

S-1.

**Caregiving Burden Linked to More Menopause Symptoms**

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**Objective:** As the US population ages, the need for family caregiving increases. A typical caregiver in the US is a partnered, middle-aged woman. Many women caregivers find themselves in the "sandwich generation" where they may be caring for both children and parents. Caregiving has been associated with adverse outcomes including a higher risk of anxiety, depression, and coronary heart disease. Employed midlife women caregivers are more likely to quit or change their jobs compared to non-caregivers. Limited literature has evaluated the impact of caregiving on menopause symptoms. This study aimed to assess the association between caregiving and menopause symptom burden in midlife women. **Design:** A cross-sectional analysis from the Hormones and Experiences of Aging (HERA) study was undertaken utilizing questionnaires completed by women aged 45-60 years receiving primary care at one of four Mayo Clinic geographic locations between March and June 2021. Caregiving status was assessed by asking the participants whether they were currently caring for or making healthcare decisions for someone with a medical condition or disability. Participants were also asked about care recipients and their conditions, time spent providing care, and their daily stress levels. Menopause symptoms were assessed using the Menopause Rating Scale (MRS) which consists of 11 items including somatic, psychological, and urogenital domains. Each item is scored on a scale from 0 to 4 for severity. The cut-off score for moderate or greater menopause symptom burden is 8 for the somatic and psychological domains, and 6 for the urogenital domain. The association between caregiving status and moderate or greater menopause symptom burden on at least one MRS domain was evaluated using a multivariable logistic regression model adjusting for caregiver relationship status, employment, current hormone therapy use, and daily stress levels. **Results:** A total of 4295 women were included in the analysis, 19.7% of whom were caregivers. Women were of mean age 54.6 yrs, White (96.6%), partnered (77.9%), educated (93.5% with at least some college), employed (91.6%), and 37.6% had moderate or greater menopause symptoms in at least one domain. Women were classified according to the number of hours/week spent caregiving: no caregiving, <5 hrs/week, 5-14 hrs/week and ≥15 hrs/week. Caregivers were evenly distributed among the three caregiving groups. The proportion of women who had moderate or greater menopause symptoms in at least one domain increased sequentially as the number of caregiving hours increased: 34.1% in the <5 hrs/week group, 42.6% in the 5-14 hrs/week, and 50.4% in the ≥15 hrs/week (p<0.001). In the univariate analysis, caregiving for ≥15 hrs/week significantly increased the odds of having moderate or greater menopause symptoms in at least one domain compared to no caregiving (OR 1.77, 95% CI 1.39-2.26, p<0.001); this was noted across all symptom domains. The association remained significant in multivariable analysis after adjusting for potential confounders (OR 1.57%, 95% CI 1.22-2.02, p<0.001). **Conclusion:** This cross-sectional study is the first to identify an association between caregiving hours and menopause symptom burden. With the expected increase in the demand for caregiving on midlife women as the population ages, there is a critical need for efforts to improve menopause care and to provide support for women in this transition. Further, women with menopause symptoms should be assessed for potential contributing factors, including the stress brought on by caregiving in order to provide appropriate counseling, treatment, and support.

**Sources of Funding:** None

S-2.

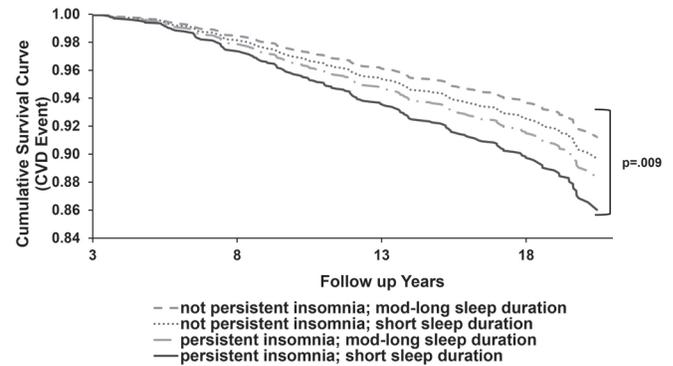
**Trajectories of Sleep Over Midlife and Cardiovascular Disease Risk: The Study of Women's Health Across the Nation**

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**Objective:** Poor sleep is common over midlife and the menopause transition. Poor sleep has been linked to cardiovascular disease (CVD) risk, but little work considers sleep patterns over midlife. We tested how insomnia and sleep duration trajectories over two decades of midlife were related to CVD events in women. **Design:** Participants were 3016 (48% White, 28% Black, 8% Chinese, 9% Japanese, 7% Hispanic) women in the Study of Women's Health Across the Nation aged 42-52 years, pre- or early perimenopausal, and free of hormone therapy and CVD at baseline. They completed up to 16 visits over 22 years, including questionnaires [insomnia symptoms: trouble falling asleep, waking during the night, waking earlier than desired; sleep duration; vasomotor symptoms (VMS); depressive symptoms], height, weight, blood pressure,

phlebotomy, and CVD event ascertainment (fatal/nonfatal myocardial infarction, stroke, heart failure, revascularization). Trajectories of insomnia symptoms or sleep duration were determined via group-based trajectory modeling and next tested in relation to CVD in Cox Proportional Hazards models (covariates site, age, race, education, CVD risk factors, and additionally, VMS, snoring, depression). **Results:** Four trajectories of insomnia symptoms emerged: few insomnia symptoms (38%), moderate insomnia declining over time (19%), insomnia increasing over time (20%), and persistent insomnia (23%). Women with persistent insomnia had increased CVD risk [HR=1.69(95%CI:1.18, 2.41), p=.004, vs. low insomnia, multivariable]. Three trajectories of sleep duration were: persistent short (5 hrs: 14%), moderate (6 hrs: 58%), and long (8 hrs: 28%). Women with persistent short sleep had marginally increased CVD risk [HR=1.48(95%CI:0.99, 2.22), p=.06, vs. moderate, multivariable]. Women with both persistent insomnia and short sleep were at highest CVD risk [HR=1.89, 95%CI(1.18, 3.04), p=.009, relative to low insomnia/moderate-long sleep duration, multivariable; Figure]. Relations of insomnia to CVD persisted also adjusting for VMS, snoring, or depression. **Conclusion:** Insomnia symptoms, when persistent over midlife or occurring with short sleep, may increase women's risk for CVD. Poor sleep should be targeted with sleep interventions.

**Sources of Funding:** Funding: NIH, DHHS, via NIA, NINR, ORWH U01NR004061; U01AG012505, U01AG012535, U01AG012531, U01AG012539, U01AG012546, U01AG012553, U01AG012554, U01AG012495, U19AG063720



**Insomnia-sleep duration trajectories in relation to CVD, multivariable**

S-3.

**Cost-Effectiveness of Sequential Abaloparotide/Alendronate for US Women and Men With Osteoporosis and a Recent Vertebral Fracture**

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**Objective:** Osteoporosis affects about one in three women and one in five men aged >50 years. Despite a vertebral fracture substantially increasing the risk of a subsequent fracture, a vast majority of US women and men with osteoporosis and a recent vertebral fracture are not treated with an osteoporosis medication. There is increasing evidence suggesting the clinical benefits of sequential treatment with an anabolic (such as abaloparotide [ABL]) followed by an antiresorptive (such as alendronate [ALN]) in patients at very high fracture risk. However, no evidence supports the cost-effectiveness of this treatment strategy in patients with a recent vertebral fracture. Given the increasing importance of efficiently allocating scarce resources, this study was designed to assess the cost-effectiveness of sequential ABL/ALN compared to relevant treatment strategies in both US women and men with osteoporosis and a recent vertebral fracture. **Design:** An economic model designed from the US healthcare decision-maker perspective was used to estimate the lifetime costs and health outcome (expressed in quality-adjusted life years [QALYs]) of sequential ABL/ALN compared to a similar sequence starting with another anabolic (unbranded teriparatide [TPTD]), to ALN monotherapy and to no treatment. The population included US women and men aged 50 to 80 years with a recent vertebral fracture and densitometry-confirmed osteoporosis (bone mineral density T-score ≤-2.5). Model data were derived from US literature and approved by US clinical experts. The incremental cost-effectiveness ratios (ICERs) expressed in costs (in 2022 dollars) per QALY gained were estimated for sequential ABL/ALN compared to each alternative strategy. If the ICER fell below the US cost-effectiveness threshold valued at \$150,000 per QALY gained, sequential ABL/ALN was considered cost-effective. Probabilistic sensitivity analyses were conducted to assess the effects of joint uncertainty across most input parameters. **Results:** In all simulations, sequential ABL/ALN was associated with more QALYs for lower costs compared to sequential unbranded TPTD/ALN. Furthermore, sequential ABL/ALN was cost-effective compared to no treatment and ALN monotherapy in men aged ≥50 years and women aged ≥55 years. The probabilistic sensitivity analyses suggested that sequential ABL/ALN was cost-effective in 86% of the simulations in women aged 70 years at the US cost-effectiveness threshold compared to 1%, 13%, and 0% for unbranded TPTD/ALN, ALN monotherapy, and no treatment, respectively. Similar probabilities in men were 90% (sequential ABL/ALN), 8% (sequential unbranded TPTD/ALN), 2% (ALN monotherapy), and 0% (no treatment). **Conclusion:** This study suggests that sequential ABL/ALN led to more QALYs for less

costs than sequential unbranded TPTD/ALN, and is cost-effective compared to ALN monotherapy in US women aged  $\geq 55$  years and men aged  $\geq 50$  years with osteoporosis and a recent vertebral fracture.

**Sources of Funding:** This study was funded by Radius Health, Inc.

#### S-4.

##### Long-term cognitive effects of menopausal hormone therapy: Preliminary data from the KEEPS Continuation Study

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**Objective:** Findings from the Kronos Early Estrogen Prevention Study (KEEPS)-Cog trial suggested no cognitive benefit or harm after 48 mos of early postmenopausal hormone therapy (HT) taken in early menopause. Long-term effects of early menopausal HT are understudied. The KEEPS-Continuation reevaluated cognition, mood, and neuroimaging effects in KEEPS women, ~10 yrs after randomization (~6 yrs after trial completion). Preliminary cognitive findings are presented here. **Design:** Women enrolled in KEEPS were randomized to placebo or HT [oral conjugated equine estrogens (oCEE+progesterone) or transdermal 17- $\beta$ -estradiol (tE2+progesterone)] for 48mos. After ~10 yrs (M(SD)=9.57(1.08) yrs), KEEPS-Continuation assessed long-term HT effects. Cognitive tests from KEEPS and KEEPS-Continuation were analyzed as 4 factor scores. Because KEEPS-Continuation visits occurred 8-14 yrs post-randomization, Linear latent growth models (LGM) with distal outcomes, tested whether baseline cognitive performance and change-in-cognition across KEEPS visits predicted "distal" KEEPS-Cognition cognition, and whether HT randomization modified this relationship. Covariates included education, age, and APOE4 carrier status. LGMs summary fit measures were assessed along with residuals for mean and covariance. **Results:** Of KEEPS enrollees, N=299 (41%) participated in KEEPS-Continuation. Similar health characteristics were observed at randomization for participants (age<sub>mean</sub>=65.8; range: 56-71) and non-participants (i.e. women not enrolled in KEEPS-Continuation). For women in the KEEPS-Continuation, cognitive performance was not influenced by either HT formulation. Instead, models showed strong associations between baseline and change-in-cognition during KEEPS and the same measures in KEEPS-Continuation (**Table 1**); i.e., strongest predictor of cognitive performance in KEEPS-Continuation was cognitive performance in KEEPS. KEEPS-Continuation cross-sectional comparisons confirmed that both HT-groups performed similarly to placebo on cognitive measures. **Conclusion:** Preliminary KEEPS-Continuation analyses detected no long-term cognitive effects of short-term (48mos) menopausal HT vs placebo. Subsequent analyses will examine the influence of HT vs. placebo on mood and amyloid PET, and non-randomized use of HT post KEEPS on all outcomes. These data provide important information for recently menopausal women with good cardiovascular health considering HT for menopausal symptoms.

**Sources of Funding:** NIH/NIA RFA057547

Association of KEEPS baseline cognition and slope (change over time in cognition during KEEPS) with later cognition (KEEPS Continuation)

Cognitive Tests	oCEE		tE2	
	Estimate (95% Confidence interval)	P-Value	Estimate (95% Confidence interval)	P-Value
Association between change over time in cognition at KEEPS and later cognition				
SLOPE of Verbal Attention & Executive Function performance	0.011 (-0.088, 0.110)	0.832	-0.022 (-0.121, -0.077)	0.657
SLOPE of Speeded Language & Mental Flexibility performance	-0.005 (-0.108, 0.098)	0.924	-0.013 (-0.114, -0.088)	0.800
SLOPE of Auditory Attention & Working Memory performance	-0.062 (-0.173, 0.050)	0.279	-0.042 (-0.152, -0.067)	0.445
SLOPE of Verbal Learning & Memory performance	-0.076 (-0.183, 0.032)	0.167	-0.068 (-0.172, -0.036)	0.203
Association between KEEPS baseline cognition and later cognition				
LATER Verbal Attention & Executive Function performance	-0.012 (-0.090, 0.066)	0.760	-0.046 (-0.126, -0.033)	0.254
LATER Speeded Language & Mental Flexibility performance	-0.021 (-0.094, 0.052)	0.579	-0.032 (-0.112, -0.048)	0.437
LATER Auditory Attention & Working Memory performance	0.011 (-0.082-0.104)	0.817	0.052 (-0.031, -0.134)	0.222
LATER Verbal Learning & Memory performance	-0.084 (-0.181, 0.012)	0.086	-0.076 (-0.177, -0.024)	0.138

#### S-5.

##### Stress in the body, on the brain: Hair and salivary cortisol levels linked with depressive symptom severity and cognitive performance among healthy late peri/early postmenopausal women

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**Objective:** To determine the degree to which hair and salivary cortisol levels correlate with depression symptom severity and cognitive performance on verbal memory, verbal learning, attention, and working memory tests among healthy women in late peri/early

postmenopause. **Design:** Forty-three healthy participants in late perimenopause or early postmenopause provided hair and saliva samples, self-reported depression symptom severity, and completed cognitive tests over two consecutive days. Participants were recruited from across the US and completed study procedures from home while video conferencing with study personnel. Inclusion criteria included female sex;  $\geq 40$  years of age; late perimenopause transition ( $\geq 1$  missed period in the last year) or early postmenopause ( $\leq 24$  months since last period) stages; own computer with internet;  $\geq 1$  ovary and an intact uterus. Exclusion criteria included current smoking; exogenous hormones use within 6 months; current systemic steroid, beta-blocker, or opioid medication use; recent use of NSAIDs; serious health problems; recent alcohol/drug abuse; current pregnancy/breastfeeding; absence of hair; or hair bleach use. Participants provided one hair sample; the closest 2 cm to the scalp were assayed for hair cortisol levels. The next day, two saliva samples were collected between 2-3 PM participant local time, at the start and end of a 30-minute rest period. Saliva samples were assayed for salivary cortisol level; the two timepoints were averaged to generate a basal cortisol level. Depression symptom severity was assessed using the Center for Epidemiologic Studies Depression Scale (CES-D). Verbal learning and verbal memory were assessed using the California Verbal Learning Test – Third Edition. Attention and working memory were assessed using the n-back and the continuous performance tasks (CPT). Bivariate correlations were run between variables. **Results:** Higher levels of hair cortisol ( $r=.385$ ,  $p=.024$ ) and salivary cortisol ( $r=.505$ ,  $p<.001$ ) were associated with greater depressive symptom severity. Hair cortisol significantly associated with measures of attention and working memory. Higher hair cortisol correlated with fewer correct responses on the 0-back and 1-back trials ( $r=-.651$  and  $-.561$ , respectively,  $p<.01$ ), more mistakes on the 2-back trial ( $r=.732$ ,  $p<.001$ ), less specificity on the CPT ( $r=-.409$ ,  $p=.022$ ), but 1-back trial fewer mistakes ( $r=-.576$ ,  $p=.001$ ). Hair cortisol did not significantly correlate with performance on verbal learning or verbal memory ( $ps>.05$ ), but correlated with worse verbal memory ability on immediate recall trials ( $r=-.340$ ,  $p=.034$ ). Salivary cortisol did not significantly correlate with verbal memory recall trials, attention, or working memory performance ( $ps>.05$ ). **Conclusion:** Different patterns and strengths of association were observed between biological measures of stress (hair cortisol and salivary cortisol) and depression and cognition measures among our healthy late peri/early post-menopause sample. This work suggests that markers of hypothalamic-pituitary-axis (HPA) activation that capture total cortisol secretion over multiple months (i.e., hair cortisol) strongly correlate with cognitive performance on attention and working memory tasks, whereas measures of more acute cortisol (i.e., salivary cortisol) may be more strongly associated with depression symptom severity and verbal learning. Hair and saliva cortisol samples are relatively simple to collect with generally low participant burden and may be valuable indicators of HPA activity to consider alongside the cognitive and mental health of late peri/early post-menopausal women. Strengths include diversity of sample with respect to geographic location within the US. Limitations include cross-sectional design and that covariates were not included in these interim analyses. Study designs allowing for causal interpretations are needed to inform whether and how interventions may be helpful to promote HPA health and improve cognitive and depression outcomes during the menopause transition.

**Sources of Funding:** Ludeman Family Center for Women's Health Research

#### S-6.

##### Sex Hormones, the Gut Microbiome, and Subclinical Atherosclerosis in Women With and Without HIV

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**Objective:** The cardio-protective roles of endogenous estrogens may be particularly important in women with HIV, who have relatively reduced estrogen exposure and elevated cardiovascular disease risk. The gut microbiome metabolically interacts with sex hormones, but little is known regarding how such interplay may impact cardiovascular risk. Our objectives were to examine the relationship of serum sex hormones with the gut microbiome and subclinical atherosclerosis in post-menopausal women with and without HIV. **Design:** Among 197 post-menopausal women in the Women's Interagency HIV Study, we measured 15 sex hormones in serum using gas or liquid chromatography coupled to mass spectrometry, and assessed the gut microbiome in stool using shotgun sequencing. Carotid artery B-mode ultrasound was used to determine presence of carotid artery plaque in a subset (n=133). We examined associations of (1) sex hormones and gut microbiome, (2) sex hormones and plaque, and (3) sex hormone-related gut microbiota and plaque. **Results:** Participant median age was 58 years (interquartile range 54-61) and the majority were living with HIV (81%). Sex hormones were associated with gut microbiome diversity and specific species, similarly in women with and without HIV. For example, estrogens (including estrone, estrone-sulfate, and estradiol) were associated with higher diversity, higher abundance of species from *Alistipes*, *Collinsella*, *Erysipelotrichia*, and *Clostridia*, and higher abundance of microbial  $\beta$ -glucuronidase and aryl-sulfatase orthologs, which are involved in hormone metabolism; while androgens (including free testosterone, 5 $\alpha$ -androstane-3 $\alpha$ ,17 $\beta$ -diol-3-glucuronide [3 $\alpha$ -diol-3G], and androsterone-glucuronide), were associated with higher abundance

of *Actinomyces*, *Erysipelotrichia*, and *Clostridia* species and lower abundance of *Bacilli* and *Gammaproteobacteria* species. Several hormones were associated with lower odds of carotid artery plaque, including dihydrotestosterone, 3 $\alpha$ -diol-17G, estradiol, estrone, and dehydroepiandrosterone-sulfate. Exploratory mediation analysis suggested that estrone-related species, particularly from *Collinsella*, may mediate the protective association of estrone with plaque. **Conclusion:** Serum sex hormones are significant predictors of gut microbiome diversity and composition, likely due in part to metabolic interactions. The gut microbiome may play a role in estrogen-related cardiovascular protection.

**Sources of Funding:** B.A.P., D.B.H., Q.Q., and R.C.K. were supported by the National Heart, Lung, and Blood Institute (B.A.P. K01HL160146; R.C.K. R01HL148094; D.B.H. K01HL137557; R.C.K. and D.B.H. U01HL146204-04S1; Q.Q. and R.C.K. R01HL140976). Data in this manuscript were collected by the Women's Interagency HIV Study (WIHS) at the following sites: Bronx, U01-HL146204; Brooklyn, U01-HL146202; Data Analysis and Coordination Center, U01-HL146193; Chicago-Cook County CRS, U01-HL146245.

## THURSDAY CONCURRENT SESSION #2

### S-7.

#### Estrol (E4), a Promising New Treatment for Menopausal Vasomotor Symptoms: Beneficial Lipid and Carbohydrate Metabolism in a Phase 3 Randomized, Double-blind, Placebo-Controlled Trial

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**Objective:** Estrol (E4) is a native estrogen in development for menopausal vasomotor symptoms (VMS) in postmenopausal (PM) women. A previous phase 2 trial found that E4 was effective for the treatment of VMS, genitourinary syndrome of menopause symptoms and quality of life, with a favorable safety profile. Moreover, E4 had minimal impact on hemostasis and had potentially beneficial effects on lipids, carbohydrate metabolism, and bone turnover. Data from two Phase 3 trials demonstrated a significant reduction in the frequency and severity of moderate to severe VMS. Here, we present the results on lipid and carbohydrate metabolism from a Phase 3 trial (E4Comfort I), which was conducted at 151 enrolling sites in 14 countries in Europe, Latin America, Russia, and North America. **Design:** In this randomized, placebo-controlled, double-blind phase 3 trial, 640 postmenopausal women 40–65 years of age were randomized to receive E4 15 mg (n=213), E4 20 mg (n=213), or placebo (n=214) daily for 12 weeks. To ensure endometrial protection all non-hysterectomized women received progesterone 200 mg once daily for 14 days after completion of E4 treatment. Beside the primary VMS efficacy objective, the impact on lipid and carbohydrate metabolism was assessed, for which blood samples were taken at baseline and at Week 12 (W12). Lipid parameters included total cholesterol (total C), high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), total C/HDL-C ratio, triglycerides (TG) and lipoprotein (a). Parameters for carbohydrate metabolism included fasting plasma glucose, insulin, glycated hemoglobin (HbA1c) and homeostasis model-assessment-estimated insulin resistance (HOMA-IR). Samples were analyzed by a central laboratory. Mean and mean change from baseline to W12 were calculated and statistical analyses on changes from baseline to week 12 were performed using ANCOVA. **Results:** Statistically significant changes (p<0.05) from baseline at W12 were observed for cholesterol/HDL ratio (decrease), HDL-C (increase), and lipoprotein (a) (decrease) for both E4 15 mg and E4 20 mg compared to placebo. Statistically significant decreases in LDL-C and increases in TGs were observed only for E4 15 mg compared to placebo. TGs were numerically increased with E4 20 mg, but this was not statistically different from placebo. Reductions in fasting plasma glucose and HbA1c from baseline to Week 12 were statistically significant with E4 15 mg and E4 20 mg compared to placebo. Decreases in insulin levels and HOMA-IR for the E4 treatment arms compared to the placebo arm did not reach statistical significance. **Conclusion:** 12-week treatment with E4 15 mg and E4 20 mg resulted in beneficial effects on the lipid profile with an increase in HDL-C and a decrease in total C/HDL-C ratio, LDL-C and lipoprotein (a). Beneficial effects were also seen on carbohydrate metabolism with a decrease in fasting plasma glucose and in HbA1c associated with an obvious trend to decrease in insulin and HOMA-IR.

**Sources of Funding:** Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Liège, Belgium

### S-8.

#### Effect of fezolinetant on moderate-to-severe vasomotor symptoms in subgroups based on hormone therapy history: pooled data from two randomized phase 3 studies

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**Objective:** Two phase 3 studies (SKYLIGHT 1 and 2; NCT04003155 and NCT04003142) demonstrated the efficacy, safety, and tolerability of fezolinetant treatment for vasomotor symptoms (VMS) due to menopause. As a nonhormonal agent, fezolinetant may be a potential therapeutic alternative for those unable or unwilling to take hormone therapy (HT). Additional analyses using pooled data from SKYLIGHT 1 and 2 assessed

fezolinetant efficacy in participant subgroups who were considered potentially unsuitable for HT. **Design:** SKYLIGHT 1 and 2 had the same design. Both were double-blind, placebo-controlled studies of once-daily placebo, fezolinetant 30 mg or 45 mg for 12 weeks in women  $\geq 40$ – $< 65$  y with moderate-to-severe VMS (minimum average  $\geq 7$  hot flashes/day). HT history subgroups were mutually exclusive and categorized using the following hierarchy: contraindicated; caution; stopped for medical concerns; averse; naive/willing. Subgroup assignments were based on participant answers to the HT questionnaire that was completed as part of the electronic case report form at baseline. **Results:** A total of 1022 participants took  $\geq 1$  dose of study medication and comprised the pooled group (placebo, n=342; fezolinetant 30 mg, n=339; fezolinetant 45 mg, n=341). Irrespective of HT history, there was an improvement in the frequency of moderate-to-severe VMS from baseline to weeks 4 and 12 (Table) in both fezolinetant groups compared with placebo. Improvement is indicated by a least squares mean difference of  $< 0$  for fezolinetant vs placebo. Similarly, there was an improvement across all HT history subgroups in the severity of moderate-to-severe VMS from baseline to weeks 4 and 12 in both fezolinetant groups compared with placebo. In the subgroup who were HT unsuitable (including averse), treatment-emergent adverse events (TEAEs) occurred in 41.3% (121/293) of the placebo group, 40.8% (118/289) of the fezolinetant 30 mg and 39.4% (112/284) of the fezolinetant 45 mg groups. The most frequent TEAE was headache (5.5% placebo; 4.2% fezolinetant 30 mg; 5.6% fezolinetant 45 mg). There was 1 drug-related serious TEAE (transaminases increased) in the fezolinetant 30 mg group. **Conclusion:** This pooled analysis from SKYLIGHT 1 and SKYLIGHT 2 demonstrates the efficacy of fezolinetant in reducing the frequency and severity of VMS due to menopause compared with placebo in participants considered unsuitable for or unwilling to take HT. The findings are consistent with the effect observed in the overall participant population. In addition, fezolinetant was well tolerated in the HT unsuitable (including averse) subgroup.

**Sources of Funding:** Astellas Pharma Inc. Medical writing support was provided by Becky Ayles of Envision Pharma Inc. and funded by Astellas Pharma Inc.

Table

HT subgroup	Frequency of moderate-to-severe VMS at week 12 based on pooled data					
	Fezolinetant 30 mg (n=339)			Fezolinetant 45 mg (n=341)		
	Number in subgroup	n	LS mean difference vs placebo (95% CI)	Number in subgroup	n	LS mean difference vs placebo (95% CI)
Contraindicated or caution	211	166	-2.50 (-3.43, -1.56)	212	182	-2.68 (-3.60, -1.75)
Contraindicated	39	33	-2.06 (-4.02, -0.10)	57	50	-1.98 (-3.73, -0.22)
Caution	172	133	-2.25 (-3.25, -1.25)	155	132	-2.45 (-3.47, -1.43)
Stopper	68	51	-3.17 (-4.45, -1.88)	68	63	-3.87 (-5.13, -2.60)
Stopper for medical concerns	16	13	-3.67 (-6.33, -1.02)	16	13	-4.03 (-6.57, -1.50)
Averse	61	47	-1.17 (-2.55, 0.21)	57	47	-1.86 (-3.25, -0.46)
Naive/willing	39	31	-1.59 (-3.81, 0.64)	42	37	-2.84 (-5.00, -0.69)
Unsuitable	288	226	-2.28 (-3.04, -1.52)	285	242	-2.55 (-3.30, -1.80)
Unsuitable excluding averse	227	179	-2.56 (-3.41, -1.72)	228	195	-2.75 (-3.59, -1.91)

LS=least squares; VMS=vasomotor symptoms  
 HT contraindicated: undiagnosed abnormal genital (vaginal) bleeding; known/suspected or history of breast cancer or estrogen dependent tumors; arterial/venous thromboembolic disease or other thrombotic disorder; acute liver disease, or liver function tests that have failed to return to normal; known/suspected pregnancy; hypersensitivity to estrogen and progesterone therapy.  
 HT caution: participants who indicated they had been advised by their healthcare professional not to take HT or with the following medical condition(s) that warrants a cardiovascular or breast cancer risk assessment before prescribing HT: diabetes mellitus; hyperlipidemia; smoker; obesity; migraine; family history of breast cancer in first degree relative or participant with mutation of BRCA 1 and 2; lupus; epilepsy.  
 HT unsuitable: contraindicated, caution, stopped for medical concerns or averse.

