided for participation in the study. To learn more, please email: Tracy.Swibas@ucdenver.edu or call 720-848-6418. (COMIRB# 12-1157)

The B-WELL study is to test whether decreasing time spent sitting and adding short intervals of walking improves the health of older adults. Participants will exercise 4 days a week, for 30 minutes a day, for 6 months. If you or someone you know has been diagnosed with Parkinson’s disease and is interested in participating in this clinical research, please contact Drew Hepler at 720-848-6480, or Andrew.Hepler@ucdenver.edu. (COMIRB# 13-2594).

**STUDIES FOR WOMEN:**

The FAME study is examining how the loss of estrogen changes metabolism and risk of disease in women. Eligible participants are healthy women between the ages 45 and 70 years who are not using hormone therapy and who are either within 6 years of menopause or more than 10 years past menopause. Volunteers will be asked to wear estrogen patches for one week prior to one of two study visits, and then to participate in a study designed to measure insulin metabolism. Up to $400 in compensation will be provided for participation in the study. To learn more, please email: Tracy.Swibas@ucdenver.edu or call 720-848-6418. (COMIRB# 12-1157)

The GEM study investigates the relationship between volume of aerobic exercise and positive changes in DNA methylation over four months among previously sedentary women and whether aerobic exercise reversibly influences DNA methylation in genes associated with breast cancer. We are looking for women between the ages of 30 and 45 who plan to live in the Denver Metro area for the next 10 months. Eligible participants should not be exercising regularly but should be willing to participate in an exercise program 4 times per week for 16 weeks. Monetary compensation will be provided for time (up to $300). To learn more, please call 303-492-9549 or email: GEM.CUstudy@gmail.com. (COMIRB# 13-2314)

**SHAPE 2** is a study to investigate how the menopause transition and the loss of estrogen impacts the health and function of arteries in women. We are looking for Premenopausal women 18-49 years, Perimenopausal women 40-55 years and Postmenopausal women 45-70 years (non-smokers). Volunteers should NOT be taking Birth Control or Hormone Replacement Therapy (HRT), or exercising vigorously more than 2 days per week. To learn more, please call Lila Sisbarro at 720-848-6419 or email shape.study@ucdenver.edu. (PI Kerrie Moreau COMIRB# 06-0537).

To learn more about a study, offer comments, suggest an article, request this newsletter electronically or be removed from our mailing list contact: Drew Hepler, 720-848-6480, Andrew.Hepler@ucdenver.edu.