### S-9.

#### Effects of Estradiol on Frontostriatal Activation and Anhedonia in Perimenopausal Women: A PharmacofMRI Study

Crystal E. Schiller, PhD, Julianna Prim, PhD, Erin Walsh, Gabriel Dichter, Megan Hynd, Rachel Phillips, Margo Nathan, MD, Laura Lundegard, Josh Bizzell, Aysenil Belger, David Rubinow, MD. Psychiatry, The University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC

**Objective:** Investigating the neural pathophysiology of perimenopause-onset major depressive disorder (PO-MDD), a homogeneous depression subtype with an established neuroendocrine trigger, may increase the likelihood of identifying neurobiological markers in affective disorders. Here, we present data from a pharmacofMRI trial investigating estradiol (E2) effects on frontostriatal activation and anhedonia in PO-MDD. **Design:** Women with PO-MDD (n=16) and those without depression (i.e., controls; n=19) received transdermal E2 for three weeks, two fMRI sessions (pre- and post-E2), and weekly clinical assessments. During each fMRI session, participants completed the Monetary Incentive Delay task to measure neural response during reward anticipation. The primary clinical outcome was the Mood and Anxiety Symptom Questionnaire-Anhedonia Subscale (MASQ-AD). **Results:** Following E2 administration, the PO-MDD group reported decreased anhedonia ((t(15) = 2.66, p=0.018). Contrary to our hypotheses, there were no group differences in striatal activation at baseline nor did striatal activation change with E2 treatment in either group. Whole brain analyses revealed significant Group (PO-MDD v. Control) x Time (Baseline v Post-E2) interaction appeared in a cluster spanning the right inferior, middle, and precentral gyri during reward anticipation (Z=2.58 and pFWE<0.05). PO-MDD showed reduced activation within this cluster

following E2 treatment, whereas controls did not ( $t=3.0$ ,  $p<.009$ ). In both groups, E2 administration reduced activation in the cerebellum, left inferior and medial frontal gyri, and right occipital pole ( $Z=2.58$ ,  $pFWE<.05$ ). **Conclusion:** The concurrent reduction of anhedonia and right prefrontal activation during reward anticipation in PO-MDD after 3 weeks of E2 administration suggests a potential mechanism for the rapid antidepressant effects of E2. Future research will examine dopamine transmission and frontostriatal activation at the network level to better understand the role of E2 in perimenopause. **Sources of Funding:** NIH K23MH105569 (CES); R01MH128238 (GD, CES)

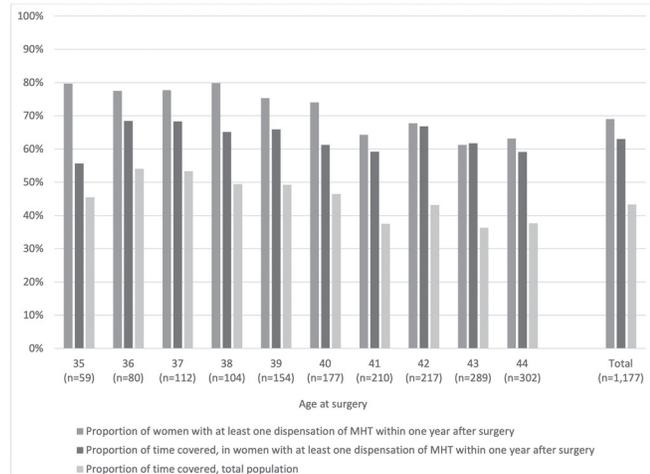
## S-10.

### The use of menopausal hormone therapy after bilateral oophorectomy in premenopausal Swedish women: a register-based study

Micaela Sundell, PhD-student<sup>1,2</sup>, Jan Brynhildsen<sup>3,1</sup>, Mats Fredrikson<sup>1</sup>, Mikael Hoffmann<sup>4</sup>, Anna-Clara Spetz Holm<sup>1,5</sup>. <sup>1</sup>Department of Biomedical and Clinical Sciences, Linköpings universitet, Linköping, Sweden; <sup>2</sup>Department of Obstetrics and Gynaecology, Region Kalmar lan, Kalmar, Sweden; <sup>3</sup>Faculty of Medicine and Health, Orebro universitet, Orebro, Sweden; <sup>4</sup>Linköpings universitet Institutionen for medicin och halsa, Linköping, Sweden; <sup>5</sup>Department of Obstetrics and Gynaecology, Universitetssjukhuset i Linköping, Linköping, Sweden

**Objective:** To investigate the use of menopausal hormone therapy (MHT) in premenopausal women after bilateral oophorectomy. **Design:** Swedish women aged 35–44 years without malignancy who underwent bilateral oophorectomy 2005–2020 were identified using the Swedish National Quality Register of Gynecological Surgery (GynOp). In 2020, 98% of all clinics in Sweden conducting oophorectomies or hysterectomies reported to GynOp. Data on MHT dispensations were retrieved from the Swedish Prescribed Drug Register. **Results:** In total 1,231 of all women ( $n = 1,706$ ) were dispensed MHT at some point after surgery, whereof 1,177 were dispensed within one year. This proportion increased from 64% in 2005 to 84% in 2019 ( $p < 0.001$ ). However, in 2020, during the COVID-19 pandemic, there was a small decrease in MHT dispensations, as has previously been reported for other drugs. The mean duration of the first treatment episode for the women who were dispensed MHT within one year after surgery ( $n = 1,117$ ) was 25 months. The median age at time of surgery was 41 years. Younger women were more likely to have received at least one dispensation compared with women who underwent bilateral oophorectomy closer to the age of expected menopause (OR 0.88, 95% CI 0.85–0.92,  $p < 0.001$ ). Women with a simultaneous hysterectomy were more likely to receive at least one MHT dispensation (77%) compared with women with exclusively oophorectomy (65%) (OR 1.88, 95% CI 1.51–2.32,  $p < 0.001$ ). The total follow-up time for all women was 10,484 woman-years. In the total population, 4,537 treatment years transpired, corresponding to 43% of mean time covered. In women dispensed MHT within one year, the proportion of time covered was 63%. **Conclusion:** Only 69% of all women without malignancy who underwent bilateral oophorectomy were dispensed MHT within one year after surgery, and the treatment duration was limited. It is important to further study the reasons behind the low dispensation rate in this group to increase adherence to treatment guidelines, improve quality of life, and avoid increased morbidity and mortality.

**Sources of Funding:** The Medical Research Council of Southeast Sweden (FORSS-64640, FORSS-746391 FORSS-981620).



Percentage of women dispensed MHT within one year after bilateral oophorectomy during 2005–2020, and the proportion of time covered shown separately for the treated population ( $n = 1,177$ ) and the entire population ( $n = 1,706$ ). Stratified by age at surgery.

## S-11.

### Treatment satisfaction among women with moderate to severe vasomotor symptoms (VMS) due to menopause and physicians who treat women with VMS in the United States

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**Objective:** Hormone therapy (HT) and nonhormonal therapy (non-HT) are available to treat women with vasomotor symptoms (VMS) due to menopause. This study assessed treatment satisfaction among women with moderate to severe VMS and among physicians who treat women with VMS in the United States. **Design:** This noninterventional study consisted of 2 phases: qualitative interviews and quantitative surveys. The interviews were administered to 4 patients and 2 physicians to inform design of a quantitative survey for a larger sample of women with VMS. Participants were recruited from nationally representative patient and physician panels. Participating patients were women in perimenopause or postmenopause aged 40–65 years who experienced moderate to severe VMS due to menopause in the past year and received  $\geq 1$  HT, non-HT, or over-the-counter (OTC) medication for VMS in the past 3 months. Participating physicians were obstetrician–gynecologists (OB-GYNs) and primary care physicians (PCPs) who treated  $\geq 15$  women with VMS in the past 3 months. Treatment satisfaction was measured by the Menopause Symptoms Treatment Satisfaction Questionnaire (MS-TSQ) among patients and by an adapted MS-TSQ among physicians. MS-TSQ total scores (0–100; higher scores indicate greater satisfaction) were summarized by treatment class (HT, non-HT, and OTC medication). Surveys queried participants on unmet treatment needs and expectations for new treatments. **Results:** Interviews were conducted June 22–29, 2022, with 4 women (2 with moderate and 2 with severe VMS) and 2 physicians (1 OB-GYN and 1 PCP). All 4 women wanted more effective treatments with minimal side effects and convenient administration. Both physicians relied on patients to initiate conversation about VMS treatment and would consider prescribing a new non-HT with similar efficacy and convenience to HT. Surveys were completed by 401 women with VMS (201 moderate and 200 severe VMS; mean age 53 years, and >90% White) and 207 physicians treating VMS (101 OB-GYNs and 106 PCPs; mean age 53 years, and 60% male). Patient satisfaction scores were similar across treatment classes. Mean (SD) patient MS-TSQ scores were 66 (20), 60 (20), and 58 (21) for the most common HT, non-HT, and OTC treatments, respectively. Physician satisfaction with existing treatments was generally higher for HT than for non-HT and OTC. Mean (SD) physician MS-TSQ scores were 75 (12), 62 (15), and 52 (17) for the most common HT, non-HT, and OTC treatments, respectively. Women most reported “lack of effectiveness” (41%) and “lack of improvement in quality of life” (27%) as features of current treatments that do not meet their expectations, while physicians reported “long-term safety concerns” (57%), “lack of effectiveness,” and “not covered by insurance” (both 44%) as features not meeting their expectations. Both patients and physicians would consider trying a new non-HT for VMS (both 76%) if the non-HT offered “better symptom control than current treatment” (71% of patients) and “fewer long-term safety concerns” (82% of physicians). Patients most valued when the new treatment could improve sleep quality (60%) and reduce severity (59%) and frequency (58%) of VMS. Physicians most valued when the new treatment could reduce severity (67%) and frequency (60%) of VMS and have a better safety profile (56%). **Conclusion:** Patient satisfaction is similar across treatments, while physicians are most satisfied with HT and least satisfied with OTC medications. Patients’ primary concern with their current treatment is lack of effectiveness, while physicians were primarily concerned with long-term safety. Treatment satisfaction, unmet needs, and new treatment expectations differed between patients and physicians; however, the need for safer and more effective treatments for VMS was identified.

**Sources of Funding:** The study was sponsored by Astellas Pharma, Inc. (Northbrook, IL). Writing support provided by Nicole Boyer, MPH, PhD, and LeeAnn Braun, MPH, MEd, of Peloton Advantage, LLC, an OPEN Health company, was funded by Astellas.

## S-12.

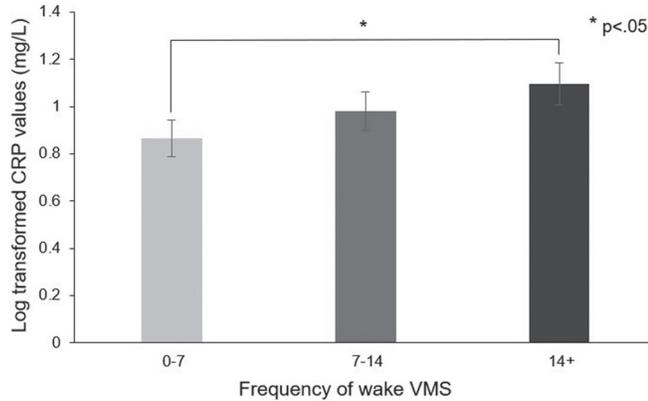
### Physiologically-measured vasomotor symptoms and systemic inflammation among midlife women

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**Objective:** Vasomotor symptoms (VMS) are the classic menopausal symptom experienced by approximately 70% of midlife women. VMS are associated with impairments in quality of life and potentially with physical health risk, such as cardiovascular disease. Emerging data suggest that VMS may be associated with heightened systemic inflammation, which is related to risk for cardiovascular disease. However, this research is exclusively based upon self-reported VMS, which are subject to reporting and memory biases. This study tested whether more frequent physiologically-assessed VMS are associated with heightened systemic inflammation. We also considered the role of endogenous estradiol in these associations. **Design:** The analytic sample included 276 women from the MsHeart study of nonsmoking peri- and post-menopausal women aged 40–60 years with and without VMS. Women completed ambulatory physiologic VMS monitoring (sternal skin conductance) and self-report measurement of VMS during wake and sleep, as well as fasting phlebotomy (inflammatory markers and estradiol) measures via liquid chromatography tandem mass spectrometry. Relationships between VMS and high sensitivity C-reactive protein (hsCRP) and interleukin-6 (IL6) were tested in separate linear regression models controlling for age, education, race/ethnicity, body mass index, and immune medications. Estradiol was included in a separate step. **Results:** Among women who reported VMS, 14 VMS/24 hours were physiologically detected

(wake: 11; sleep: 3). Among these women, more physiologic VMS during wake were associated with higher hsCRP in multivariable models [b(SE)=.12 (.05), p=.03; Figure]. Results were not explained by estradiol levels. VMS were not significantly associated with IL6. **Conclusion:** This first study examining physiologically-measured VMS in relation to inflammation found that VMS during wake were associated with higher hsCRP, independent of covariates. VMS may be associated with greater circulating inflammation among midlife women, which has implications for later health.

**Sources of Funding:** RFIAG053504, R01HL105647, K24HL123565, UL1TR000005, 5T32HL007560-38



### TOP-SCORING ABSTRACT PRESENTATIONS

#### S-13.

#### Self-Reported Efficacy of Hormone Therapy and Symptom Burden in Menopausal Patients with Obesity

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**Objective:** There is paucity of data on impact of comorbidities on the efficacy of hormone therapy in menopause. Our study aimed to investigate the association of obesity and self-reported efficacy of hormone therapy in peri- and postmenopausal women. **Design:** We conducted a medical record review based study of patients presenting to a menopause clinic at an urban, university-affiliated, academic medical center in the Midsouth between July 2018 and December 2022. Statistical analysis was performed with student t-tests and odds ratios. P-values  $\leq 0.05$  were considered statistically significant. During the five-year study period, 119 eligible patients were included. Obesity was defined as a body mass index  $\geq 30$ . **Results:** There was no statistically significant difference in age, duration of menopause, use of hormone therapy and therapy acceptance between the 2 groups. Women with obesity were more likely to self-identify as black, report presence of vasomotor symptoms, genitourinary/vulvovaginal symptoms, mood disturbances, and decreased libido. Women with obesity were less likely to experience symptomatic relief after either systemic and/or localized hormone therapy compared to women without obesity. (OR 0.07; 95% CI 0.01, 0.64) (p-value 0.006) **Conclusion:** Our pilot study suggests that menopausal women with obesity experienced an increase in symptom burden and lower efficacy of hormone therapy. We are not aware of prior studies examining the impact of obesity on symptom burden and efficacy of hormone therapy in menopausal women.

**Sources of Funding:** None

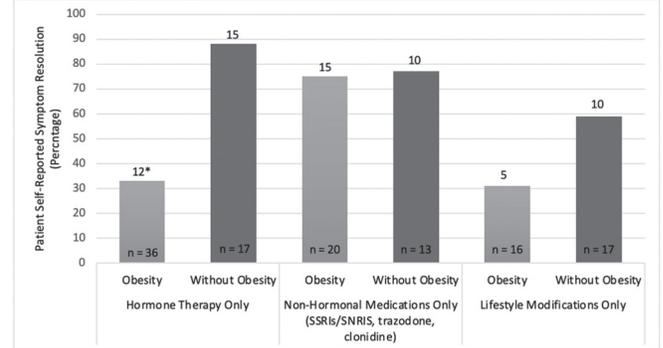
#### Patient Self-Reported Symptom Relief in Systemic and Localized Hormone Therapy

	Systemic Hormone Therapy (N = 20)		Localized Hormone Therapy (N = 33)		Non-Hormonal Medications Only (SSRIs/SNRIS, trazodone, clonidine) (N = 33)		Lifestyle Modifications Only (N = 33)	
	Obesity (N = 12)	Without Obesity (N = 8)	Obesity (N = 24)	Without Obesity (N = 9)	Obesity (N = 20)	Without Obesity (N = 13)	Obesity (N = 16)	Without Obesity (N = 17)
Self-Reported Symptom Improvement, N (%)	1 (8.3%)	7 (88%)	11 (46%)	8 (89%)	15 (75%)	10 (77%)	5 (31%)	10 (59%)
P-value	0.0004*		0.026*		0.900		0.112	

#### Characteristics of Clinical Comparison Groups: Patients with and without Obesity

Patient Characteristic	No Obesity (N = 47)	Obesity (N = 72)	P-value
Years since menopause, mean (SD)	2.3 ( $\pm 1.8$ )	3.1 ( $\pm 2.0$ )	0.571
Age at clinic presentation, years, mean (SD)	56.5 ( $\pm 8.2$ )	54.6 ( $\pm 7.9$ )	0.513
Perimenopausal	6 (13%)	15 (21%)	0.259
Postmenopausal	41 (87%)	57 (79%)	0.259
Hormone Therapy Only	17 (36%)	36 (50%)	0.138
Localized Hormone Therapy	9 (19%)	24 (33%)	0.091
Systemic Hormone Therapy	8 (17%)	12 (17%)	0.961
Non-Hormonal Medications only (ex: SSRIs/SNRI, clonidine, trazodone)	13 (28%)	20 (28%)	0.989
Lifestyle Modifications only	17 (36%)	16 (22%)	0.097
Vasomotor Symptoms (hot flashes, night sweats), N (%)	21 (45%)	53 (74%)	0.002*
Genitourinary/ Vulvovaginal Symptoms, N (%)	10 (21%)	43 (60%)	<0.001*
Mood disturbances (anxiety, depression) N (%)	0 (0%)	8 (11%)	0.018*
Decreased libido, N (%)	5 (11%)	21 (29%)	0.017*

Figure 1. Patient Reported Symptom Relief



#### S-14.

#### Hormone therapy prescribing trends in a nationally representative sample of ambulatory care visits among midlife and older U.S. women from 2018-2019

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**Objective:** Menopausal hormone therapy (HT) is first-line treatment for vasomotor symptoms of menopause and is used to manage premature menopause, treat symptoms associated with genitourinary syndrome of menopause, and prevent osteoporosis. After the Women's Health Initiative trials were published in 2002-2004, HT prescribing rates decreased due to fears regarding risk of cardiovascular disease, venous thromboembolism, and breast cancer. HT prescription rates fell an estimated 38%-66% in 2002, and by 2008, rates dropped by more than 70%. More recently, research has examined the benefits and risks of HT by timing of initiation, and newer formulations of HT have been developed that are bioidentical as opposed to synthetic. United Kingdom prescribing rates have increased by >13% from 2010 to 2021, but no recent U.S. studies have reported prescribing rates in representative ambulatory care samples. This study aims to provide updated information on prescribing trends for HT in U.S. ambulatory care settings from 2018-2019. **Design:** Data from the 2018-2019 National Ambulatory Medical Care Survey (NAMCS), which uses multistage probability sampling to obtain a representative sample of U.S. ambulatory care visit data, were analyzed to examine HT prescribing in ambulatory visits involving U.S. women aged 50 and older. Descriptive statistics were used to examine documented prescription or continuation of HT (including estradiol, ethinyl estradiol and conjugated estrogen therapy, with or without progestin therapy) in ambulatory visits across both years, stratified by key patient demographic and clinical characteristics, and incorporating NAMCS sampling weights. Initial differences in the prevalence of HT prescribing by key demographic and clinical patient characteristics were examined using Rao-Scott Chi-Square tests. Multivariable logistic regression was used to examine independent associations between patient characteristics and HT use in ambulatory visits. **Results:** In 2018-2019, HT was documented in an estimated 2.2% of 10,997 U.S. ambulatory visit records (representing approximately 24.3 million visits) involving female patients aged 50 and older. In multivariable analysis, HT was more likely to be documented in visits involving women diagnosed with depression (OR 2.0, 95%CI 1.1, 3.7) or polypharmacy defined by five or more total medications (OR 5.0, 95%CI 2.8-8.9), but less likely to be documented in visits with women of Hispanic ethnicity (OR 0.2, 95% CI 0.1- 0.5), or with heart disease (OR 0.3, 95%CI 0.1- 0.7) or diabetes (OR 0.4, 95% CI 0.2-0.9). No significant associations were found between HT prescribing or continuing rates and age, race, presence of obesity, cancer, dementia, stroke, thromboembolic disease, hypertension, hyperlipidemia, or osteoporosis (p>0.05 for all). **Conclusion:** In this national sample of U.S. healthcare visits from 2018-2019, the prevalence of HT prescription or continuation was low in women aged 50 or older presenting for ambulatory care visits. Prescribing of HT was more likely in visits with women who had depression or polypharmacy, but less likely in visits with women who were Hispanic, had ischemic or congestive heart disease, or diabetes mellitus. These findings suggest that HT prescribing may be appropriately lower in certain patient groups where HT use may be associated with adverse outcomes, such as ischemic or congestive heart disease, while HT may be inappropriately withheld from patient groups who may

benefit from HT, such as those with diabetes. Additionally, HT prescribing rates may be higher in women seeking mental health care and those with high overall medication utilization. Findings also raise questions about potential disparities in access to or utilization of menopause treatment among Hispanic women. Evaluating HT prescribing rates in all women in the U.S. could allow for a more thorough understanding of patient and prescriber concerns and hesitations surrounding use of HT.

**Sources of Funding:** None

### S-15.

#### Menopause in the workplace: Assessing impact and exploring available supports: a Canadian experience

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**Objective:** Women account for almost half of the Canadian workforce of which more than five million are over the age of 40. Approximately one-quarter of the country's 19 million person labour force are either going through the menopause transition or are postmenopausal. Despite this sizable demographic, menopause remains a largely unacknowledged and unsupported issue in many workplaces, with one in ten women leaving their jobs due to menopause-related challenges. The aim of this study is to assess the impact of menopause on women's experiences in the workplace and to evaluate the level of support they receive with regards to managing menopause related symptoms. By addressing this knowledge gap, we hope to inform strategies for improving workplace culture and policies to better support menopausal & perimenopausal women. **Design:** The survey was conducted by Leger Canada in partnership with Menopause Foundation of Canada, between August 2 and August 11, 2022. 1,023 Canadian women aged 40-60 were surveyed, ensuring representation across various demographic variables including region, education, income, and ethnicity ensuring a diverse range of perspectives from across the country. **Results: Impact on work performance and relationships** 4 out of 10 reported that perimenopause or menopause had a negative impact on their work experience. 32% reported that their symptoms affected their work performance and 16% indicated that their symptoms negatively affected work relationships. 24% women resorted to hiding their symptoms while at work, and nearly 8% needed extra sick days/time off. Approximately one-third of women expressed concern that their symptoms would affect their work performance and that their colleagues perceived them as weak, old, or 'past their prime'. **Discussions around menopause** 40% of working women reported a perceived 'stigma' around discussing menopause in the workplace, and 34% stated that it was a taboo subject. Nearly half (47%) of women felt embarrassed to discuss their symptoms with their employer, and 40% did not feel they had anyone to talk to at work. **Supports at workplace** Only 23% of working or retired women reported receiving support from their employer to manage their menopausal symptoms. Less than 20% noted that their workplace offered supports such as benefits for treatment of menopause symptoms, adjustments to the work environment, or awareness sessions for employees and managers. 67% of women agreed that workplaces should offer support to perimenopausal /menopausal women and 75% of women wish for additional supports from their workplace, including benefits to cover menopause symptom treatments, policies incorporating menopause, time off and flexible working arrangements, and better training and education for employers, supervisors, and colleagues on the issue. 70% women agreed that having more supports at workplace would have a positive impact on their general well-being. **Conclusion:** The underreporting and taboo associated with menopause and its symptoms in the workplace have significant implications for the well-being and productivity of female employees. There is an urgent need to dispel the silence and stigma around menopause at work and to provide support to women undergoing this natural transition. Creating a menopause-inclusive workplace, while prioritizing education and training on this issue, as well as developing policies and support systems can help address the unique needs of women experiencing menopause-related challenges. This is the first study in the Canadian literature discussing these concerns.

**Sources of Funding:** none

Survey responses to workplace equity and menopause

Survey questions	I don't know	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree	Net Agree
Stigma about talking menopause at workplace	26%	15%	19%	25%	15%	40%
My symptoms did/are affecting my performance at work	8%	33%	27%	26%	6%	32%
My symptoms did affect/ are affecting/ could affect how others perceive me at work	9%	38%	30%	19%	4%	23%
I am/ was/embarrassed to talk to my supervisor about my perimenopause/menopause symptoms	15%	20%	18%	21%	26%	47%
My workplace was/ is supportive to help women to cope with peri-menopausal /menopausal symptoms	39%	22%	16%	18%	5%	23%
Workplaces should offer support to women dealing with perimenopausal/ menopausal symptoms	18%	5%	10%	37%	30%	67%
I feel more support at work during perimenopause/menopause could have a positive impact on general well being	21%	4%	5%	42%	28%	70%

### S-16.

#### Menopausal Vasomotor Symptoms and Plasma Alzheimer's Disease Biomarkers

Rebecca C. Thurston, PhD<sup>1</sup>, Pauline Maki, PhD<sup>2</sup>, Yuefang Chang, PhD<sup>3</sup>, Minjie Wu, PhD<sup>4</sup>, Howard Aizenstein, PhD<sup>4</sup>, Carol A. Derby<sup>5</sup>, Thomas K. Karikari<sup>6</sup>. <sup>1</sup>Psychiatry, Epidemiology, and Psychology, University of Pittsburgh, Pittsburgh, PA; <sup>2</sup>Psychiatry, Psychology, and Obstetrics & Gynecology, University of Illinois Chicago, Chicago, IL; <sup>3</sup>Neurosurgery, University of Pittsburgh, Pittsburgh, PA; <sup>4</sup>Psychiatry, University of Pittsburgh, Pittsburgh, PA; <sup>5</sup>Neurology, Albert Einstein College of Medicine, Bronx, NY; <sup>6</sup>Psychiatry and Neurochemistry, Goteborgs universitet Sahlgrenska Akademin, Goteborg, Sweden

**Objective:** Women comprise two thirds of individuals with Alzheimer's disease (AD). Midlife and the menopause transition are important times for women's cognitive health, as the hallmarks of AD begin to emerge at midlife. Prior work links the cardinal menopausal symptom, vasomotor symptoms (VMS), with poor memory performance and with alterations in brain structure, function, and connectivity. These associations are evident when VMS are monitored objectively with ambulatory skin conductance monitors. However, it is unknown whether VMS are associated with AD biomarkers. Recent advances in assessing AD in vivo include the emergence of AD blood-based biomarkers, which are particularly useful to assessing risk decades before the emergence of AD dementia. The study objective was to determine whether objectively-assessed VMS are associated with adverse AD biomarker profiles. **Design:** Between 2017 and 2020 the MsBrain study enrolled 274 women aged 45-67 who had a uterus and at least one ovary and were late perimenopausal or postmenopausal. No participants had a neurological disorder or recent use of hormonal or non-hormonal VMS treatments. Women underwent assessment of their VMS via ambulatory skin conductance monitoring for 24 hours, physical measures, an interview, three days of sleep actigraphy assessment, and a fasting blood draw for apolipoprotein E genotyping, estradiol (via liquid chromatography-tandem mass spectrometry), and the assessment of plasma concentrations of AD biomarkers amyloid  $\beta$  (A $\beta$ ) 42/40 ratio, phosphorylated tau (p-tau 181 and 231), glial fibrillary acidic protein (GFAP), and neurofilament light (NFL) (via Single molecule array technology). AD biomarkers were considered both continuously and A $\beta$ 42/40 additionally considered as clusters using the K-medoids clustering method. Associations between sleep and wake VMS and AD biomarker levels or clusters were tested in linear or logistic regression models with covariates age, race/ethnicity, education, body mass index, and apolipoprotein E4 status. **Results:** A total of 248 (mean age=59.06 years, 81% white, 99% postmenopausal) MsBrain participants contributed data. Objectively-assessed VMS, particularly sleep VMS, were associated with significantly lower A $\beta$ 42/40 [B(SE)=-.0010 (.0004), p=.018, multivariable]. Further, a greater number of sleep VMS were associated with an increased likelihood of being in the low/abnormal A $\beta$ 42/40 cluster [OR(95%CI)=1.18(1.05, 1.33), p=.006, multivariable]. Findings remained significant after additional adjustments for estradiol and actigraphy assessed sleep duration and wake after sleep onset. **Conclusion:** Sleep VMS were associated with adverse A $\beta$ 42/40 profiles, indicating that VMS experienced during sleep may be a marker of women at risk of AD dementia. Women with a high burden of sleep VMS may warrant AD dementia risk reduction efforts.

**Sources of Funding:** Funded by National Institutes of Health, National Institute on Aging grants RF1AG053504 and R01AG053504 (Thurston & Maki).

## FRIDAY CONCURRENT SESSION #1

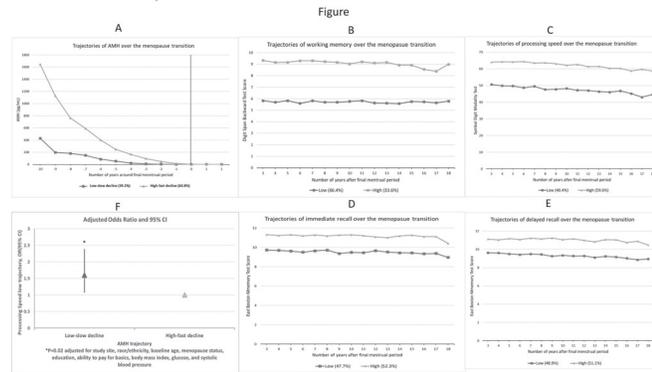
### S-17.

#### Associations of Trajectories of Anti-Müllerian Hormone over the Menopause Transition with Trajectories of Cognitive Function after Menopause: The SWAN Study

Samar R. El Khoudary, PhD<sup>1</sup>, Meiyuzhen Qi<sup>1</sup>, Arun Karlamangla<sup>2</sup>, Nanette Santoro<sup>3</sup>, Sybil Crawford<sup>4</sup>, Mary Sammel<sup>5</sup>, Joel Finkelstein<sup>5</sup>. <sup>1</sup>Epidemiology, University of Pittsburgh, Pittsburgh, PA; <sup>2</sup>University of California Los Angeles, LA, CA; <sup>3</sup>University of Colorado, Aurora, CO; <sup>4</sup>University of Massachusetts, Worcester, MA; <sup>5</sup>Massachusetts General Hospital, Boston, MA

**Objective:** Women have a greater prevalence of Alzheimer disease than men. They experience a faster cognitive decline starting as early as post menopause. Anti-Müllerian hormone (AMH), which drops progressively over the menopause transition (MT), has recently shown paracrine/autocrine actions in regulating synaptic transmission in the hippocampus in mouse model. Whether AMH trajectory over the MT contributes to cognitive function trajectory post menopause is unknown. Our aim was to assess associations of AMH trajectories over the MT with trajectories of cognitive function in 4 domains after menopause. **Design:** SWAN participants who transitioned without using hormone therapy or having had a hysterectomy or bilateral oophorectomy, and had AMH measured over the MT and cognitive function domains [working memory, processing speed; and verbal episodic memory immediate and delayed recall] measured repeatedly post menopause were included. Group-based trajectory modeling was used to identify the trajectories of AMH and cognitive function domains relative to FMP. Associations of AMH trajectories with cognitive function trajectories were assessed using multivariable logistic regression adjusted for study site, race/ethnicity and baseline age, menopause status, education, ability to pay for basics, body mass index, glucose, and systolic blood pressure. **Results:** We evaluated 735 women (Baseline age $\pm$ SD: 46.84 $\pm$ 2.44 years). Two distinct AMH trajectories were identified (Figure-A): *High-fast decline* and *Low-slow decline*. For cognitive function, women clustered into either a high or a low trajectory group for each cognitive domain (Figure-B-E). In final models, compare to women in the High-fast decline AMH trajectory, women in the Low-slow decline group were at a

higher risk of experiencing a low processing speed trajectory after menopause (Figure-F). No other associations were found. **Conclusion:** AMH decline over the MT could be a novel marker of cognitive function, particularly processing speed, later in life for women. **Sources of Funding:** The Study of Women's Health Across the Nation (SWAN) has grant support from the National Institutes of Health (NIH), DHHS, through the National Institute on Aging (NIA), the National Institute of Nursing Research (NINR) and the NIH Office of Research on Women's Health (ORWH) (Grants NR004061; AG012505, AG012535, AG012531, AG012539, AG012546, AG012553, AG012554, AG012495, and U19AG063720).



## S-18.

### Medical and Recreational Cannabis Use in the Menopause Transition: Evaluation of Trends from a Large, Nationally Representative Sample of Midlife Women

Carolyn J. Gibson, PhD, MPH<sup>1,2</sup>, Amy L. Byers, PhD<sup>1,2</sup>, Beth E. Cohen, MD, MAS<sup>1,2</sup>, Salomeh Keyhani, MD, MPH<sup>1,2</sup>. <sup>1</sup>San Francisco VA Health Care System, San Francisco, CA; <sup>2</sup>University of California San Francisco School of Medicine, San Francisco, CA

**Objective:** With rapidly expanding legalization and normalization, recreational and medical cannabis use is increasing. The menopause transition may be a critical and underrecognized period for cannabis use, with limited evidence for benefit and potential for harm. Women and adults aged 50 and older have been identified as among the fastest growing groups of users. Medical cannabis use is also more often reported in both women and older adults, frequently targeting common menopause- and aging-related symptoms including insomnia, anxiety, and chronic pain. Cannabis is also directly marketed to women for menopause symptom management despite a lack of scientific studies. Medical cannabis use for these chronic concerns may contribute to more frequent use, increasing risk for the development of tolerance and adverse health outcomes. However, little is known about the prevalence or characteristics of cannabis use among women in and after the menopause transition. To address this gap, we sought to examine frequency, forms, and motives of cannabis use in a large, nationally representative sample of midlife U.S. women. **Design:** Data were drawn from a cross-sectional survey of women and gender-diverse members of Ipsos KnowledgePanel, an established U.S. probability-based online panel. Eligible members were aged 45-64 and self-identified as female sex at birth, with no use of gender-affirming hormone therapy or surgery. A nationally representative sample was derived with purposive sampling by race/ethnicity within the specified age range and the application of sample weights for all analyses. Participants completed structured-item questions to self-report sociodemographic characteristics, menopause status, and frequency, forms (smoking, vaping, topicals, edibles), and motives (recreational, medical or therapeutic) of lifetime and past 30-day cannabis use. Descriptive statistics incorporating sample weights were conducted for key characteristics. **Results:** The final analytic sample included data from 5,174 women (mean age: 55, SD 6). The majority were postmenopausal (68%; natural menopause: 46%, surgical menopause: 22%); White, Non-Hispanic (63%); and working full- or part-time (67%). Over 42% of participants reported lifetime cannabis use in any form, most commonly via smoking or edible products. Over 30% of participants who reported ever smoking cannabis endorsed daily or near-daily smoking for a year or longer. Most reported recreational use (62%); 25% reported both recreational and medical use, and 13% reported that their only motive was medical use to manage symptoms and chronic health conditions. The most common therapeutic targets for medical use were chronic pain (28%), anxiety (24%), sleep (22%) and stress (22%). Cannabis use to manage menopause symptoms was endorsed by 6% of women with a history of use, primarily to target menopause-related mood and sleep difficulties. Over 10% of participants had used cannabis in the past 30 days, most often smoking (56%), ingesting edible products (52%), or using cannabis in more than one form (39%). Among those with past 30-day use, 31% reported smoking cannabis on a daily or near-daily basis, while 19% reported daily or near-daily use of edible cannabis products. **Conclusion:** Both current and lifetime medical and recreational cannabis use was relatively common in this nationally representative sample of midlife women. Consistent with past research largely focused on men and younger adults, smoking is the most common form of cannabis use, and sleep, mood, and chronic pain are primary targets for medical cannabis use among women in midlife. A sizeable minority endorse smoking and/or using edible products on a daily or near-daily basis, which may increase health risks related to cannabis use. These findings highlight the importance of recognizing and discussing cannabis use in the health care setting, and the need for additional research to evaluate the potential harms and/or benefits of use in this vulnerable population.

**Sources of Funding:** Tobacco-Related Disease Research Program (T32KT4693, PI: CJG), VA HSR&D CDA (IK2 HX002402, PI: CJG), VA Research Career Scientist Award (IK6 CX002386, ALB).

## S-19.

### Efficacy of a behavior change intervention for menopausal symptoms delivered through a mobile application

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**Objective:** Behavior change interventions, based on randomized controlled trials, have proven to be effective in the management of menopausal symptoms. Today, many people are using mobile applications to access medical information and seek such interventions. This research study explores the efficacy of a behavior change intervention for menopausal symptoms, administered via a mobile application to a real world cohort. This study therefore assesses not only the ability of behavior change interventions to improve symptoms, but also the efficacy of a mobile application as a contemporary mode of delivery. **Design:** Data is obtained via an in-application baseline assessment and repeated self-reported symptom check-ins. The in-application symptom check-in tracks 14 symptoms aligned with the Greene-Climacteric-Scale which are scored for severity from 0 (None) to 4 (Severe). Users are provided with a personalized 12 week plan, consisting of three 4 week modules under the focus areas: mood, weight, sleep, body (pelvic floor symptoms), sex and hot flashes. Additionally, users have access to in-application educational material and live coach support. The overall study cohort were users that completed a baseline symptom check-in and at least one subsequent symptom check-in. Sub-cohorts were also analyzed for users who completed a full behavior change plan, users who completed at least one module, and users who only engaged with material outside of behavior change plans. Symptom change was assessed within cohorts via paired t-tests comparing baseline to final symptom scores. Comparative symptom change between different sub-cohorts was assessed via unpaired t-tests. **Results:** The overall study cohort included 76 individuals aged between 40 and 60 with a mean age of 49.95 years. Overall, 65.8% of users showed symptom improvement with an average total improvement in symptom severity of 13.8% ( $\Delta = -0.22$ ,  $n = 76$ ,  $p = 0.001$ ). The sub-cohort of users who completed full plans had the most positive outcome, with 75.7% of users improving, and an average symptom improvement of 20.6% ( $\Delta = -0.31$ ,  $n = 37$ ,  $p = 0.0001$ ). 54.6% of the users who did not complete behavior change plans, but who engaged with educational material and tracked their symptoms in the app also improved, however the result was not significant, with an average of 6.8% improvement ( $\Delta = -0.13$ ,  $n = 22$ ,  $p = 0.37$ ). An unpaired t-test showed no significant difference between sub-cohorts. For the individual modules which target specific symptom groups, the pelvic floor and weight interventions were most effective, resulting in an average 50.8% improvement in pelvic floor related symptom severity ( $\Delta = -0.89$ ,  $n = 20$ ,  $p = 0.037$ ), and an average 28.4% improvement in self-reported weight management ( $\Delta = -0.83$ ,  $n = 12$ ,  $p = 0.013$ ) for users who completed those specific interventions. Users who did not complete pelvic floor and weight interventions, showed on average no improvement in these symptoms. Psychological symptoms improved in the overall cohort by an average of 18.8% ( $\Delta = -0.27$ ,  $n = 76$ ,  $p = 0.002$ ) with approximately equal improvement between the cohort who completed the mood intervention ( $n = 29$ ) and those who did not ( $n = 47$ ). Similarly, sleep symptoms improved in the overall cohort by an average of 16.7% ( $\Delta = -0.42$ ,  $n = 76$ ,  $p = 0.003$ ) with both cohorts who completed ( $n = 28$ ) and who did not complete the sleep module ( $n = 48$ ) showing no statistically significant difference in their improvement scores. **Conclusion:** This observational study demonstrates that a mobile application delivering behavior change interventions can be effective in helping women manage their menopausal symptoms, and that women seek and utilize this method of delivery. Results indicate that users trying to manage weight issues and pelvic floor dysfunction benefitted from completing targeted behavior change interventions. Meanwhile, for psychological and sleep symptoms, simply engaging with the in-application educational material and symptom tracking was associated with a positive impact on symptoms.

**Sources of Funding:** Vira Health

## S-20.

### Effects of a Pelvic Yoga Program on Genitourinary Quality of Life in Midlife and Older Women with Urinary Incontinence: a Multisite Randomized Trial

Alison Huang, MD, MAS<sup>1</sup>, Margaret Chesney, PhD<sup>1</sup>, Michael Schembri<sup>1</sup>, Harini Raghunathan<sup>1</sup>, Sarah Pawlowsky<sup>2,1</sup>, Leslee Subak<sup>3</sup>. <sup>1</sup>University of California San Francisco, San Francisco, CA; <sup>2</sup>San Francisco State University, San Francisco, CA; <sup>3</sup>Stanford University, Stanford, CA

**Objective:** Pelvic yoga has been recommended as a complementary behavioral treatment strategy for women with genitourinary symptoms such as urinary incontinence that frequently emerge in midlife, but there is little evidence of its impact on women's genitourinary quality of life (QOL). We examined changes in genitourinary QOL among midlife and older women in a randomized trial of a group-based pelvic yoga program versus non-specific physical conditioning program for incontinence. **Design:** The Lessening Incontinence with Low-impact Activity (LILA) study is a multisite trial of a group-based yoga program designed by an expert yoga and clinician panel to improve pelvic function in midlife and older women. Ambulatory women aged 45 or older with incontinence were recruited from the general communities surrounding three study sites in California in 2019-2022. Eligible women were randomly assigned

to a therapeutic yoga program consisting of twice weekly group instruction by trained yoga instructors and once weekly individual practice of study-specific Hatha yoga techniques for 3 months, versus a general physical conditioning program involving equivalent-time group instruction and individual practice of skeletal muscle stretching and strengthening exercises. Linear mixed models examined change in scores on multiple validated self-report measures of genitourinary symptom bother or quality of life over 3 months, including the Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire (IIQ), and Patient Perception of Bladder Condition (PPBC), adjusting for site and intervention cohort. **Results:** Among the 240 participants randomized (121 to yoga, 119 to physical conditioning), mean age was 62.0 ( $\pm 8.7$ ) years (total range 45 to 90 years), and 40% self-identified as racial or ethnic minorities (14% Latina/Hispanic, 6% African American, 16% Asian American, 4% multiracial). At baseline, mean scores on genitourinary QOL measures were 38.8 ( $\pm 19.2$ ) for the UDI-6, 101.0 ( $\pm 7$ ) for the IIQ, and 3.4 ( $\pm 1.0$ ) for the PPBC. Over 3 months, scores on all genitourinary QOL measures improved by more than the minimum important difference thresholds in the pelvic yoga group (Table), and improvements in UDI-6 scores were modestly greater in the pelvic yoga than the physical conditioning group (estimated between-group difference of 5.8 (95%CI 1.0-10.6) points in favor of yoga,  $P=.02$ ). However, no significant between-group differences in change in overall IIQ or PPBC scores were detected (Table). **Conclusion:** Among midlife and older women with urinary incontinence, genitourinary QOL assessed by multiple self-reported measures improved over 3 months among women assigned to a group-based pelvic yoga program, but improvements were only modestly greater than or similar to those observed with a non-specific muscle conditioning program. Findings from this multisite trial provide new evidence to support benefits of engagement in pelvic yoga among midlife and older women with genitourinary symptoms, but also suggest that women may derive benefit from other general physical-based interventions.

**Sources of Funding:** National Institutes of Health

	Pelvic Yoga		Physical Conditioning		Between-Group Difference	
	Mean change (95% CI)*	P	Mean change (95% CI)*	P	Mean change (95% CI)*	P
Urogenital Distress Inventory-6 (score range 0-100)**	-18.9 (-22.3, -15.4)	<.001	-13.1 (-16.5, -9.6)	<.001	-5.8 (-1.0, -10.6)	.02
Incontinence Impact Questionnaire (score range 0-400)**	-38.5 (-52.8, -24.2)	<.001	-31.4 (-45.6, -17.2)	<.001	-7.1 (12.9, -27.1)	.48
Patient Perception of Bladder Condition (score range 1-6)**	-0.7 (-0.9, -0.5)	<.001	-0.7 (-0.9, -0.5)	<.001	0.0 (0.3, -0.3)	.94

\*Change estimates were obtained from linear mixed models, controlling for study site and group intervention class.  
\*\*For all measures, higher scores indicate worse genitourinary quality of life

## S-21.

**Menopause Care in the Veterans Healthcare Administration: A Qualitative Investigation of Women Veteran and Provider Perspectives** Haley Miles-McLean, PhD<sup>1,2</sup>, Anna Blanken, PhD<sup>3,4</sup>, Francesca Nicosia, PhD<sup>3,5</sup>, Carolyn J. Gibson, PhD<sup>3,4</sup>. <sup>1</sup>Veterans Integrated Services Network 5 Mental Illness Research Education and Clinical Center, Baltimore, MD; <sup>2</sup>Psychiatry, University of Maryland School of Medicine, Baltimore, MD; <sup>3</sup>San Francisco VA Health Care System, San Francisco, CA; <sup>4</sup>Psychiatry & Behavioral Sciences, University of California San Francisco, San Francisco, CA; <sup>5</sup>Institute for Health & Aging, University of California San Francisco School of Medicine, San Francisco, CA

**Objective:** Women Veterans are the fastest growing population served by the Veterans Healthcare Administration (VHA). Over half of women VHA users are aged 45 or older, an important time for menopause-related concerns. Accordingly, VHA has prioritized improvement of women Veterans' healthcare. Despite this, little is known about Veteran experiences and the practice of menopause care (e.g., psychoeducation, pharmacotherapy) within VHA. **Design:** We conducted a qualitative study to better understand Women Veterans' and VHA providers' experiences related to menopause care. Women Veterans and VHA primary care providers, the typical providers for reproductive and comprehensive healthcare in VHA, were recruited from 8 VA Women's Health Practice-Based Research Network (WH-PBRN) sites nationwide. Sites were selected to include rural and urban settings and reflect geographic diversity and representation of minoritized racial/ethnic populations. We conducted semi-structured telephone interviews focused on key domains related to menopause, including current practices, healthcare communication, care preferences, and needs. Using a rapid qualitative analysis approach, data from each patient and provider interview transcript were entered into a matrix. Individual participant matrices were synthesized into domain summaries, from which we identified key themes. Eligible women Veteran participants were aged 45-64, had >1 primary care clinic visit within the prior two years at one of the selected WH-PBRN sites, and provided informed consent. Eligible VHA providers were staff primary care providers who had been at a selected WH-PBRN site for >3 months. **Results:** Women Veteran participants ( $n=31$ , age  $M=56.3$  years,  $SD=5.13$ ) were primarily postmenopausal (72%). Most women Veterans self-reported their race as either white (56%) or Black (22%). Provider participants ( $n=13$ ) were on average 14.7 ( $SD=11.0$ ) years post-residency training. Veterans and providers offered diverse perspectives related to receiving and delivering menopause care in VHA. Regarding **current practices**, providers described varied approaches and treatment recommendations for assessment and management of menopause symptoms, including some who do not address menopause at all. Veterans also reported variability in ways they access menopause care within VHA, some discussing menopause with all providers, and others who never raise menopause concerns. Within **healthcare communication** both Veterans and providers described variability regarding comfort with discussing menopause symptoms, particularly genitourinary or sexual concerns; with who initiates discussions of menopause; and where menopause concerns fall in relative importance

to other health issues. Regarding **care preferences**, Veterans identified a preference for whole-person care, including non-pharmacological and medication options. Providers highlighted a preference for adequate mental health care options. Finally, regarding **needs**, Veterans indicated a desire for better menopause education, trusting relationships with empathetic providers, sufficient appointment time to address all concerns, and a collaborative treatment approach. Providers identified needing clear ways to consult with other disciplines, additional training resources, standardized assessments, and decision-making tools for medical interventions. **Conclusion:** In this study, women Veterans and providers described their experiences related to menopause care within VHA. Findings suggest that menopause care in VHA can vary widely from both Veteran and provider perspectives, emphasizing a need for more resources, education, and shared decision-making strategies to assist Veterans and providers navigating this stage of life.

**Sources of Funding:** This research was supported by a VA HSR&D CDA (IK2 HX002402) to C.J.G. and drew upon VA Women's Health Research Network infrastructure, including the VA Women's Health Practice-Based Research Network (VA HSR&D SDR 10-012).

## FRIDAY CONCURRENT SESSION #2

### S-22.

#### Post-Traumatic Stress Disorder Symptoms and Sexual Functioning Among Midlife Women

Karen P. Jakubowski, PhD<sup>1</sup>, Pauline Maki, PhD<sup>2</sup>, Karestan Koenen<sup>3</sup>, Carolyn J. Gibson<sup>4</sup>, Rebecca C. Thurston, PhD<sup>1</sup>. <sup>1</sup>Psychiatry, University of Pittsburgh, Pittsburgh, PA; <sup>2</sup>Psychiatry, University of Illinois Chicago, Chicago, IL; <sup>3</sup>Harvard University T H Chan School of Public Health, Boston, MA; <sup>4</sup>San Francisco VA Health Care System, San Francisco, CA

**Objective:** Post-traumatic stress disorder (PTSD) symptoms are common, reported by approximately 10% of women, and are related to adverse mental and physical health outcomes and lower wellbeing. However, limited work has examined relations between PTSD symptoms and sexual functioning among midlife women. We tested whether PTSD symptoms were associated with worse sexual functioning among midlife women after accounting for potentially confounding factors. **Design:** Participants were 274 postmenopausal women not taking hormone therapy or selective serotonin reuptake inhibitors or serotonin norepinephrine reuptake inhibitors. Women reported past-month PTSD symptom severity (PTSD Checklist-Civilian Version; total score range=17-85, also yields three symptom clusters: re-experiencing, hyperarousal, and avoidance/numbing), past-month sexual function (6-item Female Sexual Function Index; queries sexual desire or interest, including vaginal intercourse, self-stimulation, and sexual fantasy; total score range=2-30, lower scores=worse sexual function), depressive symptoms (Center for Epidemiological Studies-Depression), and alcohol use (yes/no), and provided medical history and medication use via interview. Per FSFI scoring, analyses were restricted to women reporting past-month sexual activity, resulting in an analytic sample of  $N=121$ . Associations between PTSD scores (log) and sexual function were tested in linear regression models adjusted for age, race/ethnicity, education, vaginal estrogen use, alcohol use, and depressive symptoms. **Results:** Women were 45-66 years old (mean age=58 years) and identified as Asian or Pacific Islander (2%), Black (16%), Multiracial (1%), or White (81%). On average, women reported low to moderate severity of PTSD symptoms ( $M=23.9$ ,  $SD=6.8$ ) and normal sexual function ( $M=20.5$ ,  $SD=5.1$ ). Moderate and severe PTSD symptoms were related to lower sexual functioning [B(SE)= -6.00 (2.47),  $p=.016$ ; multivariable, Figure 1]. When specific aspects of PTSD symptoms were considered, greater avoidance/numbing symptoms were related to poorer sexual function [B(SE)= -3.20 (1.61); multivariable,  $p=.049$ ]. **Conclusion:** Greater past-month PTSD symptomatology was related to worse sexual functioning. Results suggest the importance of assessing and addressing PTSD symptoms among midlife women to improve women's sexual health and functioning as they age.

**Sources of Funding:** K23HL159293; RF1AG053504; K24HL123565

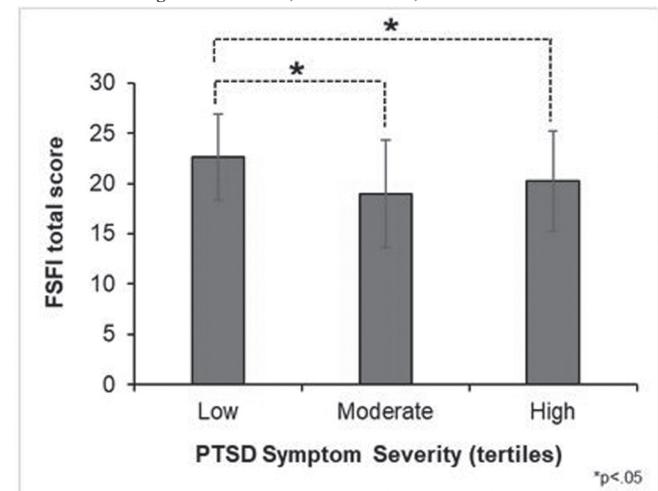


Figure 1. PTSD symptom severity and FSFI sexual function total score

## S-23.

**Associations of sexual function and sexual orientation in cisgender women**  
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**Objective:** Cisgender, sexual minority women (SMW) reportedly have worse mental and physical health outcomes compared to cisgender, heterosexual women, including increased rates of substance use, obesity, and stroke. There is a paucity of literature on sexual function in SMW. Study results have varied, with some showing no significant differences in sexual function between SMW and heterosexual women, while others have reported better sexual function in SMW compared to heterosexual women. Improved understanding of the relationship between sexual function and sexual orientation may lead to improved care for SMW. This study aimed to evaluate sexual function and sexual distress in cisgender SMW compared to cisgender, heterosexual women. **Design:** A retrospective analysis was completed using questionnaire data in the Data Registry on Experiences of Aging, Menopause and Sexuality (DREAMS) collected from women aged 18 and older who presented to women's health clinics at Mayo Clinic in Rochester, Minnesota, Scottsdale, Arizona, and Jacksonville, Florida from December 2016 thru February 2023. The Female Sexual Function Index (FSFI) and Female Sexual Distress Scale (FSDS) were used to assess sexual dysfunction (FSFI  $\leq$  26.55 and FSDS  $\geq$  11). A multivariable logistic model assessed the association between sexual dysfunction and SMW after adjusting for age, race/ethnicity, body mass index (BMI), menopause status, current hormone therapy use, quality of life, relationship status, depression (PHQ-9  $\geq$  5), anxiety (GAD  $\geq$  5), history of abuse in the last year, adverse childhood experiences, sleep, and relationship satisfaction. **Results:** A total of 6,241 sexually active women were included in the analysis. Of these, 3% (189/6241) were SMW and 97% (6052/6241) were heterosexual; mean age 51.6 years, 92.6% White, 84.7% married/partnered, 26.5% on hormone therapy, 53.5% with BMI  $\geq$  30 kg/m<sup>2</sup>, and 62.9% postmenopausal. Hormone therapy use rates were similar between SMW and heterosexual women (21.6% vs 26.7,  $p=0.15$ ), while SMW had significantly lower quality of life scores (7 vs 8,  $p=0.012$ ) and relationship satisfaction scores (4.3 vs 4.6,  $p=0.022$ ), compared to heterosexual women. SMW were more likely to endorse anxiety and depression symptoms compared to heterosexual women (52.7% vs 35.5%,  $p < 0.001$ ; 53.8% vs 37.3%,  $p < 0.001$ , respectively). On univariate analysis, SMW had lower total FSFI scores (18.2 vs 19.7,  $p=0.073$ ) than heterosexual women, though this was not a statistically significant difference. SMW had higher total FSDS scores (17 vs 15,  $p=0.037$ ), demonstrating significantly greater sexual distress compared to heterosexual women. No statistically significant differences were seen for sexual dysfunction by combined endpoint on univariate (SMW 63% vs heterosexual 57.3%,  $p=0.12$ ) or multivariable (OR 1.15, 95% CI 0.84-1.58,  $p=0.37$ ) analysis. **Conclusion:** Risk for sexual dysfunction was similar between SMW and heterosexual women presenting to a tertiary care center. Notably, sexual distress scores were higher for SMW compared to heterosexual women. Quality of life and relationship satisfaction scores were statistically significantly higher in heterosexual women compared to SMW, while hormone therapy use rates were similar. Anxiety and depression symptoms were higher in SMW, consistent with prior research on minority stress. Limitations of this study include the observational design and lack of generalizability given that the women were predominantly White, partnered, employed, educated, and presenting for menopause or sexual health concerns. Additionally, the FSFI may not effectively represent the sexual experiences of SMW given its development with and focus on heterosexual populations. Evaluating these variables in larger, more diverse cohorts could facilitate more culturally agile care for SMW.

**Sources of Funding:** None

## S-24.

**Cognitive Behavioural Therapy for Sexual Concerns During Peri- and Post-Menopause: Preliminary Outcomes**

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**Objective:** Sexual concerns are reported by 68% to 86.5% of peri- and post-menopausal women, which negatively impact physical and emotional well-being. Despite this, little attention has been paid to this area in the literature and no well-established, non-pharmacological treatments exist. The primary objective of this study is to evaluate the efficacy of a four-session individual Cognitive Behavioural Therapy protocol in improving sexual satisfaction and reducing distress during peri- and post-menopause (CBT-SC-Meno). Secondary objectives include sexual functioning, relationship satisfaction, body image, menopausal symptoms, depression, and anxiety. **Design:** Participants (n=20) recruited during peri- or post-menopause experiencing primary sexual concerns were assessed for study eligibility during an initial assessment. Eligible participants (n=15) were assigned to a waitlist control condition for four weeks, after which they completed four individual CBT sessions focusing on sexual concerns. Participants completed measures assessing sexual satisfaction, distress, and desire [Female Sexual Function Index (FSFI), Female Sexual Distress Scale-Revised (FSDS-R), Female Sexual Desire Questionnaire (FSDQ)], as well as menopause symptoms [Greene Climacteric Scale (GCS)], body image [Dresden Body Image Questionnaire (DBIQ)], relationship satisfaction [Couples Satisfaction Index (CSI)], depression [Beck Depression

Inventory-II (BDI-II)], and anxiety [Hamilton Anxiety Rating Scale (HAM-A)] at baseline, post-waitlist, and post-treatment. Participants also completed the Client Satisfaction Questionnaire at post-treatment. **Results:** No significant changes were observed during the waitlist period across all measures, apart from the FSDQ concern subscale. Participants experienced a significant decrease in symptoms of sexual distress, concern, and resistance, menopausal symptoms, and symptoms of depression. Significant increases in sexual dyadic desire, sexual functioning, body-image satisfaction, and relationship satisfaction were also observed. No significant changes were observed in anxiety symptoms, although post-waitlist scores were indicative of mild anxiety. Further, 100% of participants indicated that they were very satisfied with the treatment and that it helped them cope with their symptoms more effectively. Qualitative treatment satisfaction outcomes were captured and will be reported at the time of presentation. **Conclusion:** To our knowledge, this study is the first to examine the efficacy of a CBT protocol aimed at improving sexual concerns experienced during peri- and post-menopause. Preliminary results suggest CBT-SC-Meno leads to significant improvements across sexual concern domains, as well as commonly co-occurring symptoms including body-image, relationship satisfaction, menopausal and depression symptoms. As consumer demand increases for non-pharmacological treatments for peri- and post-menopause symptoms, this form of treatment may not only be preferred by some, but necessary for others as medications, including long-term hormonal-based treatments, have known associated adverse risks.

**Sources of Funding:** Women's Health Clinical Mentorship Grant (#433269) from the Canadian Institute of Health Research.

Change in clinical symptoms measures from post-waitlist to post-treatment (n=15)

Measure	Post-Waitlist	Post-Treatment	t	p	d
FSFI	14.72 (7.34)	21.83 (8.07)	3.59	0.003*	0.92
FSDS-R	30.80 (9.19)	20.33 (10.93)	3.82	0.002*	1.04
FSDQ					
Dyadic Desire	34.93 (14.86)	47.00 (17.09)	3.55	0.003*	0.75
Solitary Desire	11.13 (5.45)	13.13 (6.19)	1.92	0.076	0.34
Resistance	38.13 (11.96)	28.40 (12.54)	3.65	0.003*	0.79
Positive Relationship	41.93 (6.17)	41.53 (8.37)	0.20	0.841	0.05
Sexual Image	12.53 (3.20)	11.93 (2.46)	1.21	0.246	0.21
Concern	10 (4.52)	7.20 (3.57)	2.37	0.033*	0.69
GCS	21.40 (7.28)	11.73 (8.23)	3.99	0.001*	1.24
CSI <sup>†</sup>	100.50 (11.99)	106.43 (9.26)	2.96	0.011*	0.55
DBIQ	96.73 (15.59)	110.73 (22.05)	2.69	0.018*	0.73
BDI-II	14.73 (9.24)	6.87 (7.77)	4.68	0.000**	0.92
HAM-A	13.60 (7.28)	8.80 (8.64)	1.98	0.068	0.60

<sup>†</sup>1 participant did not complete the CSI.

\* $p < 0.05$ ; \*\* $p < 0.001$

## S-25.

**Qualitative findings from a pilot randomized controlled trial of mindfulness for low sexual desire in midlife and older women**

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**Objective:** Low libido is common among midlife and older women, but treatment options are limited in this population. We recently published results from a pilot randomized controlled trial (RCT) of a mindfulness intervention for midlife and older women with low libido. The purpose of the current presentation is to illustrate women's experiences with the trial and the mindfulness treatment through qualitative data. **Design:** We conducted individual interviews with participants in a RCT of a group-based mindfulness intervention versus an educational control group (N=25) as well as participants who were initially interested but did not attend any groups (N=9). A semi-structured interview guide was developed by the principal investigator (PI), a co-investigator, and qualitative research specialist. The qualitative research specialist conducted the interviews with trial participants over video conference. The PI conducted interviews with those who were interested but did not attend any sessions via telephone. All interviews were audio recorded and transcribed. We used a phenomenological approach to analysis. The qualitative research specialist and the PI used a subset of interviews to develop and refine a codebook, then the PI assigned codes to all data. Codes were grouped into subthemes and themes and key insights were extracted. **Results:** Three key themes emerged. First, women were **intrigued** by the combined topics of sexuality and mindfulness. One woman said, "It was just really intriguing to me... the interesting part was mindfulness, which I really wasn't that familiar with before I took the course. I just thought that was a unique way to go about it." Second, women in both intervention and control groups valued the sense of **community** they gained from participating. One woman commented, "I definitely got to know that I'm not the only one going through menopause. I'm not the only one who doesn't want to have sex. I'm not the only one in pain." Third, experiences with attending groups over **videoconferencing** software were largely positive. One woman said, "Well, I'm getting used to it, and it's kind of fun. That you can talk to people, you know, and not be in the same space. It's cool." Women had suggestions about the groups. First, they praised the facilitators and the **interactive** nature of sessions. One woman commented, "She really encouraged people and gave ample opportunity for us to share with each other... I liked that. 'Cause my house is all men. My husband and three sons, and nobody wants to hear me bitch about menopause. So it was really great to get together with these women every week and talk about women's stuff." However, they wanted a better understanding of the **randomization** process prior to participating and requested more **didactic** information about sexuality and aging. One woman from the control group explained, "I thought it was going to be focusing more on libido and

menopause. So when we were talking about bone density, I was like, oh, huh. I mean, it was interesting and helpful, but it wasn't what I was expecting. I was in the control group, I think," and another said, "I wanted her to be more like a class. Like, here's some slides and we're going to talk about this. Having a little bit more visual reinforcement." Participants who were randomized but did not attend any sessions listed **time conflicts** and lack of private space to participate in groups as their top reasons for dropping out. One of these women said, "I was excited about this one. And I got in my e-mail a list of dates and times for meeting. And I was looking over it and every single one of them I KNEW I would be working. And I'm looking at all of them like, this one too? Come on!" **Conclusion:** Women with low sexual desire are curious about mindfulness, group interventions are well received in this population, and participants desire a balance of didactic and interactive elements.

**Sources of Funding:** National Institute of Health's National Institute on Aging (K23AG052628) and National Heart Lung and Blood Institute (K24HL123565).

## S-26.

### Development of a Clinical-Grade AI Model for Menopause: An Analysis of Accuracy and Correlation with Human Clinical Experts

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**Objective:** Menopause represents a crucial phase in a woman's life, presenting unique challenges and health considerations. In recent years, advancements in artificial intelligence (AI) have shown promise in transforming healthcare delivery. In this manuscript, we present the development of a clinical-grade AI model specifically tailored for the menopause specialty. By leveraging a diverse dataset consisting of menopause experts' clinical content, patient interactions, social media discussions, and evidence-based medicine, we aimed to create an AI model capable of providing accurate and reliable responses to medical queries pertaining to menopause. **Design:** Our study employed a comprehensive dataset that encompassed a wide range of menopause-related information sources. This included clinical content from renowned menopause experts, anonymized patient interactions, data from relevant social media platforms, as well as evidence-based research from books and medical journals. The AI model was trained using state-of-the-art natural language processing techniques and machine learning algorithms, with careful consideration given to data quality, feature engineering, and model optimization. **Results:** The evaluation of our AI model demonstrated highly accurate responses to menopause-related medical questions. To assess its performance, we conducted a comparative analysis by correlating the AI model's answers with those provided by human clinical experts in the menopause specialty. The results indicated a strong correlation between the responses generated by the AI model and the expert opinions, highlighting the model's reliability and efficacy. These findings provide substantial evidence for the potential of AI in supporting clinical decision-making in the field of menopause. **Conclusion:** The development of a clinical-grade AI model specifically designed to address medical queries in the menopause specialty is approaching. The utilization of a diverse dataset, comprising menopause experts' clinical content, patient interactions, social media data, and evidence-based medicine, has contributed to the model's high accuracy in providing responses correlated with those of human clinical experts. These findings underscore the potential of AI technologies to enhance menopause management and offer valuable insights for clinicians and researchers. Looking ahead, integrating AI into clinical practice can empower healthcare professionals and improve patient outcomes in the field of menopause.

**Sources of Funding:** None

## POSTER PRESENTATIONS

### P-1.

#### A randomized, pilot trial comparing vaginal hyaluronic acid to vaginal estrogen for the treatment of genitourinary syndrome of menopause

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**Objective:** The objective was to compare the preliminary efficacy of a non-hormonal alternative, vaginal hyaluronic acid (HLA), to standard of care hormonal therapy, vaginal estrogen, for treatment of genitourinary syndrome of menopause (GSM). **Design:** This was a randomized, parallel arm trial of two study treatments: HLA vaginal suppository (investigational, 5mg HLA) and vaginal estrogen cream (standard of care, 0.01%). Post-menopausal women with GSM were randomized in a 1:1 ratio and followed for 12 weeks to compare the primary outcome, the vulvovaginal symptom questionnaire (VVSQ) score, between groups. Secondary outcomes included: the female sexual function index (FSFI), vaginal symptom index (VSI), visual analog scale (VAS) for dyspareunia, vaginal itching, and vaginal dryness, patient global impression of improvement (PGI-I), vaginal maturation index (VMI), and vaginal pH. Descriptive statistics characterized participants at study entry. Treatment effects were estimated through linear models adjusted for baseline score. The difference between groups at 12 weeks, adjusted for baseline score, is presented for continuous outcomes, with the associated 95% confidence interval (CI), and the risk difference is estimated for categorical outcomes with the exact 95% CI. The two-sample t-test assuming unequal variance was used to test the hypothesis that HLA improved primary and secondary outcomes. **Results:** From September 2021 to August 2022, 49 women were randomized: 26 to vaginal estrogen and 23 to HLA. Baseline characteristics were similar in both groups. There was no observed difference in overall VVSQ score adjusted for baseline between HLA and vaginal estrogen at 12 weeks

(-0.38, 95% CI -3.53, 2.78; p=0.8095) and all sub-domains improved in both groups after 12 weeks (Table 1). The VAS score, total VSI score, total FSFI score were all also improved and the level of improvement did not differ between study arms (Table 1). Similarly, vaginal pH did not differ between groups (-0.17, 95% CI -0.27, -0.08; p=0.2376). There was a significantly higher level of improvement for the VMI (33.94, 95% CI 21.25, 46.63; p<0.001) in the vaginal estrogen group as compared to HLA. Most patients noted improvement on the PGI-I in both study arms (Table 1). No treatment-related serious adverse events occurred in either group. **Conclusion:** Vaginal HLA and vaginal estrogen both improved GSM symptoms after 12 weeks of treatment. Vaginal HLA may be a promising non-hormonal therapy for the treatment of GSM.

**Sources of Funding:** Bonafide Health, LLC

Table 1. Outcomes by Randomized Treatment

		Vaginal Estrogen		Hyaluronic Acid		Mean difference adjusted for baseline at 12 weeks (95% CI)	p-value
		Baseline (n=26)	Change at 12 weeks (n=23)	Baseline (n=23)	Change at 12 weeks (n=22)		
Vulvovaginal symptom questionnaire, mean (SD) or mean difference (95% CI)	Overall	5.2 (5.2)	-3.7 (-6, -1.3)	5.8 (4.7)	-3.3 (-5.5, -1.1)	-0.38 (-3.53, 2.78)	0.8095
	Symptoms	1.7 (1.7)	-0.7 (-1.4, 0)	2.4 (2.1)	-1.1 (-2.2, -0.1)	0.40 (-0.79, 1.58)	0.5027
	Emotions	0.9 (1.3)	-0.7 (-1.3, -0.1)	1 (1.3)	-0.6 (-1.3, 0)	-0.06 (-0.88, 0.76)	0.8848
	Life-impact	0.7 (1.5)	-0.8 (-1.5, -0.1)	0.8 (1.3)	-0.7 (-1.3, -0.1)	-0.1 (-0.97, 0.77)	0.8171
	Sexual-impact	1.9 (1.8)	-1.4 (-2.3, -0.5)	1.6 (1.7)	-0.8 (-1.6, 0)	-0.62 (-1.79, 0.56)	0.297
Visual analog scale score, mean (SD) or mean difference (95% CI)	Dyspareunia	5.3 (3.6)	-3.6 (-5.1, -2.1)	5.1 (3.4)	-3 (-4.4, -1.5)	-0.61 (-2.62, 1.40)	0.5409
	Vaginal itching	2.5 (2.8)	-0.8 (-2.6, 1)	2.6 (2.8)	-1.6 (-3, -0.3)	0.83 (-1.36, 3.01)	0.4492
	Vaginal dryness	6.6 (2.3)	-4 (-5.6, -2.5)	6.3 (2.5)	-3.4 (-4.7, -2.1)	-0.65 (-2.62, 1.31)	0.5058
	Overall	6.8 (3.7)	3.3 (1.4, 5.3)	6 (3)	2.8 (1.2, 4.4)	0.58 (-1.86, 3.01)	0.6368
Vaginal symptom index score, mean (SD) or mean difference (95% CI)	Dryness	2.3 (0.9)	1.2 (0.6, 1.7)	2 (0.9)	0.9 (0.4, 1.3)	0.31 (-0.39, 1.01)	0.3749
	Soreness	1.2 (1.2)	0.7 (0.1, 1.3)	1.1 (0.9)	0.5 (0, 1.1)	0.15 (-0.63, 0.93)	0.6997
	Irritation	1.1 (1.1)	0.6 (0, 1.2)	1.3 (0.9)	0.7 (0.2, 1.2)	-0.12 (-0.89, 1.28)	0.7614
	Discharge	0.2 (0.6)	-0.4 (-0.8, -0.1)	0.2 (0.5)	-0.1 (-0.3, 0.1)	-0.30 (-0.69, 0.09)	0.1291
	Dyspareunia	2.1 (1.1)	1.3 (0.9, 1.8)	1.5 (1.1)	0.8 (0.4, 1.3)	0.53 (-0.07, 1.13)	0.0810
	Overall	13.4 (8.8)	-9.1 (-12.2, -6)	13.8 (8.6)	-5.3 (-8.1, -2.5)	-3.85 (-7.91, 0.22)	0.0629
	Desire	2.7 (1.1)	-0.5 (-0.8, -0.2)	2.5 (1.1)	-0.5 (-0.8, -0.1)	-0.01 (-0.42, 0.41)	0.9817
Female sexual function index score, mean (SD) or mean difference (95% CI)	Arousal	2.4 (1.9)	-1.4 (-2, -0.8)	2.4 (1.8)	-0.6 (-1.3, 0.1)	-0.78 (-1.69, 0.12)	0.0888
	Lubrication	1.6 (1.7)	-2.1 (-3, -1.3)	1.9 (1.8)	-0.9 (-1.5, -0.3)	-1.24 (-2.22, -0.26)	0.0147
	Orgasm	2.3 (2.2)	-1.6 (-2.5, -0.7)	2.5 (2.2)	-1.3 (-2, -0.5)	-0.33 (-1.4, 0.79)	0.5577
	Satisfaction	2.9 (1.5)	-1 (-1.7, -0.4)	3.1 (1.6)	-0.5 (-1.1, 0)	-0.48 (-1.32, 0.35)	0.2516
	Pain	1.5 (1.8)	-2.5 (-3.3, -1.7)	1.4 (1.7)	-1.5 (-2.3, -0.7)	-1.01 (-2.14, 0.11)	0.0763
Patient global impression of improvement, % (n)					0.05 (-0.10, 0.19)	0.608	
	A little better or higher	--	95.7 (22)	--	90.9 (20)		
	No change or worse	--	4.3 (1)	--	9.1 (2)		

Visual analog scale score was collected by measuring where the patient placed an X on a 10 cm line between the end points of no symptoms or extreme symptoms

### P-2.

#### False Positive Pap Smear as the first sign of Genitourinary Syndrome of Menopause

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**Objective:** Around 2010, we noticed an increase in the number of perimenopausal women presenting with abnormal Pap smears (cervical dysplasia) at our clinics. These women had no previous history of cervical abnormalities and were in long-term, stable sexual relationships with one or two partners. After consulting with our pathologist, we

learned that vaginal atrophy could be the cause of these abnormal results. Our objective is to investigate and determine the prevalence of false positive cervical dysplasia in premenopausal women, caused by genitourinary syndrome of menopause (GSM) and to evaluate the effectiveness of local estrogen therapy as a treatment option through a prospective study. We aimed to provide evidence-based data on the impact of GSM on cervical health and the potential cost savings from using local estrogen therapy to prevent unnecessary interventions and procedures. **Design:** A prospective follow-up study was conducted on perimenopausal and post-menopausal women with cervical dysplasia and low risk for sexually transmitted infections (STIs). The study included women between the ages of 30-70 years with Pap smears (cervical dysplasia) and low risk for STIs. Participants were recruited from multiple centers. Participants were placed on local vaginal with or without systemic estrogen therapy for multiple centers for several months. A Pap smear was conducted for 4 months and then 1 year after the initiation of therapy, followed by regular Pap smear follow-up. A sample size of 1500 patients was included in the study over a period of 12 years. Participants were recruited through our centers and through referral from our pathologist. Women between the ages of 30-70 years with abnormal Pap smears (Cervical dysplasia) and low risk for STIs, with no previous history of cervical abnormality and in a long-term stable sexual relationship with a maximum of 1 or 2 sexual partners were included in the study. Women with a history of cervical cancer, cervical dysplasia or any other Gynecological malignancies were excluded from the study. **Results:** A total of 1500 perimenopausal women with abnormal Pap smears were included in the study over a period of 12 years. Most patients (96.7%) were successfully treated with local estrogens. The study revealed that a high number of patients who initially presented with cervical dysplasia underwent further interventions such as colposcopies, biopsies, LEEP excisions, cryotherapy, and even cone biopsies and hysterectomies due to the persistence of cervical atrophy. However, after treatment with local estrogens, most patients (over 96%) showed normal Pap smear results. This suggests that false positive cervical dysplasia in the perimenopausal period is often secondary to the genitourinary syndrome of menopause as the first sign of this syndrome, before any other symptoms of menopause has been presented and can be easily treated with the use of local estrogens. On the other hand, it was observed that some patients who underwent cone biopsies and hysterectomies and did not receive local estrogens treatment experienced persistence of "vaginal dysplasia". This is likely due to the persistence of vaginal epithelial atrophy, which led to a continued false reading of cervical dysplasia. The use of local estrogens in this population not only prevented a significant number of unnecessary interventions, but also saved billions of dollars per year. **Conclusion:** In this study, we report an early sign of genitourinary syndrome of menopause: false positive cervical dysplasia caused by cervicovaginal atrophy resulting from decreased estrogen levels during perimenopause. We also demonstrate how the use of local estrogen therapy can prevent a significant number of interventions and procedures, resulting in significant cost savings. This is particularly relevant as the number of Pap smears conducted in this population represents 50-60% of all Pap smears performed on women.

**Sources of Funding:** none

### P-3.

**Optimizing Menopausal Management in Incarcerated/Reentry Women**  
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**Objective:** The rate of female incarceration is increasing and many women are behind the wall for long periods of times. As a result, the correctional system has a larger population of peri- and post menopausal women. With the correctional system historically focused on male individuals, there have been gaps in female health needs including education, awareness, and health care accessibility. One important healthcare consideration amongst the aging female inmate population is menopause management. The menopause transition is linked to a variety of physical and psychological symptoms that may persist over 10 years and can have a serious influence on one's well-being. Symptoms due to menopause can be exacerbated in incarcerated women as there may be restricted availability of therapeutic interventions. Adding to the stress of being in prison, incarcerated women usually do not have the ability to alter their lifestyle to ameliorate menopausal symptoms (such as wearing layers of clothes, drinking cold beverages as needed, and taking frequent showers). Focused attention to this group of women, as is being done with the NJ Reentry Program is an effective way to address these menopausal women's health issues. **Design:** A literature-based review of articles pertaining to menopause management within incarcerated populations was conducted through online databases including PubMed and Google Scholar. Keywords and phrases such as "menopause in prisons" were used to narrow and specify results. **Results:** The data suggest that there are obvious barriers to optimal management of menopausal symptoms for aging women in prison. For example, many incarcerated women do not have access to optimal management of their symptoms. Further, once reentered into their communities, many menopausal women cannot afford medical care and prescriptions; as well, many cannot afford the co-pays. Supporting this finding, in targeted research conducted by the North Carolina Department of Public Safety it was found that less than 5% of incarcerated women between the ages of 45 and 54 received estrogen-containing medication. The NJ Reentry Team is one entity that recognizes the needs of women, including menopausal women and is implementing ways to optimize wellness for them, both while incarcerated and upon their reentry. **Conclusion:** In general, female inmates experience more specific health issues than male inmates, which results in a higher demand for prison and reentry health services. It is important to consider how female health issues, such as menopause, may impact the overall wellness of women both while

incarcerated and upon reentry to their community. More attention to the incarcerated/reentry menopausal woman and support for her comprehensive health and wellness care is essential.

**Sources of Funding:** None

### P-4.

**Relationship between the type of hormone therapy and incidence of myocardial infarction and stroke in Korea**

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**Objective:** To investigate the relationship between hormone therapy (HT) types and myocardial infarction (MI) and stroke incidence in postmenopausal women in Korea. **Design:** This nested case-control study used data from the National Health Insurance Service database. Among the women aged  $\geq 50$  years and menopausal between 2004 and 2007, MI and stroke incidence up to 2017 was analyzed in 36,446 women using or having used HT for  $>1$  year and in 36,446 women who did not use any HT for more than 1 year. HT types and duration were classified into three categories. **Results:** With HT initiation in women  $\geq 50$ s, MI risk (MIR) was lower with all types of HT. When using estrogen-progestogen therapy (EPT) and estrogen-only therapy (ET) in 50s, EPT in 60s, and tibolone in 70s, Stroke risk (SR) was decreased. Except for the using EPT for 3-5 years, MIR decreased when using any HT. SR was decreased when using tibolone for  $\geq 5$  years or when using EPT and ET for 1-3 or  $\geq 5$  years. **Conclusion:** In Korean women  $\geq 50$ s, EPT decreased MIR and SR; for all ages, any HT for  $>5$  years showed lower MIR and SR. After the WHI study, HT use decreased, and different results with previous studies may have occurred because HT was prescribed only for those with a low risk.

**Sources of Funding:** none

### P-5.

**Increasing Access to Healthcare for Older Women Through Faith Based Organizations**

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**Objective:** Throughout time, faith and medicine have been intertwined, leading to the fortuitous outcome of both health promotion and disease prevention. Faith Based Organizations (FBOs) still remain a cornerstone in modern society, as well as serving as centers for spiritual wellness. A FBO is classified as any religious place where congregants come together with similar beliefs, missions, and values. Research highlights that regular congregants of FBOs primarily consist of women, with more than 50% being older women (Derose et al., 2018). Therefore, FBOs are the ideal location to target under-screened older women. This literature review will explore the outcomes of having accessible healthcare for older women in Faith Based Organizations. **Design:** A Literature review via PubMed, the Rutgers University Libraries, and Google Scholar was conducted. Keywords included "accessible healthcare for women in faith based organizations," and "accessible healthcare for older women in faith based organizations." **Results:** According to the World Health Organization, having accessible healthcare in FBOs helps to bridge the gap in health disparities by reaching traditionally underserved populations (2008). Furthermore, a church-based Health Promotion program was conducted to make healthcare more available to the aging population in Jamaica. A project aimed at healthy eating habits to target diabetes among African American women found that 63% of women believed that the church was a respected institution to promote healthy lifestyle behavior. Similarly, Project Joy cardiovascular health initiative served to provide heart health education to African American women. Project Joy led to positive results among their target participants (Tomlinson, 2018). Likewise, Abuelas en Acci3n (AEA) targeted Latina women aged 50 or older by incorporating faith-centered and culturally sensitive approaches. The results showed that participants felt empowered which enabled them to follow the program consistently (Schwingel et al., 2015). Furthermore, another faith-based study aimed at increasing older African Americans' participation in clinical trials was successful in recruiting a cohort of mostly older women (Frew et al., 2015). As a form of community-based participatory research, faith-based interventions have the potential to garner support from hard-to-reach populations (Schwingel et al., 2015). **Conclusion:** Church-based support has been linked to the uptake of other screening behaviors, such as mammography screening and HIV testing (Christensen et al., 2022) and has the potential to enhance physical, spiritual, and mental health (Schwingel et al., 2015). Therefore, utilizing the trust and stability of FBOs, with local community health resources, and the knowledge that minority congregants are more than 50% older females, can help alleviate the multiple barriers women in these communities face regarding equitable access to care.

**Sources of Funding:** None

### P-6.

**Estetrol (E4): A Promising New Treatment for the Spectrum of Menopausal Symptoms**

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**Objective:** The extensive program of pre-clinical and clinical research that has been undertaken in the last 30 years to understand the properties and clinical applications of E4 is a great example of successful translational medicine. We summarize and contextualize the key findings, outcomes, and present an update on new insights. **Design:** Narrative

review of the published literature. **Results:** There are four naturally occurring estrogens in humans - E1, E2, E3, and E4. E1, E2, and E3 were first synthesized in the late 1920's and 1930's and were quickly recognized as potential therapeutic agents. E4, a human fetal estrogen produced during pregnancy by the fetal liver, was first described in 1965 but its translation to therapeutic use was more recent; with approval recently granted for the use of E4 in a combined oral contraceptive in the US, Canada, Europe, and Australia. Studies are also underway to determine its suitability as a menopausal hormone therapy in postmenopausal women for the relief of vasomotor symptoms (VMS). The effects of estrogens are primarily mediated through the estrogen receptors (ERs), ER $\alpha$  and ER $\beta$ , via genomic modulation by estrogen/ER complexes in the nucleus, and via rapid non-genomic signaling events initiated at the membrane by estrogen/ER complexes. Studies have found that E4 binds to both ER $\alpha$  and ER $\beta$  but has a 4-5 fold binding preference for ER $\alpha$ . E4 has the capacity to induce transcriptional activation in the nucleus via both the classical and nonclassical genomic pathways, like E2. Investigations have shown that binding of E4 and E2 to the ER $\alpha$  ligand binding domain results in similar conformational changes in the receptor. Recent investigations also revealed that, although E4 was less potent, the recruitment and binding patterns of coregulators to ER $\alpha$  are similar. Evidence from recent clinical trials has shown that nuclear ER $\alpha$  activation by E4 mediates numerous processes and, like E2, it is capable of eliciting many of the positive estrogenic actions (such as epithelial proliferation in the uterus and vagina, the prevention of bone demineralization, glucose homeostasis, and cardioprotective effects). This has important implications for its potential use in the menopause. Daily treatment with E4 for 12 weeks in a phase II trial (NCT02834312) led to improvements in the symptoms of genitourinary syndrome of menopause, vaginal atrophy, and quality of life as assessed using the Menopause Rating Scale, in addition to improved VMS in postmenopausal women. Short-term treatment with E4 in this study also resulted in a reduction in markers of bone turnover associated with osteoporosis. Although E4 activates ER $\alpha$  pathways in a similar way to E2, it does not activate membrane associated non-genomic signaling in all tissues. This unique feature is associated with E4's potential to mitigate some of the unwanted effects of estrogen treatment on non-target tissues such as the breast. Preclinical data indicate that E4 has a weaker potency to induce human breast cancer cell growth *in vitro* and *in vivo* when compared to E2. Clinical data have also shown that E4 has a pro-apoptotic effect on tumor tissue in pre- and post-menopausal women with ER+ early breast cancer, as well as anti-tumor effects in postmenopausal women (5 out of 9 subjects) with locally advanced and/or metastatic ER+/HER2- breast cancer treated with 20 or 40 mg E4. The primary metabolites of E4 in plasma following oral administration are E4-16-glucuronide, E4-3-glucuronide, and E4-glucuronide-sulfate, thus confirming that E4 is the terminal end-product of metabolism. This contrasts with other estrogens, including E2 which is converted to hydroxylated metabolites associated with DNA damage relevant in breast cancer development, and E1, which has been associated with thrombin generation. Notably, E4 in combination with DRSP does not impact thrombin generation and exhibits a neutral homeostatic profile. **Conclusion:** An extensive program of pre-clinical and clinical research was undertaken to understand the properties of E4 in the hope that E4 would be a distinct and improved estrogen for therapeutic use. Evidence to date provides support for this.

**Sources of Funding:** Funded by Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Belgium.

## P-7.

### Menopause in Healthcare Workers: Entirely Digital Program Provided as Healthcare Benefit to Treat Symptoms, Address Quality of Life, and Improve Work Satisfaction

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**Objective:** Menopause impacts an estimated 55 million US women per year with data suggesting a cost of \$26.6 billion per year due to lost productivity and health expenses. Menopause is particularly relevant for health systems, with a workforce that is 76% female and >50% of employees over age 50. Given the pressing challenge of employee retention, it is imperative to understand and effectively treat healthcare workers' menopause experience and build solutions to support this population. Recent data suggest that menopause plays an important role in women's work sentiment and productivity: 21% have passed on a promotion, 40% report menopause symptoms affect work performance or productivity on a weekly basis, and 17% have quit or are considering resigning because of menopause symptoms. To address this critical unmet health and workforce need, a joint venture between a leading health system and a technology startup created a menopause telehealth company. An initial pilot was offered as a covered benefit to health system employees. **Design:** This observational cohort analysis evaluated pilot members seeking menopause support from February to May 2023. The entirely digital program provided medical care with NAMS-certified ObGyn physicians in conjunction with health coaching for lifestyle factors and health behavior modifications delivered by board-certified health coaches. In June 2023, baseline and end of pilot data were analyzed to understand trends in symptoms, quality of life, health behaviors, and work satisfaction and performance. **Results:** Baseline information was available for n=49, and follow up survey responses were obtained for n=26-36. Average age was 51, with 39% of members in menopausal transition, 37% postmenopausal, 8% premenopausal, 14% unsure of their menopause status, and 2% declining to respond. While 84% of participants sought to address menopause symptoms, other goals of care included: weight management (82%), fitness (51%), sex life (49%), support with preventative health (47%), mood (45%), and relationships (20%). Health habits at baseline were as follows: 24% did not consider themselves to have a healthy diet, 35% did not exercise daily, and 43% slept between

2-6 hours/night. After the pilot, 92% reported progress toward at least one health goal. At baseline, 57% reported menopause-related issues affected their personal life and ability to enjoy things they love, 65% reported not having enough energy throughout the day, and 51% reported menopausal symptoms impacted their work. At the end of the pilot, 69% reported feeling more medically supported, 67% stated they felt more positive about their employer, and there were positive trends for missing fewer workdays and feeling more productive at work. 78% were interested in referring someone they knew for care on the platform. **Conclusion:** Menopause is a critical issue for healthcare workers with impact going beyond conventional symptoms alone. Importantly, participants in this pilot program described wide-ranging quality of life as well as work sequelae stemming from menopause, spanning lack of enjoyment in life to missed days of work. Given crucial workforce shortages for healthcare, it is particularly important to develop solutions that effectively treat symptoms as well as support work and quality of life concerns. Healthcare workers were eager to participate in an entirely digital offering and derived health and work benefits from a comprehensive menopause program. This analysis demonstrates an exciting opportunity to further evaluate new models of menopause care that deliver substantial health benefits to midlife women as well as business impact for employers.

**Sources of Funding:** Aegis Ventures and Northwell Holdings

## P-8.

### Association between health conditions and the body adiposity index (BAI) in climacteric women attending Primary Health Care (PHC)

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**Objective:** The study proposes to investigate the association between health conditions and body adiposity index (BAI) in climacteric women attending Primary Health Care (PHC). **Design:** Cross-sectional study with climacteric women selected by probability sampling between August 2014 and August 2015. Structured and pre-tested questionnaires were used to assess sociodemographic characteristics, behavioral habits, and clinical factors. Anthropometric measurements such as body adiposity index (BAI) and hip circumference (HC) were obtained using standard equipment and techniques. The index was calculated with a mathematical equation that uses the measurements of hip circumference (cm) and height (m). The values found for these variables were applied to the equation that divides the hip circumference measures (cm) by height (m) multiplied by the square root of height (m), and the result is decreased by 18. Excessive adiposity is considered when IAC  $\geq$  33%, according to studies by Bergman and collaborators (2011). Women were classified as having metabolic syndrome when changes were present in three or more components (triglycerides, HDL-cholesterol, fasting glycemia, abdominal circumference and elevated systolic blood pressure) according to the criteria defined by the NCEP/ATP-III. The level of physical activity was assessed by the short version of the International Physical Activity Questionnaire (IPAQ). Descriptive analyses were performed for all investigated variables from their frequency distributions. Then, bivariate analyses were performed through Poisson regression, and for multiple analyses we used hierarchical Poisson regression to identify factors associated with BAI in climacteric women. **Results:** The sample was composed of 874 women, out of which 58.8% were in pre-menopause and 41.2% were in postmenopause. Out of these women, 31.4% of the premenopausal and 24.4% of the postmenopausal women had an altered BAI. In premenopause, the altered BAI was associated with the presence of MS (RR = 1.72 [95%CI 1.05-1.31]); and in post menopause, it was associated with the consumption of fatty meat/chicken at least 3 times a week (RR = 1.28 [95%CI 1.01-1.80]), with MS (RR = 1.15 [95%CI 1.03-1.29]), and with the absence of physical activity (RR = 1.00 [95%CI 1.10-1.57]). **Conclusion:** Climacteric women showed high prevalence of BAI associated with MS, consumption of animal fat, and absence of physical activity. In primary health care, knowing the health conditions of climacteric women associated with the prevalence of visceral adiposity, measured by the BAI, can be a preventive marker of future diseases.

**Sources of Funding:** None

## P-9.

### Menopause and Multiple Sclerosis: A Need for Clarity for OBGYN Providers

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**Objective:** Multiple Sclerosis (MS) is a chronic demyelinating disease that afflicts over 1 million people in the United States with the highest incidence in the northeast of the country. Women of childbearing age are mostly affected at a ratio of 3:1 compared to men. As the treatment armamentarium for MS continues to expand, patients in the menopausal period with MS who will need care will also rise. Symptoms of MS and menopause can often overlap such as mood, sleep, and bladder function, creating challenges for providers in the management of patients. This study intends to understand the clinical care and knowledge gaps of obstetric and gynecological providers for patients

with Multiple Sclerosis in menopause. **Design:** All obstetricians and gynecologists with qualifications of MD, DO, PA, or APN within a single health network were contacted over email to complete a REDCap survey. The survey assessed the knowledge and gaps within the field of obstetrics and gynecology for MS patients. Responses were collected during a period of 12 weeks. The institutional review board approved all procedures at Hackensack University Medical Center (Hackensack, NJ; IRB Pro2022-0237). 35 respondents were included in the study with a response rate of 29.2%. The majority of respondents were general obstetricians and gynecologists (n=27, 77.1%) with a large range of experience [0-5 years (n=11, 31.4%), greater than 20 years (n=12, 34.3%)] in a variety of settings [inpatient (n= 25, 71.4%), outpatient (n=21, 20%), academic hospital (n=24, 68.6%), community hospital (n=4, 11.4%), multi-specialty group (n=1, 2.9%), single specialty group (n=11, 31.4%), solo private practice (n=2, 5.7%)]. **Results:** The majority of respondents reported having treated a patient with MS before (n=25, 71.4%), and 40% reported having treated a patient with MS within the last 6 months to 1 year. Self-reported confidence was assessed with 17 reporting poorly (48.6%), 16 somewhat (45.7%), and 2 very (5.7%) confident. After completion of the survey, 1 respondent remained very confident (2.9%), and 14 (40%) and 20 (57.1%) reported somewhat and poor confidence respectively in their knowledge of managing patients with MS. 18 participants (54.5%) stated that menopause was not associated with changing symptoms. No additional screenings were recommended by 78.8% of participants. Those who did recommend additional screenings advised monitoring FSH and estrogen levels and screening for osteoporosis. These recommendations did not differ by the number of years of experience (p=0.7668). **Conclusion:** Providers are unclear if menopause is associated with changing of MS symptoms. Consistent with the literature, studies have demonstrated both improvement and worsening of symptoms during menopause with others indicating a transitory aggravation in symptoms. Similarly, there are no current guidelines on the recommendations of treatment for menopause in MS patients such as hormone replacement therapy. Further research is therefore required to understand the role of menopause in MS to establish clear guidelines for providers.

**Sources of Funding:** None

## P-10.

### Correlations Among COMMA-recommended VMS Outcomes in MsFLASH Trials

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**Objective:** The historical lack of conceptual or methodological agreement on the measurement of vasomotor symptoms (VMS) creates barriers for exchanging, pooling, and comparing data. The study purpose was to advance understanding of VMS measurement using recommendations of the Comma Core Outcomes in Menopause (COMMA) global initiative and pooled baseline and post-treatment data from midlife women enrolled across three MsFLASH trials. Specific aims were to examine (1) correlations among VMS frequency, severity, bother, interference (including impact on sleep), and standardized sleep scales (insomnia severity, sleep quality/disturbance) at baseline and post-treatment and (2) relationships between satisfaction with VMS treatment and baseline to post-treatment changes in VMS frequency, severity, bother, interference (including impact on sleep), and standardized sleep scales (insomnia severity, sleep quality/disturbance). **Design:** Across the three randomized controlled trials, participants self-reported VMS frequency, severity, and bother using daily diaries; completed standardized measures of VMS interference, insomnia severity, and sleep quality/disturbance; and completed four MsFLASH-designed items measuring satisfaction with VMS treatment. Participant characteristics were analyzed using descriptive statistics. Aim 1 relationships were analyzed using Pearson's correlations for the pooled sample at baseline and post-treatment (n=899) and at post-treatment for participants who received placebo only (n=389). The Aim 2 analysis included independent samples t-tests and analysis of variance. **Results:** Participants were mostly postmenopausal (82.9%) and a mean of 54.5 years old. VMS frequency was fairly correlated with severity, bother and interference for pooled baseline and placebo post-treatment samples ( $r^2$ 's=0.21 to 0.39) and moderately correlated with severity, bother and interference for pooled post-treatment ( $r^2$ 's=0.40 to 0.44). VMS severity, bother, and interference were moderately correlated with one another ( $r^2$ 's=0.41 to 0.48), with one exception ( $r=0.37$ ). VMS severity and bother were strongly correlated ( $r^2$ 's=0.90 to 0.92). VMS interference was moderately correlated with insomnia ( $r^2$ 's=0.45 to 0.54) and fairly to moderately correlated with sleep quality/disturbance ( $r^2$ 's=0.31 to 0.44). Other VMS outcomes were weakly to fairly correlated with insomnia ( $r^2$ 's=0.07 to 0.33) and sleep quality/disturbance ( $r^2$ 's=0.06 to 0.26). Greater improvement in all outcomes over time was associated with greater satisfaction with VMS treatment ( $p$ 's < .0001). **Conclusion:** This pooled analysis advances understanding of VMS outcomes measurement. Findings suggest (1) VMS frequency was not strongly correlated with other VMS outcomes, (2) severity and bother are highly correlated, (3) 3-item and 10-item interference measures performed equally well, (4) the insomnia severity measure that was used may be more relevant to VMS research than the sleep quality/disturbance measure, (5) findings were similar over time, and (6) each of the four items measuring satisfaction with VMS treatment performed well. These findings have implications for selection of measures and raise questions to be addressed in future research.

**Sources of Funding:** Grant numbers: U01AG032656, U01AG032659, U01AG032669, U01AG032682, U01AG032699, U01AG032700, U01AG032682, UL1RR025761.

## P-11.

### “Quick Flutter Skip”: Women’s Descriptions of Menopause Palpitations

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**Objective:** Very little is known about how peri- and post-menopausal women describe palpitations and their healthcare experiences related to the symptom. Additional understanding is foundational for building tools to assess palpitations in clinical practice and research, preparing women to talk with their providers about the symptom, and determining where interventions may be needed. The objective of this study was to describe peri- and post-menopausal women's experiences of palpitations and their healthcare experiences related to the symptom. **Design:** Qualitative data used for this study were drawn from a larger case-control study where the primary objective was to compare electrocardiogram (ECG) results between peri-/postmenopausal women who did and did not report palpitations. Participants who screened eligible, consented, and were verified eligible based on a 2-week symptom diary wore a multi-day ECG patch, and completed a semi-structured interview via a secure videochat platform. After verifying interview transcriptions, authors analyzed narratives using standard content analytic procedures. **Results:** Participants reporting palpitations (n=14) were a mean of 54 years old (SD=4.83, range 46 to 62). Women self-reported as being non-Latina White (n=8), non-Latina Black (n=4), Latina White (n=1), or non-Latina Asian (n=1). Most were married (71%, n=10), working full time (n=11, 79%), postmenopausal (n=79%), and reported no difficulty paying for basics (n=11, 79%). Mean body mass index was 30.47 (SD=7.59). Participants often had difficulty describing the quality of their palpitations and other symptom dimensions (frequency, severity, distress, duration and temporal pattern, aura, associated symptoms, and aggravating/alleviating factors). Although all participants with palpitations endorsed feeling a racing or rapid heartbeat, there was a great deal of inter-individual variability in other sensations that were felt as well as in other symptom dimensions. Participants also reported variability in their healthcare experiences. Although half of the participants indicated their provider was aware of their palpitations, there was variation in the types of diagnostic tests ordered. The other half of the participants had not reported their palpitations to a provider despite having access to one. Some of these women created worse case scenarios for their palpitations under which they would seek care. These scenarios were directly related to their decisions to avoid healthcare. **Conclusion:** Participants reporting palpitations (n=14) were a mean of 54 years old (SD=4.83, range 46 to 62). Women self-reported as being non-Latina White (n=8), non-Latina Black (n=4), Latina White (n=1), or non-Latina Asian (n=1). Most were married (71%, n=10), working full time (n=11, 79%), postmenopausal (n=79%), and reported no difficulty paying for basics (n=11, 79%). Mean body mass index was 30.47 (SD=7.59). Participants often had difficulty describing the quality of their palpitations and other symptom dimensions (frequency, severity, distress, duration and temporal pattern, aura, associated symptoms, and aggravating/alleviating factors). Although all participants with palpitations endorsed feeling a racing or rapid heartbeat, there was a great deal of inter-individual variability in other sensations that were felt as well as in other symptom dimensions. Participants also reported variability in their healthcare experiences. Although half of the participants indicated their provider was aware of their palpitations, there was variation in the types of diagnostic tests ordered. The other half of the participants had not reported their palpitations to a provider despite having access to one. Some of these women created worse case scenarios for their palpitations under which they would seek care. These scenarios were directly related to their decisions to avoid healthcare.

**Sources of Funding:** Indiana University Ethel Clarke Fellowship and a Collaboration in Translational Research Grant from the Indiana Clinical and Translational Sciences Institute funded, in part by UL1TR002529 from the NIH/NCATS Clinical and Translational Sciences Award.

## P-12.

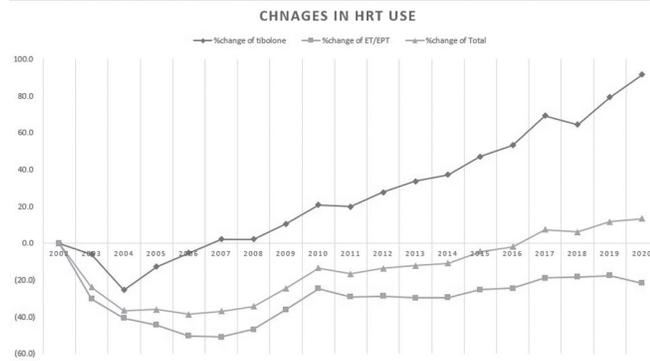
### Hormone replacement therapy and Breast cancer incidence in Korean women.

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**Objective:** Following the Women's Health Initiative (WHI) publication in 2002, HRT (Hormone replacement therapy) use for postmenopausal women has decreased worldwide. Since then, it has been reported that breast cancer incidences have decreased in many Western countries, but the relationship whether the decrease in HRT use has affected breast cancer incidences is still unclear. In the case of breast cancer in Korea, incidences by age group have different characteristics from the West. In addition, there was a question that the breast cancer risk caused by HRT could also have different aspects in Korea. Therefore, the purpose of this study is to track the change of HRT use in Korea since 2002 to 2020, and analyze breast cancer incidence in Korean women to reveal the relationship between the use of HRT and breast cancer risk in Korean women. **Design:** This study used tumor registry information from 2002 to 2020 in Kosis (Korean Statistical Information Service). We compared age-specific and age-adjusted breast cancer incidence rates from 2002 to 2020. Information on the prescriptions of Estrogen, Estrogen-progestin drugs, Tibolone used for HRT in Korea from 2002 to 2020 was collected from pharmacy data. **Results:** In Korea, the rate of change in ET/EPT (Estrogen therapy/Estrogen-Progestin therapy) prescriptions decreased from 2002 to 2007, to the lowest level of -50.9%, and then gradually increased to -24.6% in 2010,

but then decreased again, and the ET/EPT prescription in 2020 was to be -21.7% as of 2002. However, in the case of Tibolone, the prescription amount decreased to -25.4% in 2004, and then gradually increased, showing that it was +91.7% in 2020. Changes in the prescription amounts of ET and EPT were analyzed separately from 2007 to 2020, and in the case of EPT, it showed a slight increase from 2007 to 2010, but has continued to decrease since 2020. The number of breast cancer in Korea continued to increase from 2002 to 2020, and incidence rate per 100,000 people also increase from 34.3 in 2002 to 96.4 in 2020. In particular, the number of breast cancer patients in women over the age of 50 who are commonly prescribed HRT is increasing more steeply compared to women under the age of 50. Comparing the changes in hormone receptor expression rate in Korea by year, ER positive was 58.2% and PR positive was 50.7% in 2002, and it gradually increased to 76.7% and 67.3% in both cases, at 2019. **Conclusion:** In the case of Korean women, the incidence of breast cancer steadily increased from 2002 to 2020, and in particular, the incidence of breast cancer increased rapidly in women over the age of 50. The proportion of ER and PR positive breast cancer also increased. However, the prescription amount of Estrogen/Estrogen-progestin drug for HRT in Korea has decreased compared to 2002. In the case of EPT, the prescription amount showed a steady decline for 10 years from 2010. In conclusion, HRT, especially EPT, does not tend to increase breast cancer incidence in Korean women, and further research on breast cancer risk factor suitable for Korean women is needed.

**Sources of Funding:** None



**P-13.**

**Survey of perimenopause symptom prevalence and tracking – importance for the patient and clinician**

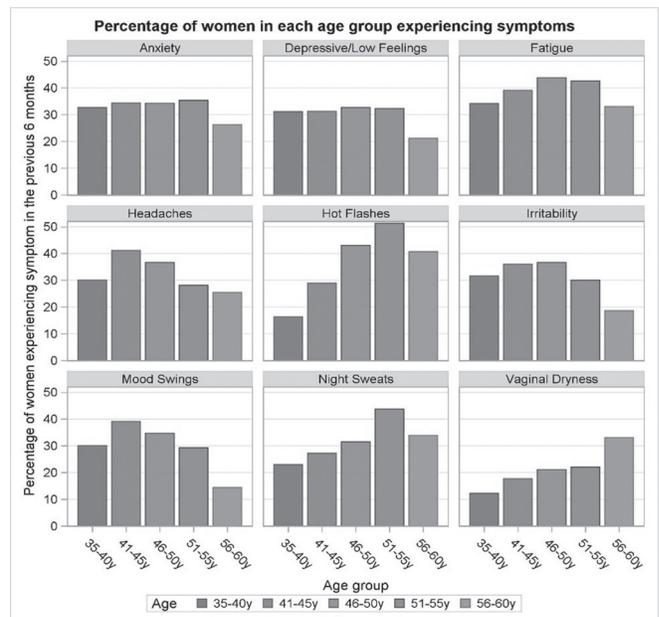
Sarah Berga<sup>2</sup>, Suruchi Thakore<sup>2</sup>, Lucy Broadbent<sup>1</sup>, Joanna Pike<sup>4</sup>, Fiona Clancy, PhD<sup>1</sup>. <sup>1</sup>R&D, Clearblue Innovation Centre, Bedford, United Kingdom; <sup>2</sup>Jacobs School of Medicine and Biomedical Sciences, University at Buffalo, Buffalo, NY; <sup>3</sup>Reproductive Endocrinology and Infertility, University of Cincinnati, Cincinnati, OH; <sup>4</sup>Marketing, Swiss Precision Diagnostics GmbH, Geneva, Switzerland

**Objective:** Over 55 million US women are approaching or in menopause, with the typical age at menopause of 51 years. Often perimenopause symptoms start years before and may be confused with other health issues. The prevalence of menopause symptoms in women age 35-60, and the use of methods to track them, was investigated. **Design:** 1022 US women aged 35–60y completed an online survey (conducted by Hotspex, February 2022). Incidence of 22 menopause-related symptoms experienced in the previous 6 months were surveyed and ranked. The use of methods to track menopause symptoms, and perceptions and attitudes towards menopause, were also studied. **Results:** Vasomotor symptoms including hot flashes (16-51%) and night sweats (23-44%) increased with age, but declined in the 56-60y cohort (41% and 34%). Vaginal dryness also became more troublesome with age, peaking in 56-60y cohort (33%). Fatigue was consistently listed in the top 5 symptoms for all age groups (incidence of 33-44%). Younger women were more likely to experience mood symptoms including irritability (30-37%) and mood swings (29-39%) but these were less common among those 56-60y (19% and 14% respectively). Use of cycle tracking apps was most common in women <45y (7-10%), however, few women of any age used menopause tracking apps (<3%). **Conclusion:** Though menopause symptoms are common across all ages, women seldom track them. Tracking perimenopausal symptoms along with menstrual cycles would be beneficial to facilitate conversation between patient and physician and to better tailor personalised treatment/management plans.

**Sources of Funding:** None

Percentage of women using apps to help track or treat menopausal symptoms:

App type	35-40y	41-45y	46-50y	51-55y	56-60y
A general period / cycle tracking app	6.6	9.5	8.0	3.4	0.0
A menopause tracking app	2.6	0.3	2.0	0.4	0.0



**P-14.**

**Use of serial FSH measurements to detect menopause transition.**

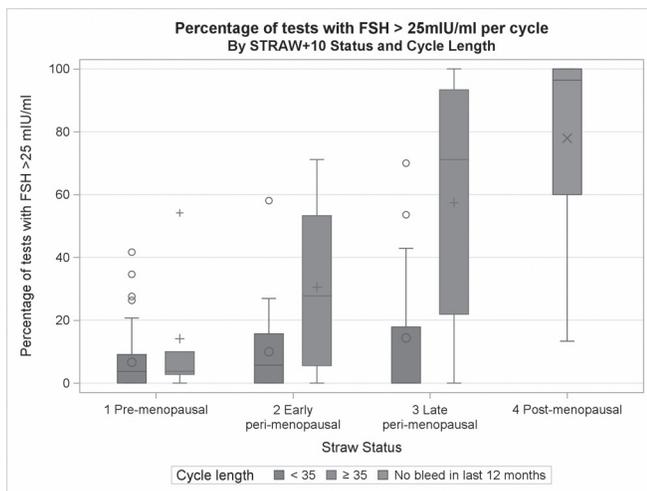
Sarah Berga<sup>2</sup>, Suruchi Thakore<sup>2</sup>, Sinead Tothill<sup>3</sup>, Nuzhat Ashra<sup>4</sup>, Fiona Clancy, PhD<sup>1</sup>. <sup>1</sup>R&D, Clearblue Innovation Centre, Bedford, United Kingdom; <sup>2</sup>Obstetrics and Gynecology, University at Buffalo Jacobs School of Medicine and Biomedical Sciences, Buffalo, NY; <sup>3</sup>Scientific and Medical Affairs, Clearblue Innovation Centre, Bedford, United Kingdom; <sup>4</sup>Statistics and Data Management, Clearblue Innovation Centre, Bedford, United Kingdom; <sup>5</sup>Reproductive Endocrinology and Infertility, University of Cincinnati, Cincinnati, OH

**Objective:** The timing and symptoms of the menopausal transition vary for each individual. The inherent variation complicates clinical recognition and diagnosis. Single measure, home follicle stimulating hormone (FSH) tests claim to determine menopause status but interpretation may be limited by fluctuations in hormones including FSH. To account for fluctuations, serial urinary FSH were measured, in combination with cycle length, to determine the utility for indicating menopausal stage. **Design:** Daily urines were collected for up to 90 days from women whose menopausal status was classified according to STRAW+10 (n=108). Quantitative urinary FSH concentrations were determined using the Tecan autoanalyzer. A FSH concentration ≥25 IU/L was classified as ‘positive’. **Results:** Median urinary FSH levels increased across the menopause transition (pre-menopause 6.4 IU/L (n=1232), early peri-menopause 10.6 IU/L (n=1044), late peri-menopause 32.8 IU/L (n=2725), post-menopause 45.0 IU/L (n=872)). Averaging across cycles, the percentage of positive tests increased as women moved through menopause stages (3.8%, 8.0%, 37.6%, 96.4% from pre- to post-menopause respectively). FSH alone differentiated pre- from post-menopause. The addition of cycle length (< and ≥ 35days) to FSH concentration (< and ≥ 25 IU/L) differentiated peri- from pre- and post-menopause. Percentage of positive FSH tests increased with longer cycle length as defined by STRAW+10 cohorts. **Conclusion:** Serial urinary FSH measurements at home, combined with cycle length information, could provide women with an initial indication of her menopause stage.

**Sources of Funding:** None

Average FSH concentration for each STRAW+10 status group

STRAW+10 Classification	Number of FSH observations	Mean	SD	Median	Min	Max
1 Pre-menopausal	1232	9.97	11.12	6.38	0.37	120.55
2 Early peri-menopausal	1044	16.71	17.98	10.58	0.35	203.27
3 Late peri-menopausal	2725	40.48	33.86	32.78	0.00	247.44
4 Post-menopausal	872	57.33	42.71	45.00	0.00	373.23



Percentage of positive FSH tests (>25mIU/ml) per cycle, by STRAW+10 and cycle length

### P-15.

#### Health Disparities and Hormone Therapy Prescribing for Peri and Postmenopausal Women: A Scoping Review.

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**Objective:** 75% of women going through menopause experience symptoms that impact their health negatively. The study's aim was to conduct a scoping review (ScR) of real-world studies to assess if healthcare disparities in menopausal hormone therapy prescribing (MHT) exist based on demographic or clinical characteristics. **Design:** PRISMA guidelines for ScRs were followed. A search strategy was conducted in the PubMed, CINAHL, Cochrane Library, Web of Science, and PsychInfo electronic databases for real-world studies written in English and conducted in the United States (U.S.) from January 1940 to December 2022. The search strategy was peer reviewed, including key words/MeSH terms for menopause, health disparities, prescribing patterns for hormone therapy and demographic/clinical characteristics. Two investigators and trained students screened abstracts and full articles. Data were extracted independently. The senior investigator resolved discrepancies. Comparators were based on social determinants of health (SDOH) including age, race/ethnicity, education, income, insurance type, body mass index, and mental health (including alcohol or substance use). Men, children, adolescents, trans-men, and women diagnosed with medical conditions where MHT was contraindicated were excluded. Randomized clinical trials were excluded, so MHT prescribing patterns were not based on a protocol or inclusion/exclusion criteria set by investigators. **Results:** The search strategy identified 169 records; 14 studies were identified by other means. After removing duplicates and ineligible studies, 20 studies were included in the ScR, conducted from 1973 through 2015. 9 studies were conducted nationally. Location missing (n=1). Remaining studies were conducted in the Mid-Atlantic (n=2), West (n=1), Northeastern (n=2), Midwest (n=2), New England (n=1), South Central (n=1) and Southeastern U.S. Regions. A wide range of populations were surveyed; various hormone preparations were prescribed or used. MHT prescribing, use, or counseling was assessed by patient survey of current use (n=7), review of medical record for Rx (n=5), patient survey of counseling on MHT, unknown if MHT Rx given (n=4), MHT Rx in the medication record, (n=2), insurance claims for MHT Rx filled (n=1) and patient survey of Rx received (n=1). The 3 most prevalent disparities associated with MHT were age, race, and education. Age was associated with disparities in MHT in 13 (65%) reports (7 studies older women were prescribed, used or counseled > than younger women, in 4 studies older < younger and 1 reported mixed results). 1 study, prescribing pattern was as expected. Race disparities were seen in 10 (50%) studies. In all 10 studies Black women either used, were prescribed MHT, or counseled less than their White, Mexican, Latina, or Asian counterparts. White women received/used MHT more than all other races, except 1 study that showed vaginal estrogen prescribed to White < Hispanic menopausal women. Education disparities were noted in 6 studies (30%). In all 6, menopausal women with < compared to > education were either counseled less, used, or prescribed less MHT. Provider characteristics were noted in 6 studies (4 studies, providers did not discuss MHT with patients; in 1 study providers did not offer MHT). In 1 study, barriers for prescribing MHT included lack of time, lack of adequate knowledge and concern about risks to patient health. Other disparities were income (n=5), medical condition (n=5), natural or surgical menopause (n=4), insurance coverage (n=2), body mass index (n=2), geographic region (n=2), smoking (n=1), and alcohol use (n=1). **Conclusion:** Limitations: variety of study designs and methods for assessing MHT prescribing. This ScR identified health disparities in MHT nationally and in seven U.S. Regions with age, race, education as most prevalent

and provider characteristics noted as barriers. Gaps in treatment can be used to inform healthcare providers about MHT prescribing disparities, with the goal of improving equitable and advanced patient care among disadvantaged populations.

**Sources of Funding:** None

### P-16.

#### Racial Disparities Among Menopausal Women with Psychiatric Conditions

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**Objective:** Though menopause hormone therapy (MHT) is an effective treatment for menopause symptoms, studies have shown that Black women have more severe vasomotor symptoms (VMS) yet are prescribed MHT less than White women. Women with psychiatric conditions (PsyC) often have worsening moods and severe VMS during the menopause transition. Despite evidence that MHT may improve responses to psychiatric medications during menopause, data is lacking on the rate of MHT prescribing. The aim of this study was to determine if there were racial disparities in MHT prescribing for menopausal Black women compared to White women with and without a psychiatric diagnosis. **Design:** A retrospective chart review using EPIC slicer-dicer was performed assessing the rate of MHT treatment among menopausal patients with PsyC seen between January 2017 and September 2022 at MetroHealth Medical Center. Inclusion criteria was female sex and age 45-60 years old. Exclusion criteria was race identified as "other or unavailable". Descriptive [statistics were used to calculate demographic and clinical characteristics. Prevalence proportions were reported for menopause and PsyC based on ICD-10 codes. A chi-square test of independence, with a significance level of .05 was used to analyze the presence of racial differences in women with menopause symptoms and PsyC who were prescribed MHT. MetroHealth's Institutional Review Board approved this study. **Results:** Between January 2017 and September 2022, 65,762 female patients between age 45-60 were seen at MetroHealth; 31.6% (20,810) were Black, 54.8% (36,035) were White and 13.9% (9,153) were "other or unavailable". Of the study population, 10.7% (6,117) had documented menopausal symptoms, 35% (19,977) had PsyC and 6.1% (3,459) had both menopausal symptoms and PsyC. 17.3% (3,459) of women with PsyC had menopause symptoms and 7.2% (2,658) of women without PsyC had menopausal symptoms. 16.9% (449) of women with menopausal symptoms but without PsyC received MHT and 20.7% (716) of women with menopausal symptoms and PsyC received MHT. Compared to White women, Black women were more likely to have menopausal symptoms, X2 (1, N = 56,845) = 49.6452, p < .0001 but less likely to receive MHT, X2 (1, N = 6117) = 53.3756, p < .00001. Black women with PsyC were more likely to have menopause symptoms than White women with PsyC, X2 (1, N = 19,977) = 30.6438, p < .02. Finally, White women who have menopausal symptoms and a PsyC were prescribed MHT more than Black women, X2 (1, N = 3459) = 31.0078, p < .0001. **Conclusion:** In a population with a high percentage of Black patients known to have more menopause symptoms, the data demonstrated a surprisingly low rate of documented menopause symptoms (11%) compared to prior reports of up to 80%. This low rate may be related to patient reporting, physician inquiry, or physician documentation of menopause symptoms. Women with PsyC were more likely to have menopause symptoms than those without a PsyC. Similarly, women with menopause symptoms were more likely to have a PsyC than women without menopause symptoms. These results support prior reports that menopause symptoms and PsyC may independently exacerbate each other. The results showed a higher percentage of women with both menopausal symptoms and PsyC were prescribed MHT compared to women with menopause symptoms who did not have a PsyC. This could indirectly reflect a higher severity of menopausal symptoms among psychiatric patients, eliciting higher rates of providers recommending MHT. Lastly, White women with PsyC and menopause symptoms were 40% more likely to receive an MHT prescription than Black women. Overall, MHT was prescribed at low rates to menopausal patients. Black women with PsyC receive MHT significantly less than their White counterparts. Educating clinicians on disparities among menopausal women with PsyC may aid in addressing this healthcare disparity.

**Sources of Funding:** None

### P-17.

#### Información es poder (information is power): Menopause knowledge, attitudes, and experiences in midlife Latinas

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**Objective:** Latinas constitute nearly 20% of midlife women in the United States (U.S.) but remain underrepresented in menopause research. Many midlife Latinas are disadvantaged by limited English proficiency, less formal education, living below the federal poverty level, lack of health insurance, and social isolation and discrimination — factors that negatively affect menopause-related symptoms and health outcomes. To provide Latinas with culturally-relevant menopause education and clinical care, it is necessary to have deeper insight into their knowledge and experience of menopause. The purpose of this study was to understand knowledge, attitudes, and experiences of the menopause transition among midlife Latinas. **Design:** We conducted a qualitative descriptive study using five focus groups with 29 Spanish-speaking midlife Latinas (aged 40-60 years). Focus groups, lasting approximately 90 minutes, were conducted in Spanish via Zoom using a semi-structured interview guide. Focus groups were led by a bilingual research assistant and community health worker with a notetaker present. Audio

recordings were transcribed verbatim, and an emergent content analysis was performed in Spanish by four bilingual coders. Codes were organized into categories, and, after careful discussion with the team, combined into themes. Survey data on socio-demographics, menopausal symptoms, menopause knowledge, and attitudes toward menopause and hormone therapy were collected over the phone. Descriptive statistics (i.e., mean, frequency, proportion) were performed to characterize study participants. **Results:** Focus group participants were on average aged  $50.3 \pm 6.3$  years, 45% postmenopausal, 79% viewed menopause positively, 76% reported vasomotor symptoms in the past two weeks, and 55% reported having “little knowledge” about menopause. Seven themes emerged from the data: 1) menopause as a stage of life (*una etapa de vida*); 2) negative self-perception of aging; 3) menopause symptoms affect everyone differently (*todo cuerpo es diferente*); 4) information is power (*información es poder*); 5) discomfort asking about menopause in Latino culture; 6) the impact of menopause on the family; 7) menopause self-management and treatment options. **Conclusion:** While Latinas reported having a positive view of menopause, focus group findings highlighted the need for comprehensive menopause education among Latinas, including the definition of menopause, potential symptoms, and treatment options. The importance of involving family members in menopause education efforts was also revealed. This study highlights the need to develop culturally-relevant education on menopause in Spanish. The next steps in this research are to determine the best menopause messaging strategies and educational formats for midlife Latinas.

**Sources of Funding:** This study was funded by the UNC-Chapel Hill’s Center for Health Promotion and Disease Prevention.

#### P-18.

#### **Being Off-time with Perimenopausal Experiences, Stress, Satisfaction, and Health and Well Being: Observations from the Women Living Better Survey**

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**Objective:** People’s expectations about the timing of developmental events, specifically the ages at which they will occur, are influenced by social and cultural contexts. When expected timing and lived experience are divergent, events such as menopause may be associated with greater stress or distress. We hypothesized that being “off-time”, that is experiencing perimenopause-related menstrual cycle changes or symptoms in a timeframe before a person expects them, would lead to worse ratings on measures of stress, satisfaction and health. **Design:** Participants responded to the online Women Living Better (WLB) survey during March to August of 2020; 1262 met eligibility criteria for inclusion in hypothesis-testing. Being “off-time” referred to experiencing changes related to perimenopause at a younger age than that at which participants anticipated experiencing such changes. Using a 1- way analysis of variance (ANOVA) we examined differences in being “off-time” vs “on-time” on 7 participant-rated measures: stress (overall and health-related stress), satisfaction with life roles and activities, and well-being and health ratings (interference with daily activities, interference with relationships, not feeling like myself, and perceived health). Using 2-way ANOVA we then tested hypothesized differences between being “off-time” and on-time and experiencing perimenopause-related menstrual cycle changes, vasomotor or volatile mood symptoms on the same 7 measures. **Results:** Those who were “off-time” vs “on-time” reported significantly poorer health ratings in a one-way ANOVA. Experiencing more noticeable perimenopause-related menstrual cycle changes was significantly related to greater health stress, overall stress, satisfaction with life roles and activities, interference with daily activities, interference with relationships, not feeling like myself (all  $p < .05$ ), but not to health ratings. Experiencing more bothersome VMS was significantly related to health stress, overall stress, interference with daily activities, interference with relationships, not feeling like myself more of the time and to poorer perceived health (all  $p < .05$ ). There were no significant interaction effects of being “off-time” and experiencing perimenopause-related menstrual cycle changes or VMS. In contrast, having more bothersome volatile mood symptoms significantly affected health stress, overall stress, satisfaction with life roles and activities, interference with daily activities, interference with relationships, not feeling like myself more of the time, and perceived health. Finally, there was a significant interaction effect of being “off-time” and volatile mood symptoms on health stress, satisfaction with life roles and activities, and perceived health (all  $p < .05$ ). **Conclusion:** Being “off-time” alone had little effect on studied measures with the exception of poorer perceived health. Experiencing more noticeable perimenopause-related menstrual cycle changes or having more bothersome vasomotor symptoms influenced several measures but there were no interactive effects with being “off-time”. In contrast, those who were “off-time” and experiencing more bothersome volatile mood symptoms reported greater health stress, lower satisfaction with life roles and activities, and poorer perceived health. These interactive effects of being “off-time” and experiencing volatile mood suggest a need for greater attention to the link between volatile mood and perimenopause. Furthermore, anticipatory guidance for those on the path to menopause should include the possibility of volatile mood symptoms.

**Sources of Funding:** None

#### P-19.

#### **Elucidating the Meaning of “Not Feeling Like Myself” during Perimenopause: Observations from the Women Living Better Study**

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**Objective:** “Not feeling like myself” (NFLM) is a phrase used regularly by those on the path to menopause. Clinicians hear it in patient encounters, but what does it mean? We asked Women Living Better Survey participants about not feeling like themselves to try to identify correlates and clarify its significance. We explored the relationship of specific bothersome symptoms women reported during the LRS and MT to their ratings of NFLM. **Design: Methods:** Participants responded to the online Women Living Better (WLB) survey from March to August of 2020; 1258 met eligibility criteria. In order to measure not feeling like myself, they were asked to respond to the item “Many women report *just not feeling like themselves* during this phase of life. How often was this true for you over the past 3 months?” Responses were chosen from a 5-point scale ranging from “none of the time” (1) to “all of the time” (5). In addition, participants provided data about their age, education level, difficulty paying for basics, satisfaction with daily activities, overall stress, and reproductive aging stage. They also were asked about 61 symptoms and rated their bother on a scale from not at all bothered (1) to extremely bothered (7). The symptoms were summed to create symptom scale bother scores for 8 scales based on results of a principal components analysis for which eigenvalues of each scale exceeded 1.00: anxiety/vigilance, fatigue/pain, brain fog, sexual symptoms, volatile mood, GI symptoms, VMS/sleep, skin and hair, breast and acne. **Analyses:** We calculated the frequencies of and bother ratings for individual symptoms as well as symptom scale scores. We correlated the symptom bother scale scores for each of the scales with an eigenvalue of  $>1.00$  derived from principal components analysis and correlated the individual scale scores with NFLM. We also used crosstabs to quantify how many participants didn’t feel like themselves 50%, 75% and 100% of the time. Next, we included the scale scores in a multiple regression model to identify those contributing significantly to the prediction of NFLM scores (1-5). **Results:** Sixty-three percent (63%) of participants reported not feeling like themselves 50% of the time or more. A preliminary examination of correlations between individual symptom ratings with NFLM scores revealed a set with an  $r > .300$ . These symptoms included: irritable ( $r = .380$ ), anxiety ( $r = .398$ ), overwhelmed/less able to cope ( $r = .463$ ), worry more ( $r = .302$ ), low feelings ( $r = .440$ ), tearfulness/crying ( $r = .306$ ), can’t calm down on the inside ( $r = .333$ ), more forgetful ( $r = .332$ ), difficulty concentrating ( $r = .378$ ), difficulty making decisions ( $r = .357$ ), and fatigue ( $r = .491$ ). Of note, correlations with vasomotor symptoms and disrupted sleep were much lower (e.g.,  $r = .167$  for waking up in the middle of the night for an hour or more, night sweats  $r = .237$ , hot flashes  $r = .277$ ). Next, we tested a multiple regression model including the symptom bother scale scores for vigilance/anxiety, fatigue/pain, brain fog, sexual symptoms, volatile mood, GI symptoms, VMS/sleep, and breast and acne symptoms. Entering symptom scores until there were no additional scale scores of  $p < .001$ , we found that vigilance/anxiety, fatigue/pain, brain fog, sexual symptoms, and volatile mood symptoms constituted the best model ( $R^2 = .390$ ,  $F = 169.76$ , 5, 1314 df,  $p < .001$ ). **Conclusion:** “Not feeling like myself” was most strongly correlated with vigilance/anxiety, fatigue/pain, brain fog, sexual symptoms, and volatile mood symptoms. Women expressing “not feeling like myself” are unlikely to see a connection between many of these symptoms and the menopausal transition. Future research to understand symptoms associated with “not feeling like myself” would allow for better support and normalization for those experiencing them. For healthcare providers, an understanding of symptoms associated with “not feeling like myself” can help guide their response when they hear this phrase. Ultimately, anticipatory guidance should have a greater role in perimenopausal care.

**Sources of Funding:** None

#### P-20.

#### **GENITOURINARY SYNDROME OF MENOPAUSE: PREVALENCE OF SYMPTOMS, ASSOCIATION WITH SEXUAL DYSFUNCTION, KNOWLEDGE OF THE PARTNER AND IMPACT ON THE COUPLE’S SEXUAL LIFE**

Lucia Costa Paiva, Md, PhD<sup>1</sup>, Maria Maria Perini, graduating student<sup>2</sup>, Janaina F. Pio, MD<sup>1</sup>, Ana Lucia R. Valadares, MD, PHD<sup>1</sup>. <sup>1</sup>Department of Obstetrics and Gynecology, Universidade Estadual de Campinas, Campinas, Brazil; <sup>2</sup>Universidade Nove de Julho, Sao Paulo, Brazil

**Objective:** To assess the prevalence of the various symptoms of Genitourinary Menopause Syndrome (GSM) and their association with female sexual dysfunction, the partner’s knowledge of the woman’s symptoms, and the repercussions on the couple’s sexual life. **Design:** A cross-sectional study was carried out with 266 couples (total of 532 individuals) between 50 and 70 years. The sample size was calculated based on the estimated prevalence of and sexual dysfunction in women at 35%, and in men at 28% and an estimation precision with a difference between the proportion of the population and with a significance level of 5%, the number of calculated women was 256 women and 225 men. The women and their partners were selected using the “snowball” technique, formed from the “ego” couples who answered the interview on sociodemographic, general health, and sexual function questions, carried out via internet telephony by interviewers trained for the project. Interviews were conducted separately with the woman and her sexual partner. Female sexual function was evaluated using the Short Personal Experiences Questionnaire (SPEQ), male sexual function Sex Quotient - Male Version (QS-M), urinary incontinence using the International Consultation on Incontinence Questionnaire - Short Form (ISIQ-SF), the incontinence questionnaire overactive bladder (ICIQ-OAB),

and questions about partner knowledge of GSM. **Results:** The average age of women was 57.45 (5.08) and men were 59.97 (6.28), most were white and 92.86% of women were in menopause. The prevalence of genitourinary symptoms in this group was 74.44%. The occurrence of sexual dysfunction was significantly more frequent in women (46.15%) than sexual dysfunction in partners (15.77%) ( $p < 0.001$ ). Vaginal dryness present in 44.15% and dyspareunia in 58.67% were associated with female sexual dysfunction ( $p < 0.01$ ) decreasing satisfactory sex in 47.82% of cases or avoiding having sex for fear of pain or lack of desire. Urinary complaints of urinary incontinence, nocturia, and urinary urgency were reported by 17.29%, 35.34%, and 24.81% respectively and did not interfere with sexual dysfunction. About 49% of the partners were aware of the woman's SGU problems. For men, their partner's vaginal discomfort led to a loss of male desire in 22.71% and 53.83% avoided intercourse because they were concerned about her pain. **Conclusion:** The prevalence of vaginal and urinary symptoms of genitourinary syndrome of menopause was high and related to female sexual dysfunction. Half of the partners were aware of the problems of SGU and the women's symptoms interfered with the sexual desire and satisfaction not only of the woman but also of her partner, which could impact the affective and sexual aspects of the couple's relationship.

**Sources of Funding:** Research Support Foundation of the State of São Paulo-FAPESP Process number: 2020/04708-1.

## P-21.

### Effect of menopause stage on cerebral hemodynamics during typical aging

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**Objective:** Changes in cerebral physiology during aging may precede the appearance of structural biomarkers of neurodegeneration, and characterizing such age-related changes is crucial for improving our understanding of typical versus atypical aging. The menopause transition has a major influence on physiology during aging, driven by changing estrogen levels. Estrogen receptors populate numerous brain regions, including the prefrontal cortex, and cerebral glucose metabolism is affected during the perimenopause stage. However, the relationship between the menopause transition and age-related changes in cerebral physiology remains incompletely understood. Here, we investigated the role of menopause stage on established measures of cerebral hemodynamics during typical aging. **Design:** We performed a cross-sectional retrospective study of 131 women and 125 men (age range = 40 – 60 years) with STRAW+10 menopause staging and arterial spin labeling (ASL) magnetic resonance imaging (MRI) data from the Lifespan Human Connectome Project in Aging. Demographic variables of interest are shown in **Table 1**. ASL MRI was used to extract two established measures of cerebral hemodynamics: cerebral blood flow (CBF; the perfusion rate of blood to brain tissue) and arterial transit time (ATT; the time taken for blood that is magnetically labeled at the level of neck to travel to brain tissue). General linear model analysis using the whole brain surface, derived via Freesurfer, was performed for CBF and ATT between age-matched subsets of men for each menopause stage (pre, peri and postmenopause). We controlled for the effects of age, years of education, and ethnicity. There were no significant differences for these variables between groups. We performed multiple comparisons correction using a family-wise error approach ( $P_{FWE}$ ), thresholded for significance at 0.05. **Results:** We found widespread significant differences in mean CBF and ATT between men and women at each menopause stage, and distinct spatial distributions of these differences were observed. For the comparison of men and premenopausal women, significant differences were localized to the middle temporal cortex for ATT and inferior parietal cortex for CBF. For comparisons between men and perimenopausal women, significant differences were identified within the superior parietal and frontal cortices for both ATT and CBF. Significant differences between men and postmenopausal women were found in the prefrontal and inferior parietal cortices. No statistically significant differences were observed between menopause stage. **Conclusion:** There is a distinct spatial effect of menopause stage in women on cerebral perfusion measures in comparison with men. This could suggest that physiological neuroprotective mechanisms exist during the menopause transition in typically aging individuals. Validation of these findings requires longitudinal analyses, and future work should also investigate the impact of lifestyle, medical history, and cardiometabolic risk on these findings.

**Sources of Funding:** This work was supported by the American Heart Association (23POST1030607) and the National Institutes of Health (NIH)/National Institute on Aging (U01AG052564, and U01AG052564-S1). This research was made possible by computational hardware provided by the Massachusetts Life Sciences Center (<https://www.masslifesciences.com/>). Data used in the preparation of this abstract were obtained from the National Institute of Mental Health (NIMH) Data Archive (NDA). NDA is a collaborative informatics system created by the NIH to provide a national resource to support and accelerate research in mental health. Dataset identifier(s): 10.15154/1528936. This abstract reflects the views of the authors and may not reflect the opinions or views of the NIH or of the Submitters submitting original data to NDA.

## Demographic information of cohort

Classification STRAW + 10 stage	N	Age Range (years) Mean (Standard dev.)	Ethnicity (% White)	Education (years) Mean (Standard dev.)	Independent samples T-test vs Male Subst p-value comparing Education p-value comparing Ethnicity
Premenopause (-5, -4, -3b, -3a)	46	40.10 – 53.30 44.64 (3.24)	52.2 %	17.17 (2.55)	$p > 0.05$ $p > 0.05$
Perimenopause (-2, -1, +1a)	33	40.60 – 56.0 49.76 (4.14)	54.5 %	17.27 (1.88)	$p > 0.05$ $p > 0.05$
Postmenopause (+1b, +1c, +2)	52	46.90 – 60.8 56.92 (3.12)	51.9 %	17.81 (1.82)	$p > 0.05$ $p > 0.05$
Male	125	40.0 – 60.8 50.50 (6.07)	56.8 %	17.64 (2.11)	

## P-22.

### Investigating the Effectiveness of Estrovera: Insights from a Patient Satisfaction Survey on Menopausal Symptom Relief

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**Objective:** Estrovera, a clinically-proven nonestrogen supplement derived from plants, was the focus of a patient survey aimed at evaluating its efficacy in alleviating menopausal symptoms such as hot flashes, mood swings, sleep disturbances, and other associated discomforts. This specially formulated supplement contains a standardized extract of ERr 731, sourced from Rhapontic rhubarb, which exhibits selective estrogen receptor modulator properties, particularly for estrogen receptor beta. This unique attribute may contribute to both its effectiveness and safety profile. The survey findings are reinforced by numerous randomized controlled trials (RCTs) that have demonstrated the safety and efficacy of Estrovera. For instance, in a 12-week RCT involving 112 perimenopausal women, ERr 731 significantly reduced the frequency of hot flashes from a median of 12 to 2 per day. Furthermore, this study reported an 83% reduction in hot flashes, accompanied by a significant decrease in anxiety levels. In another RCT involving 109 perimenopausal women, ERr 731 showed significant reduction in the total Menopause Rating Scale II (MRS) score, as well as significant decreases in all 11 individual symptom scores compared with placebo. These collective results provide compelling evidence supporting the potential of Estrovera as an effective nonhormonal solution for women seeking relief from various menopausal symptoms. **Design:** A national survey was undertaken to gather feedback on the effectiveness of Estrovera, targeting individuals who had purchased the product between July 2022 and January 2023, and had been taking it for a period of 90 days or more. A total of 7,600 patients were contacted via email, and from this group, 424 patients responded to the survey. To encourage participation, participants were offered a 10% discount on their next Estrovera purchase. The survey was conducted during the period of March to April 2023. The results obtained from the survey were subsequently reviewed and validated by the regulatory team at Metagenics in May 2023. **Results:** Among the 424 women who took part in the survey, a significant majority (90%) reported experiencing improvements in their hot flashes, while 71% reported a reduction in sleep disturbances. Additionally, an overwhelming 95% of the participants noticed improvement in their mood after incorporating Estrovera into their routine. **Conclusion:** The survey findings highlight the significant positive impact of Estrovera on patient satisfaction and its effectiveness in alleviating common menopausal symptoms experienced by women. As a result, the participants reported an improvement in their overall quality of life. These results align with the outcomes observed in previous RCTs conducted with ERr 731, further substantiating the product's efficacy and consistency in addressing menopausal symptoms.

**Sources of Funding:** This survey was funded by Metagenics, LLC.

## P-23.

### Menopause-related Services and Resources in Veterans Health Administration Medical Centers: A Women's Health Practice-Based Research Network Practice Scan

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**Objective:** Providing comprehensive health care for women Veterans across the reproductive lifespan is a priority for the Department of Veterans Affairs (VA). While this area of focus has historically targeted pregnancy-related issues, menopause has been increasingly recognized as an essential addition to the reproductive lifespan health perspective. To address program evaluation needs of the VA Office of Women's Health, we assessed current menopause-related services, resources and needs nationally across VA Women's Health Practice-Based Research Network (WH-PBRN) sites. **Design:** The WH-PBRN is a network of 76 VA facilities across diverse clinical settings and geographic regions, each with a local WH-PBRN Site Lead. The WH-PBRN facilitates research, evaluation, and quality improvement focused on women Veterans' health care. In February 2023, each active WH-PBRN Site Lead (N=73), as the local key informant, received a 10-item electronic survey, followed by a reminder email if not completed within 2 weeks of receipt. The Site Lead could also query health care providers and other colleagues at their site to assist with survey responses, if needed, for help with describing local practice arrangements. The survey was developed in collaboration with the VA Office of Women's Health, VA Women's Health Research Network staff, and content area experts, and was field tested at two sites in the network prior to being widely distributed. It was designed to provide information on current menopause-related services

and resources within site primary care settings, along with facilitators and barriers to providing menopause-related care, with structured items and open-ended prompts. Survey responses were summarized with descriptive statistics. **Results:** Of the 73 surveys sent, 60 were completed (response rate 82%). Most sites (88%) reported having consultants based at their VA who assist primary care providers with pharmacological management of menopause symptoms. Available consultants were most often identified as gynecologists (78%), clinical pharmacists (58%), and endocrinologists (43%). A majority (77%) reported having pelvic floor physical therapists (PT) available for referral for management of genitourinary symptoms related to menopause. Although 2/3 of sites reported having some educational materials on menopause available for patients, less than half of sites had materials on hormone therapy (42%), non-hormonal pharmacologic therapies (30%), and non-pharmacologic treatment options (38%) for menopause symptoms. Only 8% of sites reported having menopause-focused classes or groups for patients. Most sites agreed or strongly agreed with the need for more resources or support for a variety of menopause-associated issues (See table 1). **Conclusion:** Nearly 90% of responding VA facilities in the WH-PBRN report the presence of consultants at their facility to assist primary care in the management of menopause symptoms and nearly 80% report having pelvic floor PT available. However, most identified a need for more resources related to a variety of menopause-associated concerns within the VA, suggesting a direction for service development. Most sites did not have comprehensive, Veteran-focused educational materials available and few had menopause-focused groups or classes. Further work is needed to understand variability in resources and best practices to improve comprehensive menopause-focused care in the VA setting.

**Sources of Funding:** VA Office of Women's Health; VA Women's Health Research Network (VA HSR&D SDR10-012)

% of sites indicating need for more menopause-related resources

MENOPAUSE-ASSOCIATED ISSUE	% that agree/strongly agree that more resources/support are needed
Sexual function	90
Urologic concerns	81
Vasomotor symptoms	81
Sleep disorders	78
Vulvovaginal health	73
Mood disorders	71

#### P-24.

##### **Behavioral Health usage over the menopause transition, an analysis of actuarial data**

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**Objective:** Gennev.com is a website that provides telemedicine services for women in menopause. As part of our work in the menopause space we enlisted a large actuarial and data company, Milliman MedInsight to gather deidentified billing and claims data for major commercial insurers in the United States. This data was originally abstracted for business development purposes. We looked at usage of behavioral health related services over several subsets of the data as we know there is an increase in behavioral health issues around perimenopause and menopause up to 15-20%, and there is some data for HRT usage as beneficial in this time period. **Design:** BRANY IRB determined this to be not human subjects research and therefore not needing a review. Data was received from Milliman in pivot tables representing annual usage of services per 1000 clients and per member per month utilization numbers for the years 2020 and 2021. This data was validated by the Milliman group. These tables represented data from private insurers over millions of women, and the tables separate them into categories based on age, medical utilization patterns and diagnoses, as well as by treatments used. Comparative statistics were used to look at different categories of patient as well as to compare between expected and actual distributions within tables and groups. **Results:** See Table 1. The control group we selected was PCP users and we looked at overall inpatient and outpatient psychiatric usage per 1000 members, as well as substance abuse residential treatment days. The lowest usage was in women diagnosed with menopause but not receiving treatment, and the highest was in women receiving "other therapies" which we defined as non-HRT medications associated with treatment for hot flashes, namely venlafaxine, gabapentin and clonidine. (Table 1 available, unable to be uploaded) **Conclusion:** Actuarial data is limited in the conclusions that can be made given the lack of covariates. The strength of this data is the large data set size and the ability to look at rare outcomes and gauge impact of different variables. In this data set we see that the diagnosis of menopause alone with no intervention signals a change in how a woman relates to her symptoms and the health care system. The two treatment categories HRT and other therapies may represent women with more significant symptoms than those not requiring treatment, and among those women, treatment with HRT led to lower utilization of psychiatric care and lower rates of substance abuse inpatient treatment. The other therapies group does include use of SSRI medications, and this could bias the data to show increased effect.

**Sources of Funding:** None

#### P-25.

##### **What women tell us about the menopause transition.**

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**Objective:** Gennev is a telehealth clinic for women in midlife and menopause. As part of our intake we offer a voluntary and free Menopause Assessment (MA) that inquires about women's menstrual history, menopause symptoms and quality of life related to those symptoms. We reviewed what women are reporting in the MA about the their menopausal transition. **Design:** BRANY IRB determined this project was exempt research. The survey consists of demographic questions which include race and ethnicity and menstrual history. This data, however, is not linked to identifiable information in any way. The survey opens with an overall quality of life question (graded 0-7 with 7 representing worse quality of life). The symptoms survey inquires about the following: hot flashes, night sweats, sleep disturbance, mood changes (including anxiety), weight changes, musculoskeletal symptoms, fatigue and energy, libido changes, and skin, nails and hair changes. Data are collected and stored in a de-identified database. Analysis of results was undertaken using descriptive statistics and basic comparative statistics. **Results:** 251,260 women who have completed the MA survey. The average age of women using our online services is 51; age is not asked on the MA specifically. The racial / ethnic makeup is 62% Caucasian, 6% Latina / Hispanic, 20% African American, 2% Asian / Pacific Islander, and 2% Native American. 38.5% of patients who complete the assessment are perimenopausal by menstrual history (some menstrual changes over the last year, or <12 months. since Last menstrual period [LMP]) 8% are premenopausal (no change in menses), 31% are post menopause (>12 months since LMP). 22% of women are "unknown" position in the menopause transition, due to surgical or hormonal intervention. 63% of the women surveyed have moderate to severe impact from their symptoms on an overall QOL scale (5 or above on 0-7 scale), 14% selecting the top impact score. The most commonly reported symptoms were: -Mood changes: 63% of women reported this and of those 59% rate them moderate to severe impact on quality of life. This symptom was particularly prevalent in the pre/perimenopausal respondents, less in early menopause, much lower as menopause progressed. -Weight changes: 63% of women reported this. 62% rated this high impact on QOL. 19% gave this a 7 out of 7. -Sleep disturbances: 55% of women complained of it. 63% of women rated this at 5 or higher on the QOL scale -Libido changes: 55% of women complained of libido changes. 62% rated this a 5 or higher on the Likert scale. 19% gave it a 7 out of 7 for quality of life changes. -Hot flashes: impacted 55% of patients with 62% rating this 5 or above on QOL scale. African American Women were more likely to suffer from hot flashes. Women in the first 1-2 years of menopause had the highest impact from hot flashes when compared to the other groups. **Conclusion:** Our population is skewed towards perimenopause and women early in the menopause transition. This is a highly symptomatic time. Because of this skew, the symptoms that are most impactful are those that we clinically associate with perimenopause, namely mood, weight, night-time (sleep and night sweats) and libido changes. This is important as many interventions and studies are focused on hot flash relief, and this is not what women are most concerned about. Women are very concerned about less well studied changes and symptoms, and they deserve both good evidence-based information about them and effective management options to combat their symptoms.

**Sources of Funding:** none

#### P-26.

##### **Working with a registered dietitian / nutritionist in menopause in an integrated care model, preliminary outcomes from the first 66 patients.**

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**Objective:** Gennev is an online telemedicine platform available to patients in 50 states in the US. We provide face to face telemedicine with physicians who are expert in menopause care. We also offer an integrative care model where patients can work one on one with a registered dietitian / nutritionist (RDN) with every other week visits and text communication between visits, and this was accompanied by physician appointments at intervals determined by patient needs. RDNs are specifically trained in behavior change theory and application. A systematic review of the use of behavior change theory in dietetics practice in primary health care settings specifically showed when interventions are supported by behavior change techniques, such as cognitive behavioral therapy (CBT), health outcomes demonstrate greater improvement(1). As part of evaluating the program and utility of RDN health coaching we provided the first 66 patients with a survey at the end of their participation to give us insight into their experience. Additionally, the RDN working with a client was asked to complete a survey looking at their impression of the purpose of the visits and reason for finishing the relationship. **Design:** IRB exemption was obtained through BRANY IRB to abstract and evaluate the data. The design of the study was a retrospective analysis of patient visit variables and a qualitative look at themes and comments. The survey to patients collects information on time in program, reason for discontinuing service as well as goals and whether they were met. Survey information was downloaded and stored anonymously and could not be linked to the patient file. The RDN survey was filled anonymously and was stored without connection to the patient file. Answers in the patient survey were counted, evaluated, and presented graphically. The RDN surveys were read with an eye to "themes" and counts of themes were undertaken. **Results:** The average number of months in the integrated care program was 5.1 with a range of 1-25 mo and a median of 3 months. The average number of RDN appointments was 8.2, with a range of 1-60 and a median of 5.5. The average number of MD appointments was 1.5 with a range of 1-5 and a median of 2, 10 of the

66 patients did not meet with an MD. 78.87 % of patients were highly satisfied with the care received and the program (4-5/5). 87.5 % were highly satisfied with the support received from their coach, and 79.69 found they had seen some improvement in their symptoms from a coach. Of women who met with a physician during their participation in the program, 72.13 felt they were highly satisfied with their interaction with the physician and 72.13% felt that visit helped with their symptoms. Overall 89.92% would recommend the integrated model to a friend in menopause. The qualitative themes in the RDN survey that we looked at included reasons for using the integrated model. There were 3 main themes that emerged: 1) Weight gain and nutrition counseling around weight, symptoms and long term health (9/66), 2) Support and education around the menopause transition and with symptoms (14/66), and 3) behavioral health concerns including specifically anxiety (6/66). Of these most of the patients seeking weight or nutrition therapy or support for their symptoms were satisfied with their care and felt the program had served them well. Of those seeing the team for behavioral health support, 4/6 were referred to therapy or MD care. Additional themes that were less prevalent were around sleep management and life coaching. Some patients were using the service as a way to get access to physician care more frequently at a lower cost and some had multiple unrelated reasons for using the service. **Conclusion:** Integrated care models with an aspect of behavior change theory can be beneficial in helping patients make lasting change in behaviors and can provide symptomatic relief even in the absence of medical treatment. Our initial piloting of an integrated model of care for menopausal symptoms including weight gain and body shape changes shows that focused work can alleviate symptoms and the average amount of time needed to accomplish this in our model was 3-5 months.

**Sources of Funding:** None

## P-27.

### Menopause symptom experience and management in a diverse US population, 2019

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**Objective:** Provide information regarding US female experience of and attitudes toward menopause symptoms and use of treatments. **Design:** An online, age-weighted survey of self-identified female respondents was performed in 2019. Respondents were  $\geq$  age 18. Inclusion criteria were self-identified menopause transition or post-menopause status and  $\geq$  45 years of age. Respondents were asked about attitudes toward menopause and treatment, symptoms experienced, and treatments, including MHT, vaginal ET, DHEA, OTC products, vitamins, herbal or natural supplements, lifestyle changes or alternative therapies (yoga, acupuncture, mindful breathing). Age-weighted proportions for demographics, menopause symptoms, and treatments used were calculated. **Results:** 1818 females  $\geq$ 45 years completed the survey, 835(46%) in the menopause transition and 983(54%) postmenopausal of whom 116(12%) were  $<$ 55 years. Mean ages were 51.5(SD 4.9) and 65(SD 8.5) years, respectively. The majority, 1506(83%) were White, 268(15%) were Black and 114(6%) identified as Hispanic; 1071(59%) were married or cohabitating; 789(43%) had  $\geq$  college degree; 730(40%) had income  $\leq$ \$49,999/year; 378(21%) lived rurally, and 565(31%) reported fair or poor physical health. Among those in the menopause transition, the majority, 575(69%) were currently experiencing hot flashes, 52(63%) had fatigue, 504(60%) had brain fog, 493(59%) had mood swings, 484(58%) had weight gain and 485(58%) had night sweats. Weight gain was the most common symptom among all postmenopausal respondents, reported in 318(32%), whereas among those  $<$ 55 years the most common symptoms were fatigue in 67(58%), sleep problems in 65(56%), and hot flashes in 60(52%). Current MHT use was similar between those in the menopause transition [(100(12%)] and postmenopause [107(10.9%)], as was alternative therapies use [166(19.9%) menopause transition, 166(16.9%) postmenopause]. While 493(59%) of those in the menopause transition reported awareness of MHT therapy, only 164(20%) reported current or past use (Table 1). Among all those with past use, 300(32%), the most common reasons for discontinuation were healthcare provider recommendation in 97(32%) and concerns of increased cancer risk in 82(27%). **Conclusion:** In an online survey of diverse self-identified females living in the US we found that a majority of respondents in the menopausal transition and early postmenopause experienced significant symptoms. Many were not using MHT due to provider guidance or concern of increased cancer risk. Use of OTC products, vitamins, herbs and alternative therapies was high overall.

**Sources of Funding:** WebMD (data collection) and UW OBGYN (data analysis).

**Table 1. Menopause Treatment Use and Awareness, Menopause Transition and Postmenopause, N= 1818**

	Menopause Transition							
	Current Use		Past Use		Never Use			
	N	%	N	%	Aware		Not Aware	
MHT	100	12	64	8	493	59	178	21
Vaginal ET	61	7	45	5	496	59	233	28
OTC vaginal products	165	20	116	14	436	52	118	14
Vitamin supplements	340	41	115	14	226	27	154	18
Herbal supplements	132	16	127	15	371	44	205	25
Alternative therapies	166	20	96	11	333	40	240	29
	Postmenopause							
	Current Use		Past Use		Never Use			
	N	%	N	%	Aware		Not Aware	
MHT	107	11	236	24	484	49	156	16
Vaginal ET	105	11	179	18	505	51	194	20
OTC vaginal products	177	18	214	22	459	47	133	14
Vitamin supplements	391	40	120	12	273	28	199	20
Herbal supplements	81	8	195	20	484	49	223	23
Alternative therapies	166	17	122	12	412	42	283	29

## P-28.

### Digital Hypnotherapy for Hot Flashes: Examining Relationships between User Characteristics and Length of Program Use

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**Objective:** The Evia app delivers hypnotherapy for treating hot flashes. However, knowledge on user characteristics and factors that are associated with length of program use are currently unknown. The purpose of this study was to determine users' level of familiarity with hypnotherapy, determine how users heard about Evia, and determine factors that are associated with length of program use. **Design:** This study was correlational and included the retrospective analysis of data collected by Mindset Health, the developers of Evia. Data regarding familiarity with hypnotherapy, referral source, hot flash interference, and number and severity of hot flashes were collected from a self-report questionnaire. Data regarding length of program use, the maximum day of the program completed, was collected using in-app analytics. Participants included individuals who downloaded and subscribed to the Evia app. This included 604 participants. This study aimed to (1) determine subscribers' levels of familiarity with hypnotherapy for hot flashes, (2) determine what percentage of subscribers were referred to Evia by a healthcare professional, and (3) determine factors that are associated with program use. It was hypothesized that there would be a significant positive relationship between hot flash severity, hot flash frequency, and hot flash interference with length of program use. It was also hypothesized that individuals who were referred to Evia by a healthcare professional would have completed a significantly higher day of the program than those who were not. Lastly, it was hypothesized that individuals who had heard of hypnotherapy for menopause would have completed a significantly higher day of the program than those who had not. **Results:** Among individuals who had subscribed to Evia, 14.4% reported that they have heard of hypnotherapy for menopause before, 20.2% responded that they had heard a little bit, and 65.4% responded that they had not heard of hypnotherapy for menopause before. Results showed that 65.3% of subscribers reported that they have not tried hypnotherapy before. Among subscribers, 6% reported that they were referred to Evia by a healthcare professional. There was no significant difference in maximum program day completed between subscribers who were referred to Evia by a healthcare professional and subscribers who were not referred to Evia by a healthcare professional. There was no significant difference in maximum program day completed between subscribers who had heard of hypnotherapy before and subscribers who had not heard of hypnotherapy before. There was no significant relationship between hot flash severity and maximum program day completed. There was a significant positive relationship between hot flash frequency and maximum program day completed,  $r = .130$ ,  $p = .005$ . There was a significant positive relationship between hot flash interference and maximum program day completed,  $r = .109$ ,  $p = .009$ . **Conclusion:** Most Evia subscribers had not heard of hypnotherapy for menopause before and a majority had not tried hypnotherapy before. Expectancy can play an important role in hypnotherapy, therefore, psychoeducation components of Evia that help to foster positive expectancy are very important. Most (94%) of Evia subscribers were not referred by a healthcare professional. This could be an important target to get more individuals who are suffering from hot flashes referred to the Evia app and access to hypnotherapy. Hearing about hypnotherapy before, being referred from a healthcare professional, and hot flash severity were not significantly related to length of program use. However, hot flash frequency and hot flash interference were significantly associated with length of program use. Individuals who reported more hot flashes and greater interference completed a higher day of the program. Future studies should investigate the feasibility and efficacy of the Evia app in a randomized controlled trial design.

**Sources of Funding:** None

### P-29.

#### Examining Characteristics of Users of the Evia App: Digital Hypnotherapy for Hot Flashes

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**Objective:** Hypnotherapy has been shown to reduce hot flashes in previous clinical trials (Elkins et al., 2008; Elkins et al., 2013), however, it is not routinely used in clinical practice because of accessibility barriers such as few trained therapists and cost. To expand dissemination of hypnotherapy interventions for hot flashes, a smartphone app has been developed. Evia is an app that delivers hypnotherapy for hot flashes. The Evia app has made hypnotherapy for hot flashes more widely accessible and has the potential to help women suffering from hot flashes. However, knowledge about the characteristics of users of the Evia app is lacking. The present study examined the characteristics of users of the Evia app. **Design:** This was a cross-sectional, retrospective study with data collected during one time-point from a self-report questionnaire that is given to users when they download the Evia app. These data were collected prior to the user beginning the intervention. This study analyzed data collected from users who downloaded the app between 10/05/2021 and 07/08/2022. Users were asked about their age, stage of menopause, length of menopause symptoms, number and severity of hot flashes, what their hot flashes feel like, sleep quality, and mental health using self-report questionnaire items. **Results:** The mean age of users was 49.31. Out of 9103 valid responses, 0.5% of users reported being not menopausal, 31.2% were perimenopausal, 14.2% were menopausal, 13.1% were post-menopausal, 7.6% were uncertain and 33.5% unknown. Out of 3127 valid responses, 20.4% of users reported experiencing menopause symptoms for 0-6 months, 20.9% for 6-12 months, 20% for 1-2 years, 13.5% for 2-3 years, 11.3% for 3-5 years, 9.3% for 5-10 years, and 5.6% for 10+ years. Out of 4665 valid responses, 13.5% of users reported experiencing 0 hot flashes per day, 9.4% reported experiencing 1 hot flash per day, 13% reported experiencing 2 hot flashes per day, 12.8% reported experiencing 3 hot flashes per day, 9.7% reported experiencing 4 hot flashes per day, and 41.6% of users reported experiencing 5+ hot flashes per day. Out of 4183 valid responses, 1.9% of users reported that their hot flashes were very mild, 30.4% reported that their hot flashes were mild, 40.9% reported that their hot flashes were moderate, 20.3% reported that their hot flashes were severe, and 6.4% reported that their hot flashes were very severe. Out of 4180 valid responses, 83% of users reported that their hot flashes felt like a sudden feeling of warmth, 59.2% reported perspiration, 47.5% reported flushed appearance, 34.5% reported rapid heartbeat, 32.7% reported anxiety/an aura, 24.5% reported dizziness/weakness, and 16.4% reported nausea. Out of 2877 valid responses, results demonstrated that 18% of users reported no difficulty falling asleep each night, 30.8% of users reported a little bit of difficulty falling asleep each night, and 51.2% of users reported having difficulty falling asleep each night. Out of 2626 valid responses, results demonstrated that 47.7% of users reported their sleep quality to be terrible, 44% reported their sleep quality to be fair, 7.8% reported their sleep quality to be good, and 0.5% reported their sleep quality to be excellent. Out of 2877 valid responses, 5.9% of users reported that they never feel anxious or depressed, 39.6% of users reported that they sometimes feel anxious or depressed, 38.4% of users reported that they often feel anxious or depressed, and 16.2% reported that they constantly feel anxious or depressed. **Conclusion:** This is the first study to report on the characteristics of users of the Evia app, which delivers hypnotherapy for hot flashes. Results showed that the average age of app users is in line with the average age of natural menopause onset. Results also showed that the largest percentage of users reported experiencing 5 or more hot flashes per day and reported that their hot flashes were moderate intensity. In line with previous research regarding hot flashes and sleep, a majority of users reported difficulty falling asleep each night and reported their sleep quality to be terrible or fair. In addition, a majority of users reported that they sometimes or often feel anxious or depressed. Results of this study will help to inform the optimization and tailoring of the hypnotherapy intervention delivered via the Evia app.

**Sources of Funding:** None

### P-30.

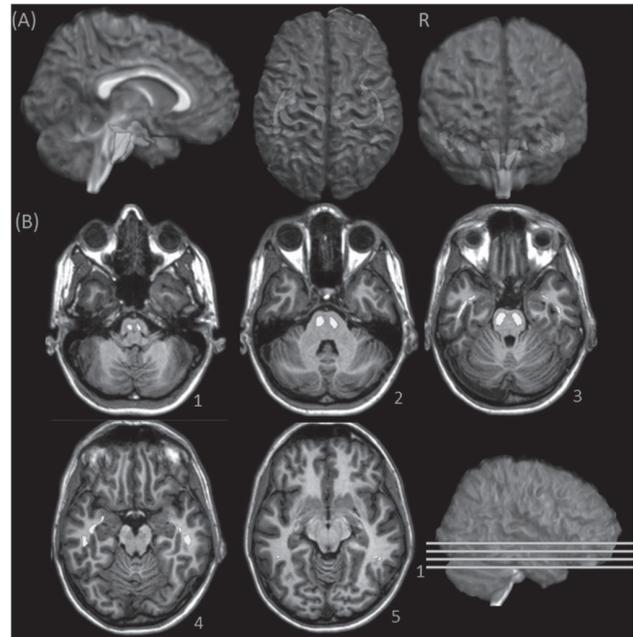
#### Long-term effects of short-term menopausal hormone therapy on white matter integrity

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**Objective:** Long-term effects of hormone therapy (HT) on the brain in women who initiated HT within a few months to <5 years following the onset of menopause remains open to further query. We investigated the long-term effects of menopausal HT on measures of white matter integrity through white matter hyperintensity volume (WMH) and diffusion MRI metrics. **Design:** The Kronos Early Estrogen Prevention Study (KEEPS) was a double blind, placebo-controlled clinical trial in postmenopausal women within 5 to 36 months past menopause. KEEPS had three treatment groups: oral conjugated equine estrogen (oCEE; 0.45 mg/d), transdermal 17 $\beta$ -estradiol (tE2; 50  $\mu$ g/d), or placebo. Progesterone (200 mg/d) was given to HT groups 12 days each month. KEEPS continuation studies brain structure and cognitive outcomes approximately

ten years after cessation of 4-years of randomized intervention. We evaluated white matter microstructural integrity in participants with MRIs who were not exposed to HT after the cessation of interventions (n=207). Mean values of WMH and diffusion MRI measures at predefined white matter atlas regions were compared between groups. **Results:** KEEPS continuation participants randomized to the tE2 group (n=68) had higher fractional anisotropy (FA; i.e. more organized white matter) in the inferior temporal white matter (p=0.008) than placebo (n=80). However, the differences between the tE2 and placebo groups were no longer significant when false discovery rate correction was applied for multiple comparisons (p<0.05). There were no significant differences in diffusion MRI measures between placebo and oCEE (n=51) groups or in WMH between oCEE or tE2 relative to placebo. **Conclusion:** We found no evidence of long-term effect of HT on WMH between treatment groups and placebo. There was some evidence of preservation of white matter integrity in the tE2 group compared to placebo in the inferior temporal white matter tracts, however these were not statistically significant after correction for multiple comparisons. Whether this finding has influence on cognitive performance needs further investigation.

**Sources of Funding:** NIH grant R21 NS066147



DTI FA results prior to FDR correction ( $p < 0.5$ ) on JHU-MNI-SS FA template (A) and JHU-MNI-SS-T1 3D template (B). Sagittal slice positions 1-4 on JHU-MNI-SS FA brain template. R=right.

### P-31.

#### Quantitative Evaluation of an Evidence-based Menopause Education Group Program

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**Objective:** Quantify outcomes of an 8-week, evidence-based, menopause group educational program offered by a primary care clinic via telemedicine to cohorts of 15 women in British Columbia, Canada. The outcomes studied included depression, anxiety, menopause symptoms, confidence in knowledge about menopause, outlook on menopause, and views on hormone therapy. This quality improvement project evaluated the program offered at womenMD Integrative Lifestyle Medicine in Victoria, BC, Canada. **Design:** Questionnaires were designed using validated tools to evaluate the impact of the program on mood, menopause symptoms, and patient attitudes. The Patient Health Questionnaire-2 (PHQ-2), Generalized Anxiety Disorder-2 (GAD-2), and Menopause Rating Scale (MRS) have been found to be reliable and validated tools for evaluating psychological and somatic symptoms pre and post-intervention. Questionnaires and study consent were emailed to participants 24 hours prior to their first class and again during the last class. Participants who missed >1 class or completed the questionnaire out of the designated time frame were excluded. The program was 8 weeks in duration, with one 1.5 hour group education session per week. The questionnaires were anonymized via Qualtrics software. The responses were compared pre- and post-intervention then analyzed using Student's paired T-tests. **Results:** A total of 118 women participated in 9 groups between September 2021 – December 2022. Women between ages 44-58, with a mean age of 53.4 in BC, Canada (n=27) had matched responses to the pre and post intervention questionnaires, a survey response rate of 22.9%. They were found to have a nonsignificant decrease of 28.9% in PHQ-2 scores (p=0.1433) and a significant 23.7% decrease in GAD-2 scores (p=0.0369). MRS scores decreased by 29.6%, which represents somatic, psychosocial, and urogenital domains of menopause (p=0.0007). Participants' confidence in menopause knowledge increased by 46.3% (p=2.1757e-11). There was a non-significant increase in positive outlook towards menopause of 10.4%, (p=0.1183) and a 23.5% increase in positive views regarding

hormone therapy ( $p=0.0001$ ). **Conclusion:** Menopause is a complex midlife transition, with symptoms that vary between women, impacting an individual's quality of life. Education creates the opportunity to build coping strategies, healthy habits, and a more positive attitude towards menopause which can support women during this life stage. Menopause education programs address a need in primary care for women to have a reliable source of information, and an opportunity to feel heard and supported in this transition. The menopause education group program offered at womenMD Integrative Lifestyle Medicine, via secure telemedicine due to pandemic restrictions, has been found to significantly impact the participants' overall menopause experience. The womenMD program also offers different symptom management techniques based on cognitive behavioral therapy (CBT) and mindfulness. The benefits of the 8-week menopause education program included reduced menopause symptoms, increased confidence in menopause knowledge and an increased positive view towards menopause and hormone therapy. Limitations of this study included the quality improvement period not involving a control group for comparison, analysis of additional therapies patients may have been using during the 8-week program, and response bias. In a limited primary care context and busy women's health clinic, group education provides women with the skills and knowledge to be agents in the promotion of their own health while improving access to care.

**Sources of Funding:** None

### P-32.

#### **Hysterectomy at the time of RRSO in BRCA patients – a single institution experience**

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**Objective:** Pathogenic or likely pathogenic (P/LP) variants in BRCA1 and BRCA2 are associated with markedly increased risks of breast and ovarian cancers. Risk-reducing bilateral salpingo-oophorectomy (RRSO) is recommended for patients with P/LP variants in BRCA1 and BRCA2, but the role of concurrent hysterectomy has been a subject of debate. In the last decade, data have emerged indicating an increased risk of uterine serous carcinomas in BRCA1 and BRCA2 carriers. Hormone replacement therapy (HRT) is crucial for women undergoing early surgical menopause after RRSO to mitigate systemic morbidity and improve quality of life. Concurrent hysterectomy is often chosen to limit progestin exposure. In patients with P/LP variants in BRCA1/BRCA2 that have undergone RRSO, there is limited information regarding the need for subsequent hysterectomy. This study examines the frequency and indications for subsequent hysterectomies in those who undergo RRSO alone. We also examined adherence to the National Comprehensive Cancer Network (NCCN) recommended age for RRSO, the use of HRT, and attention to bone density (BMD) screening. **Design:** An IRB-approved retrospective cohort study of females with P/LP BRCA1/BRCA2 variants followed in the high-risk breast center at Cleveland Clinic from 2005-2022 was performed. Patients were excluded if they were diagnosed with breast or ovarian cancer before their BRCA diagnosis. Data collected included demographics, age at BRCA diagnosis, age at RRSO (if performed), concurrent hysterectomy rates, rates and reasons for subsequent hysterectomy, use of HRT, and BMD screening. Data were analyzed using t-tests, Satterthwaite t-tests, Pearson's chi-square, and Fisher's Exact tests. **Results:** Of 1182 germline carriers, 665 were identified with P/LP variants in BRCA1 or BRCA2, and 452 eligible patients were identified: 212 in BRCA1 and 240 in BRCA2. Overall, 251 (53.3%) patients with BRCA1 or BRCA2 underwent RRSO. Only 60/212 (28%) of patients with BRCA1 and 57/240 (23.8%) of patients with BRCA2 had RRSO at the age recommended by NCCN guidelines. Concurrent hysterectomy was performed in 165 (69.3%) patients, and 11 (4.6%) had prior hysterectomy. Seven (3%) patients had a subsequent hysterectomy. Of the 7 patients who required later hysterectomy, 1 developed endometrial cancer (non-serous), 3 had benign endometrium, 1 had an endometrial polyp, 3 had fibroids, and 1 had adenomyosis. Two patients required endometrial bx, 1 had a D & C, 1 had an endometrial ablation, and 1 had a hysteroscopy. The patient who developed endometrial cancer was 67 yo at the time of RRSO and one month later returned for a hysterectomy. She had a BMI of 21 and carried a PV in BRCA2. Overall, patients with PV/LPV in BRCA1 were younger at RRSO (than those with BRCA2; (mean age 42.3(SD) vs. 49 (SD), respectively;  $p < 0.001$ ). Of the 93 evaluable patients with BRCA1 and the 89 patients with BRCA2 who underwent RRSO < age 52 (the presumed age of natural menopause), 75 (80.6%) of BRCA1 patients were offered HRT vs. 48 (53.9%) BRCA2 patients ( $p < 0.001$ ). Of those same patients, there was no difference in the rate of BMD screening after RRSO (57% for BRCA1 and 61.8% for BRCA2 patients ( $p = 0.51$ )). **Conclusion:** Our findings indicate only 7 of 230 patients who underwent RRSO alone returned for subsequent hysterectomy for medical indications. Concurrent hysterectomy during RRSO in premenopausal patients helps optimize hormone replacement and potentially reduces endometrial cancer risk. One strength of the study is the duration of follow-up of these patients. One limitation was that 2/3 of the patients had a hysterectomy at the time of RRSO, limiting the evaluable number of remaining patients and possibly creating selection bias. Our study highlights the need for improved patient and clinician education about adherence to current guidelines. The study also provided a baseline for quality improvement in early carrier identification, provision of HRT, and attention to BMD to optimize preventive care and overall patient health. Standardized referral to clinicians with subspecialty training in menopause may be prudent for pre-operative and long-term follow-up.

**Sources of Funding:** None

### P-33.

#### **Exploring the Relationships Between the Gut Microbiome & Chronic Conditions in Postmenopausal Women**

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**Objective:** The objective of this project was to review articles related to the gut microbiome and its associations with menopause. Population diversity and gut interactions with the body create a complex system that is critical in health and regulation. Gut microbiome changes are known to occur with menopause, and associations between the gut microbiome and hypertension have been elucidated through multiple mechanisms. Understanding these mechanisms gives insight into the role of menopause in the development of hypertension which can open another avenue for treatment. **Design:** Search terms for this project "'microbiome,' 'hypertension,' AND 'postmenopausal'" on Pubmed. Articles focused on only hypertension rather than all chronic conditions. **Results:** Hypertension is one of the most common medical conditions, particularly in post-menopausal women and aging populations, and is a significant risk factor for cardiovascular events. The role of the gut microbiome in hypertension has been identified through multiple studies; for example, the HELIUS cohort study has found associations between the gut microbiota, fecal short-chain fatty acids (SCFA), and hypertension<sup>2</sup>. Though fecal bacterial composition alone was not found to be associated with blood pressure across racial groups when analyzed with SCFA composition, blood pressure associations were present<sup>2</sup>. The gut microbiome is an interface to the immune system which has downstream effects that directly impact blood pressure regulation. T-cell regulation has been shown to influence blood pressure with proinflammatory T helper 17 cells (Th17) playing a role in the pathogenesis of hypertension<sup>3</sup>. *Lactobacillus* spp. survivability was found to modulate Th17 cells, directly influencing blood pressure through proinflammatory signaling<sup>3</sup>. Duodenal bacterial colonization presents another avenue to evaluate the relationships between the microbiome and hypertension. Hormonal and metabolite influences could affect hormonal signaling upstream of the large intestine; this location is less studied than fecal bacterial samples. Duodenal Bacteroides spp. and Proteobacteria spp. have associations with higher fasting glucose levels, lower duodenal microbial diversity, and microbial dysbiosis; these are seen more frequently in post-menopausal populations<sup>1</sup>. Species associated with lower fasting glucose include *Prevotella*, *Klebsiella*, and *Lactobacillus*, as well as decreased *E. coli*, which is associated with decreased risk of hypertension, where decreased *Prevotella* spp. is found in post-menopausal women<sup>1</sup>. **Conclusion:** The gut microbiome, through various bacterial populations, interactions with human cells via metabolites, immune regulation, and direct cell communication present multiple mechanisms through which hypertension is regulated. Furthermore, microbiome species changes as a function of aging and hormonal status present an additional level of nuance into the role of the microbiome on blood pressure. However, though studies have been done on gut microbial populations, interventions have yet to be tested thoroughly. Hormonal treatments have shown promise in this area, with treatment groups demonstrating duodenal bacterial populations similar to premenopausal women<sup>1</sup>. Given the extensive interplay between metabolic changes, the body, and the gut microbiome, more research is needed to fully understand the complex interplay between gut microbial changes during menopause and hypertension in order to evaluate potential intervention strategies for the future.

**Sources of Funding:** 1. Dothard MI, Allard SM, Gilbert JA. The effects of hormone replacement therapy on the microbiomes of postmenopausal women. *Menopause*. 2023 Apr 13. doi: 10.1097/GME.0000000000001819. 2. Barbara J H Verhaar, Didier Collard, Andrei Prodan, Johannes H M Levels, Aeilko H Zwinderman, Fredrik Bäckhed, Liffert Vogt, Mike J L Peters, Majon Muller, Max Nieuwdorp, Bert-Jan H van den Born. Associations between gut microbiota, fecal short-chain fatty acids, and blood pressure across ethnic groups: the HELIUS study. *European Heart Journal*, Volume 41, Issue 44, 21 November 2020, Pages 4259–4267, <https://doi.org/10.1093/eurheartj/ehaa704.3>. Wilck, N., Matus, M., Kearney, S. et al. Salt-responsive gut commensal modulates TH17 axis and disease. *Nature* 551, 585–589 (2017). <https://doi.org/10.1038/nature24628>

### P-34.

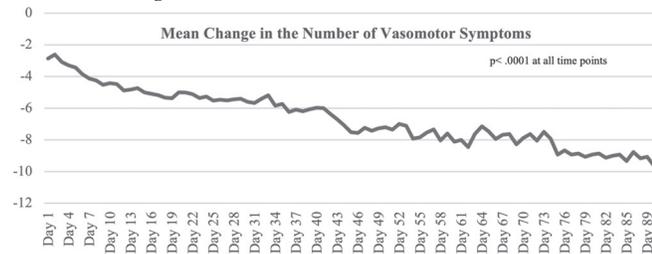
#### **Proprietary Delivery System Increases Serum Estradiol Levels and Reduces Vasomotor Symptoms in Menopausal Women**

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**Objective:** The objective of the study is to demonstrate the benefit of a novel nutraceutical with a proprietary delivery system in decreasing hot flashes in a menopausal population. Initially, two pilot studies were performed in menopausal women utilizing a new supplement regimen delivered by a lozenge using Directline® technology. The first study focused on the efficacy of the Directline® technology compared to leading competitors. The study showed a greater than 300% peak serum level and a 60% longer peak blood level compared to the market leader's gummy delivery system. The second pilot study demonstrated a significant reduction in the negative symptoms of menopause including hot flashes, insomnia, and irritability. Additionally, serum estradiol levels increased by over 360% in 2 months. Patients also experienced an improvement in day-to-day physical and mental function. Consequently, a much larger IRB-approved and third-party governed study was launched to establish if the supplement system could decrease the incidence of vasomotor symptoms in menopausal women. **Design:** An IRB-approved, open-label study was conducted to evaluate the effectiveness of the supplement system in reducing hot flashes. We included females who had not used hormone therapy in the past 12 months and were currently experiencing hot flashes. The participants were given a 90-day supply of the supplement system, consisting of three lozenges per day. They reported the number of hot flashes and provided feedback

on a daily questionnaire. Participants who consented also had four separate blood draws taken (before starting the supplement and every 30 days until the study ended) measuring a variety of hormones and other menopausal parameters. **Results:** The study involves 101 women with a mean age of 53 years old, from various ethnic and socioeconomic backgrounds. To date, 90% of participants reported a reduction in menopausal symptoms, 80% of participants reported a significant reduction in hot flashes and other menopausal symptoms, and 25% of participants reported a complete elimination of hot flashes. Participants also reported improved quality and duration of sleep and increased energy levels. To date, no serious adverse events have been reported. Blood serum is still being collected and analyzed and the study will be completed by September 2023. **Conclusion:** In a large population of menopausal women from a multitude of ethnic and socioeconomic backgrounds who utilized our proprietary nutraceutical, hot flashes, and other menopausal symptoms were significantly reduced based on our preliminary data. Additionally, a preliminary assessment of serum estradiol levels shows a significant increase over time as women continue to take the supplement system. The initial data demonstrate a statistically significant benefit based on subjective questionnaire responses and blood serum levels of estradiol proving the efficacy of both the Directline® delivery system and the ingredient profile of the supplements.

**Sources of Funding:** Rebalance Health Inc.



### P-35.

#### Menopause: Knowledge, preparedness, and experiences of Canadian women

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**Objective:** As a natural transition, menopause is experienced by many women without knowledge of the symptoms that can have significant impacts on their health and quality of life. Stigma and taboo around menopause and female aging can discourage open discussions on this topic, leading to a lack of awareness which can leave women unprepared to deal with the challenges in the mid-life. The aim of this study is to assess the awareness, preparedness, and experiences of Canadian women with menopause. This study focused on menopause-related symptoms and the impact of menopause on relationships. The results of this study provide valuable insights into development of educational and support resources to improve women's health and wellbeing during this important life transition. **Design:** The survey was conducted by Leger Canada in partnership with Menopause Foundation of Canada, between August 2 -11, 2022. 1,023 Canadian women aged 40-60 were surveyed, ensuring representation across various demographic variables including region, education, income, and ethnicity ensuring a diverse range of perspectives from across the country. Participants were included from all provinces except Prince Edward Island. **Results: Knowledge about menopause:** Only one-quarter (23%) are very knowledgeable about signs and symptoms of menopause, while three-quarters have some or no knowledge. 85% are aware that menopausal symptoms can occur before menopause begins. 55% wished they had learned about perimenopause/menopause earlier in life and 46% do/did not feel prepared for it, indicating the need and desire for access to information. 68% are currently going through, or have already been through, perimenopause or menopause. Hot flashes, night sweats, period changes, trouble sleeping, fatigue, and mood changes are the main symptoms women are familiar with and experiencing. Only one-third are aware that incontinence/leakage, pain during intercourse and skin issues are symptoms of perimenopause/menopause, while even fewer are aware that heart palpitations (25%) and urinary tract infections (18%) are symptoms. **Perception towards menopause:** While 33% have negative feelings about entering this stage of life, 20% see it as a positive thing and 44% feel neutral about it. **Impact on relationship and sex lives:** 4 out of 10 women agree their symptoms negatively impacted their relationship. 62% women in a relationship found that perimenopause/menopause negatively impacted their sex lives. 45% of those in a relationship and going through perimenopause/menopause said their symptoms impacted their confidence and self-image in front of their partner or spouse. **Support during menopause:** Four-in-ten women who are going through (or have gone through) perimenopause or menopause (38%) feel/felt alone during their experience and feel/felt like their symptoms are going/went undertreated. More than half (54%) feel that discussing perimenopause/menopause symptoms is still *taboo*, and at least one-in-five are embarrassed to talk about them with family (28%) or friends (20%). **Conclusion:** Majority women undergoing menopausal transition feel as though they are alone,

unsupported, and undertreated. To address the inequities faced by women in the prime of their lives, we must prioritize education and training on this issue, and develop policies and support systems to deal with menopause-related challenges.

**Sources of Funding:** none

Survey responses

Survey questions	I don't know	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree	Net Agree
I was not/am not prepared for perimenopause/menopause	8%	18%	28%	33%	13%	46%
I wish I learned about perimenopause/menopause and its symptoms earlier in my life	9%	13%	23%	36%	19%	55%
I was/am/would be embarrassed to ask for help/support about perimenopause/ menopause from my family / friends	5%	39%	30%	20%	6%	26%
I felt/feel alone during my perimenopause/menopause experience	4%	29%	29%	27%	11%	38%
My perimenopause/menopause symptoms negatively impacted my sex life	8%	13%	17%	38%	24%	62%
My perimenopause/menopause symptoms impacted my confidence/self-image in front of my spouse/ partner	4%	26%	25%	33%	12%	45%
My perimenopause/menopause symptoms negatively impacted my relationship with my spouse/ partner	7%	30%	23%	33%	7%	40%
I feel discussing perimenopause/ menopause symptoms is still taboo for most people	7%	17%	22%	40%	14%	54%
I was / am embarrassed to talk to my friends about my perimenopausal/ menopausal symptoms	3%	41%	36%	16%	4%	20%

### P-36.

#### Vaginal and vulvar symptoms in patients with *ESR1*-mutated, *ER+/HER2-* metastatic breast cancer by baseline characteristics

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**Objective:** Endocrine therapy (ET), particularly aromatase inhibitors (AIs) that lower estrogens to subphysiologic levels, can induce genitourinary syndrome of menopause (GSM). A previous exploratory analysis from ELAINE 1, a phase 2 study in patients with *ESR1*-mutated, *ER+/HER2-* metastatic breast cancer (mBC) that progressed on an AI-CDK4/6 inhibitor combination, showed numeric improvements in vaginal/vulvar symptoms with lasofoxifene versus fulvestrant (Goldfarb et al., 2023, ISSWSH). The objective of this analysis was to evaluate the effects of patient characteristics on baseline vaginal and vulvar symptoms in ELAINE 1. **Design:** The multinational ELAINE 1 study evaluated vaginal and vulvar symptoms as an exploratory endpoint using the vaginal (VAS) and vulvar (VuAS) assessment scales, validated instruments that assess vaginal/ vulvar dryness, soreness, irritation, and pain using a 4-point scale (0=none, 1=mild, 2=moderate, 3=severe). The mean scores for baseline VAS, VuAS, and composite VAS/VuAS (average of all reported scores for a patient) were stratified by patient characteristics (age, visceral disease, prior adjuvant tamoxifen, duration of prior AI in the adjuvant or adjuvant/metastatic setting) for those who completed the VAS/VuAS at baseline, irrespective of treatment assignment. Data were descriptively summarized. **Results:** Of 103 enrolled patients, 72 (70%) completed the VAS/VuAS, with a mean age (range) of 61.5 (37-84) years. Vaginal dryness (40%), vulvar dryness (25%), and vaginal pain (22%) were the most frequently reported symptoms at baseline; 74% patients reported no to mild baseline symptoms (score 0-1). Data are summarized in the Table. Patients had more severe vaginal/vulvar symptoms if they were under age 40 (n=3) versus patients >40, and if they did not have visceral disease compared with those who had visceral disease. Prior adjuvant tamoxifen was associated with more severe vaginal/ vulvar symptoms, as was a longer total duration of AI use in both adjuvant and metastatic settings. Duration of prior AI in the adjuvant setting alone did not impact baseline vaginal or vulvar symptoms. **Conclusion:** Results from this exploratory analysis in a limited number of ELAINE 1 patients with *ER+/HER2-* mBC showed that younger age, non-visceral disease, prior tamoxifen (a marker of pre-menopausal status at diagnosis), and a longer total duration of AI use in the adjuvant or metastatic settings may be associated with more severe baseline vaginal and/or vulvar symptomatology. ELAINE 3, the phase 3, registrational trial evaluating second-line CDK4/6 inhibitor therapy (abemaciclib) plus either lasofoxifene or fulvestrant in patients with *ESR1*-mutated *ER+/HER2-* mBC, will help further evaluate the impact of patient and disease characteristics on symptoms, as well as treatment effects on vaginal and sexual health as assessed by patient-reported outcomes.

**Sources of Funding:** Sermonix Pharmaceuticals

**Table.** Baseline VAS, VuAS, and composite scores by patient characteristics

Characteristics	VAS			VuAS			Composite VAS/VuAS		
	n	Mean±SEM	n	Mean±SEM	n	Mean±SEM			
Age, yrs	30-39	3	1.00±0.58	3	0.58±0.30	3	0.79±0.41		
	40-49	10	0.33±0.15	10	0.23±0.13	10	0.28±0.14		
	50-59	16	0.48±0.15	15	0.17±0.07	16	0.32±0.10		
	60-69	27	0.37±0.10	27	0.20±0.07	27	0.29±0.07		
≥70	16	0.21±0.11	15	0.15±0.08	16	0.17±0.09			
Visceral disease	Yes	30	0.29±0.08	28	0.24±0.08	30	0.26±0.07		
	No	42	0.44±0.09	42	0.18±0.05	42	0.31±0.06		
Adjuvant tamoxifen	Yes	21	0.54±0.13	20	0.33±0.09	21	0.42±0.10		
	No	51	0.31±0.07	50	0.16±0.04	51	0.23±0.05		
Adjuvant/metastatic AI duration, mos	0-12	6	0.17±0.17	6	0±0	6	0.08±0.08		
	12-24	21	0.36±0.11	21	0.20±0.08	21	0.28±0.09		
	≥24	45	0.42±0.09	43	0.23±0.06	45	0.32±0.06		
Adjuvant AI duration, mos	<19	54	0.37±0.08	53	0.20±0.05	54	0.28±0.06		
	≥19	18	0.41±0.13	17	0.21±0.08	18	0.30±0.09		

**P-37.****Using Technology to Advance Menopause Management: A Novel interactive Website (www.MQ6.ca)**

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**Objective:** The provision of menopausal care continues to be challenging in the post-WHI world where clinicians exhibit significant knowledge gaps and where in many locations menopausal education for healthcare providers is limited. The MQ6 menopause assessment tool and accompanying treatment algorithm were published in 2017(1) to address these knowledge gaps and to support healthcare providers in providing menopausal care. In addition to clinical utility, the MQ6 assessment tool can be self-administered by patients and used as a valuable counselling tool during the clinical encounter. The accompanying MQ6 treatment algorithm guides clinicians in creating individualized menopausal treatment plans. These tools have been utilized by both primary care and other specialists in the contexts of both clinical care and medical student/resident teaching. As medical education and professional development have expanded to multiple modalities including online platforms and ‘app’s, knowledge translation tools that involve technology are desirable and widely accepted. There is a current paucity of professional online interactive tools related to menopause management. (1) Goldstein S. An efficient tool for the primary care management of menopause. *Can Fam Physician*. 2017 Apr;63(4):295-298. **Design:** The website <https://mq6.ca> was developed to provide easy and interactive access to the MQ6-associated tools and to provide other tools and medical information to support both clinicians and patients. The 2017 algorithm was updated to reflect the most recent guidelines and menopausal products available in Canada. Content of the website was informed by the most recently published literature and expert consensus. Content on the site was peer-reviewed by a panel of menopause experts across Canada including physicians and a pharmacist (N=4). The website was then reviewed for relevance and usability by a range of end users. This included academic and community-based family physicians, resident physicians, other physicians and regulated healthcare professionals with menopausal expertise, and members of the public. Their feedback and commentary were positive on these measures. The MQ6 website went “live” on March 31, 2023. **Results:** The website content, while focussed on supporting healthcare professionals, has been designed to meet the needs of both HCPs and patients, providing medical information and counselling tools related to menopausal presentation, assessment, and treatment. There are also links to other useful resources and a robust academic reference section. The website structure was designed to provide for accessibility and interactivity on a variety of devices and to accommodate efficient expansion and updating. The interactive elements of the site include: (1) The MQ6 assessment tool/questionnaire a) In its original form, b) As binary fillable printable PDF tools for HCPs and patients, and c) As a mobile-compatible fillable tool. (2) An online interactive decision tool based on the MQ6 treatment algorithm which provides treatment recommendations that then link to product tables. This tool will function as an ‘app’ by easily creating a homepage shortcut on a computer or mobile device. **Conclusion:** The MQ6 website, an accessible and credible/peer-reviewed website resource to support menopausal care, may play an important role in addressing knowledge gaps and access to care. Preliminary online analytics indicate international uptake and will continue to be monitored. Opportunities for further evaluation of relevance, utility and impact and for additional content development will be explored.

**Sources of Funding:** Unrestricted educational grant from the Canadian Menopause Society.

**P-38.****New treatment option for patients with genitourinary syndrome of menopause (GSM): randomized clinical trial comparing the effect of non-invasive radiofrequency with vaginal estrogen therapy and vaginal moisturizer.**

Anna V. Gueldini de Moraes, PhD, Adriana O. Pedro, PhD, Lucia Costa Paiva, Md, PhD. Gynecology and Obstetrics, Universidade Estadual de Campinas, Campinas, Brazil **Objective:** The aim of the study was to evaluate the effect of non-invasive radiofrequency procedure and compare it to vaginal estrogen therapy and vaginal moisturizer in the treatment of genitourinary syndrome of menopause (GSM) symptoms in postmenopausal women. **Design:** A total of 30 postmenopausal women meeting inclusion criteria were randomly assigned into three intervention arms to receive one of the following treatments: 3 sessions of intravaginal and vulvar non-invasive radiofrequency therapy (RF arm); 1mg of intravaginal estriol cream applied daily for 2 weeks, followed by 1mg applied 2 times weekly or 1 mg of estradiol vaginal fast-dissolving film applied daily for 2 weeks, followed by 1mg applied 2 times weekly (E arm); and intravaginal hyaluronic acid moisturizer 2 times a week (M arm). Assessments at baseline, 2 and 4 months were conducted using Vaginal Health Index (VHI), Vaginal Maturation Index, Menopause Rating Scale (MRS), Female Sexual Function Index (FSFI), International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) and International Consultation on Incontinence Questionnaire - Overactive Bladder (ICIQ-OAB). Statistical analysis was made using the Fisher’s exact test and the Chi-square test (categorical variables) and the Kruskal-Wallis test and the Wilcoxon test (numerical variables). The Tukey test was used to assess the interaction’s effect of the different arms vs the assessments over time. The profile test by contrast was used to assess the significant differences over the time of assessment. In addition, the ANOVA test was used for repeated measures to compare parameters intra and inter study arms, with the variables transformed into ranks due to the absence of a normal distribution. **Results:** The mean age of the participants was 58.0±/5.31, 57.9±/6.3, and 59.6±/6.04 years in the radiofrequency, estrogen, and moisturizer arms, respectively, with no significant intergroup difference (p=0.741). After 4 months of treatment, there was a significant effect of the interaction between groups vs follow-up time, with the RF arm performing similarly to the E arm in relation to the reduction of vaginal pH (p =0.010) and showing the best VHI score (p=0.008). Regarding the improvement in the elasticity of the vaginal wall, the RF arm performed better than the other two groups (p<0.001). Hormonal cytology analysis showed significant increase in superficial cells in both E and RF arms (better in E arm), with no significant changes in M arm (p=0.004). There was a significant improvement in the mean of the global MRS score in the RF arm, better than the other arms (p < 0.001). The frequency of urinary loss, the amount of urinary loss, the interference in quality of life and the total score evaluated by the ICIQ-UI SF showed a significant improvement in the RF arm (p=0.024, p<0.001 and p=0.001, respectively), better than to the other arms. Over time, the RF arm had the best performance in improving the FSFI total and partial scores, with no significant improvement in the other two arms (p < 0.001). **Conclusion:** After 4 months of follow-up, the clinical efficacy of non-invasive radiofrequency for the treatment of vulvovaginal symptoms of GSM was similar to vaginal estrogen therapy and was superior to vaginal estrogen therapy for urinary and sexual symptoms. These findings are promising, especially for the population that cannot or prefers not to use vaginal estrogen therapy. New studies with more patients are needed to corroborate these findings and to evaluate the long-term effects of non-invasive radiofrequency in GSM.

**Sources of Funding:** São Paulo Research Foundation (FAPESP): Grant #2020/03060-8.

**P-39.****Nonpharmacologic Interventions for Low Sexual Desire in Menopausal Women: A Systematic Review**

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**Objective:** Menopausal women experience changes in sexual functioning. Low sexual desire is the most reported sexual problem in menopausal women. The purpose of our review is to summarize existing research on the effects of nonpharmacologic interventions for low sexual desire in menopausal women. **Design:** We searched PubMed, PsychInfo, and CINAHL from January 2014 to March 2023. Original studies were included if they evaluated nonpharmacologic interventions for sexual dysfunction and investigated the effects of these interventions on sexual desire in menopausal women. Studies focusing only on premenopausal women or only on subpopulations of menopausal women with comorbidities (e.g., breast cancer) were excluded. Included studies were published in peer-reviewed journals and assessed for quality using the Critical Appraisal Skills Program Checklist. **Results:** After removing duplicates, our search identified 895 articles. Screening of abstracts excluded 863 publications, and that of full text screening an additional 17. Of the 15 studies included in the review, 13 were randomized controlled trials and 2 were quasi-experimental trials. Studies were conducted in Iran (6), Canada (2), the United States (2), Brazil, Korea, Spain, Thailand, and Turkey (1 each). The sample sizes ranged from 49-355, with a majority of studies (8) having a sample size greater than 100 and with an aggregate total of 1686 participants. Mean age was 53 years. Ten of the 15 studies excluded participants over 60 years of age. Five of the studies included both premenopausal and menopausal women. There was notable variability in the types of interventions. The following intervention categories emerged: education (9), mind focused therapies (7), physical body focused therapies (6), aromatherapies (3), and touch therapies (3). Researchers of 10 studies employed a multicomponent intervention consisting of interventions from two or more categories. Of the 15 studies, researchers of 11 studies demonstrated statistical significance suggesting that their intervention positively affected sexual desire in menopausal women. **Conclusion:** Nonpharmacologic interventions have the potential to positively impact sexual desire in menopausal women.

The small number of studies and relatively small samples sizes limit generalizability. Larger scale and longer duration studies are needed. Future researchers should include diverse menopausal women, including women who have psychological and medical comorbidities, who use hormone therapies, who are older than 60 years of age, who are not partnered, who represent sexual and ethnic minorities, and who represent low- to middle-income populations.

**Sources of Funding:** None

#### P-40.

##### **Sleep Disturbances and Hot Flashes: Can Exercise Help?**

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**Objective:** Sleep disruptions are a major symptom of those undergoing the menopausal transition that can impact quality of life. Hot flashes are likely an important factor related to sleep disruptions. While physical activity has been shown to improve sleep quality in other groups, the capacity for exercise to improve sleep disruptions in perimenopausal people remains unknown. Our objective was to test the hypotheses that 1) there is a difference in sleep quality between perimenopausal people symptomatic vs. asymptomatic for objectively measured hot flashes and 2) a single bout of moderate-intensity exercise improves short-term sleep quality in perimenopausal people. **Design:** Healthy, perimenopausal people aged 43-54 were included (n=31 to date). Perimenopause was based on the STRAW+10 criteria. Participants were free from risk factors for cardiovascular disease, reproductive abnormalities, and had not used birth control or medications to reduce hot flashes for at least six months. Participants underwent two 24-hour periods of simultaneous monitoring of objective hot flashes and wrist-worn actigraphy. Symptomatic (SY) participants experienced four or more objectively measured hot flashes in at least one of two 24-hour monitoring periods, with at least one hot flash occurring at night. Asymptomatic (AS) participants experienced fewer than four objectively measured hot flashes in one of the 24-hour periods and no hot flashes at night. In one condition (EX), participants underwent a single bout of laboratory moderate-intensity treadmill exercise (64-76% HRmax). On a separate day, participants underwent a control no-exercise (NE) condition where they were instructed not to engage in any structured exercise. Actigraphy variables (Wake After Sleep Onset, WASO; number of awakenings; sleep duration; and total sleep time) were assessed using GGIR—an R package designed to process raw accelerometer data (version 2.8.4). WASO, number of awakenings, and sleep duration were divided by total sleep time to normalize for differences in sleep period between participants. The Wilcoxon rank sum test was used to test for significance between SY and AS groups in each condition and the Wilcoxon signed-rank test was used to test for significance in each group between the NE and EX conditions (RStudio, version 2022.07.1+554). **Results:** For the NE condition, WASO, number of awakenings, and sleep time were significantly higher in the SY group compared to the AS group (median±SD; WASO, AS=0.09±0.09 vs. SY=0.13±0.06, p=0.02; awakenings, AS=1.54±0.56 vs. SY=1.98±0.41, p=0.03; sleep time, AS=7.30±1.10 vs. SY=8.35±1.44, p=0.002). Sleep duration was significantly higher in the AS group compared to the SY group in the NE condition (AS=0.91±0.09 vs. SY=0.87±0.06, p=0.02). Sleep time increased in the AS group with EX (NE=7.30±1.10, EX=7.87±1.49, p=0.004). There was a trend for an increase in WASO and decrease in sleep duration for the AS group with EX (WASO, NE=0.09±0.09 vs. EX=0.12±0.07, p=0.096; sleep duration, NE=0.91±0.09, EX=0.88±0.07, p=0.096). There was no significant difference in awakenings in the AS group with EX (NE=1.54±0.56 vs. EX=1.58±0.45, p=0.40). For the SY group, sleep duration increased while WASO decreased with EX (WASO, NE=0.13±0.06 vs. EX=0.12±0.04, p=0.03; sleep duration, NE=0.87±0.06 vs. EX=0.88±0.04, p=0.03). There was no significant difference in awakenings and sleep time for the symptomatic group with EX (both p>0.05). There was no significant difference between the symptomatic and asymptomatic groups with EX (all p>0.05). **Conclusion:** Our preliminary data support the hypothesis that those symptomatic for objective hot flashes have more disrupted sleep compared to asymptomatic people. Our data also show that these individuals may try to make up for disruptions by staying in bed longer. With one bout of moderate-intensity exercise, symptomatic people experienced a decrease in WASO and an increase in sleep duration, showing a potential positive effect of exercise on sleep. Limitations include a small sample size. Future directions include further data collection and investigating the effects of habitual physical activity, duration, and intensity of exercise on sleep disruptions.

**Sources of Funding:** Smith College STRIDE Program (Houge), NHLBI R15R15HL145650-01A1 (Witkowski)

#### P-41.

##### **Estradiol's effect on limbic and striatal resting state functional connectivity in perimenopausal-onset major depressive disorder**

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**Objective:** The transition to menopause (perimenopause) is a period of susceptibility to affective dysregulation and the development of major depressive disorder (MDD). For some women, hormone replacement therapy using estradiol, the most prevalent metabolite of estrogen, effectively relieves affective symptoms of perimenopausal MDD. Despite the benefit estradiol provides, the mechanism of action is unknown. Existing research suggests hypoconnectivity in the frontostriatal reward pathways of the brain may be responsible for the onset and exacerbation of perimenopausal MDD.

Therefore, this study aimed to probe frontostriatal connectivity changes associated with estradiol treatment for perimenopausal-onset MDD (PO-MDD) using functional magnetic resonance imaging (fMRI). **Design:** Participants with PO-MDD (n=16) and controls (n=18) received three weeks of estradiol treatment (Climara®) to assess its effects on affective symptoms and frontostriatal connectivity. fMRI was acquired, using a 3T Siemens MR scanner, at baseline and follow-up. Changes in resting state functional connectivity between baseline and follow-up were analyzed using CONN toolbox. Depression and climacteric symptoms were measured using the Inventory of Depression and Anxiety Symptoms and Greene Climacteric Scale, respectively. **Results:** Depression symptoms remitted in PO-MDD following estradiol treatment. Baseline analysis revealed that participants with PO-MDD had greater connectivity from the right amygdala to the dorsal anterior cingulate cortex ( $t_{(30)} = 5.30, p < 0.001$ ) and the medial prefrontal cortex ( $t_{(32)} = 5.17, p < 0.001$ ) than control participants. Following estradiol treatment, MDD participants showed a significant decrease in connectivity between the right amygdala and the medial prefrontal cortex ( $t_{(32)} = -2.12, p < 0.05$ ), while control participants showed increased connectivity to this region ( $t_{(17)} = 2.79, p = 0.013$ ). Additionally, participants with PO-MDD exhibited increased connectivity following treatment between the right caudate and the left posterior insula ( $t_{(26)} = 5.22, p < 0.001$ ), while controls exhibited a significant decrease in connectivity to this region ( $t_{(17)} = -4.50, p < 0.001$ ). **Conclusion:** This study provides evidence that PO-MDD is associated with hyperconnectivity between the right amygdala and frontal brain regions. Further, estradiol treatment significantly decreased right amygdala hyperconnectivity to the medial prefrontal cortex and increased connectivity from the right caudate to the left insula. These connectivity patterns may be instrumental in the development of PO-MDD and, in turn, may play a vital role in the therapeutic effects of estradiol.

**Sources of Funding:** NIMH K23 MH105569 NIMH R01 MH128238

#### P-42.

##### **Evaluating menopausal symptoms in a border population in West Texas**

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**Objective:** Menopause is a naturally occurring process for all women, caused by the cessation of ovarian function. Menopause marks a new phase in the life of women, and menopause is experienced differently by each patient. Symptoms vary widely from hot flashes, night sweats, sleep disturbances, vaginal discomfort, and sexual dysfunction. Symptoms vary in severity, duration, and impact on quality of life. Many factors influence how a woman perceives menopause symptoms, including race and ethnicity, socioeconomic factors, level of education, and cultural norms. Most studies exploring menopause and its impact were conducted in women of European descent; this limits the understanding of menopausal symptoms in patient populations of other ethnicities. It is critical to understand how women of non-European descent understand and experience menopause to deliver culturally competent care and improve the quality of life for women with severe menopause symptoms. This study seeks to better understand the menopausal symptoms and concerns experienced by a primarily Hispanic population of women living in a border town of West Texas. **Design:** In a prospective observational study, 204 women diagnosed with menopause (12 consecutive months of amenorrhea or had bilateral ovaries removed) were invited to participate in an anonymous, self-administered survey in English or Spanish regarding their knowledge of and experience with menopause. The survey included demographic factors, namely race, ethnicity, level of education, annual household income, and smoking status. Participants were asked about their experience with menopause, including: if a healthcare provider had addressed their symptoms, the presence and severity of symptoms, and experience with menopause treatments. **Results:** There were 204 women enrolled in the study, recruited from January 2021 to March 2023. Participants identified as Hispanic (76.4%), with an average age of 56.8 years (standard deviation 12.60). Survey results were compared based on age and ethnicity. Menopausal participants under 50 years age more frequently reported experiencing menopause symptoms ( $p < 0.001$ ), with 100% of patients ( $n = 28$ ) under the age of 50 reporting menopause symptoms, while 64.3% of participants ( $n = 157$ ) over the age of 50 reported symptoms. The most bothersome symptoms reported by Hispanic women were sleep disturbances (60.6%) and concerns with weight gain (75%), however, there were no significant differences described in the experience of other menopausal symptoms including hot flashes, mood changes, changes in mental abilities, weight gain, or difficulties with sexual intercourse across different ethnicities. Women self-identifying as non-Hispanic White were more likely to report having received prescription hormone therapy for menopause symptoms than Hispanic women ( $p = 0.012$ ). Non-Hispanic White participants were also more likely to report having received treatment for mood symptoms when compared to Hispanic women ( $p < 0.001$ ). **Conclusion:** A higher percentage of Hispanic women reported not receiving treatment for their menopause symptoms including prescription hormone therapy when compared to their Non-Hispanic White counterparts. Additionally, women younger than 50 years were significantly more likely to report menopause symptoms. Obstetrician-gynecologists and other physicians should be cognizant of this when addressing menopausal symptoms with patients, particularly given that no significant differences in menopausal symptoms are reported across ethnicities. This study highlights the most bothersome menopausal symptoms reported by Hispanic women and the disparities in treatments especially with regards to use of prescription hormone therapy. It further points to the importance of cultural competence in order to provide high-quality care for all women regardless of ethnicity.

**Sources of Funding:** None

**P-43.**

**Pooled fezolinetant safety data over 52 weeks from three randomized Phase 3 studies (SKYLIGHT 1, 2 and 4)**

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**Objective:** To present pooled safety data from three 52-week phase 3 fezolinetant studies (SKYLIGHT 1, 2 and 4; NCT04003155, NCT04003142, NCT04003389) in women with vasomotor symptoms (VMS; hot flashes and night sweats) associated with menopause. **Design:** SKYLIGHT 1 and 2 were double-blind, placebo-controlled studies with the same design. Women aged ≥40–≤65 y with moderate-to-severe VMS (minimum average ≥7 hot flashes/day) were initially randomized to once-daily placebo, fezolinetant 30mg or 45mg (1:1:1). After 12 weeks, those on placebo were re-randomized to fezolinetant 30mg or 45mg, and those on fezolinetant continued on their assigned dose for 40 weeks. SKYLIGHT 4 was a placebo-controlled, double-blind, 52-week long-term safety study. Safety was assessed by frequency of treatment-emergent adverse events (TEAEs) and laboratory assessments including liver safety assessments. **Results:** A total of 952 participants in the placebo group; 1103 in the fezolinetant 30mg group and 1100 in the fezolinetant 45mg group took ≥1 dose of study medication. Caffeine use was not restricted; 18% of each group were current smokers. Here we present safety data for fezolinetant 45mg (proposed dose for approval); results were consistent for 30mg. By group, TEAEs occurred in 55.3% of participants in the placebo and 62.9% in the fezolinetant 45mg group; exposure-adjusted results were consistent with these results (TABLE). The most frequent TEAEs (>5% in either group) were upper respiratory tract infections (8.2% placebo, 7.7% fezolinetant 45mg); headache (7.7% placebo, 8.2% fezolinetant 45mg); and COVID (4.1% placebo, 6.1% fezolinetant 45mg). There were 6 drug-related serious TEAEs (1 placebo, 5 fezolinetant 45mg). The incidence of elevations of hepatic transaminases was low, events were generally asymptomatic and resolved on treatment or on discontinuation. No Hy's Law cases were reported. A low incidence of bone fractures was reported, with similar incidences across groups. Endometrial hyperplasia or malignancy determined by the final biopsy diagnosis in fezolinetant-treated participants, assessed by centrally read endometrial biopsies, were within FDA pre-specified limits of ≤1% with an upper limit of 1-sided 95% CI ≤4%. There was no substantial difference in endometrial thickness measured by transvaginal ultrasonogram during the assessment period between fezolinetant- and placebo-treated participants. **Conclusion:** Pooled data affirm the safety and tolerability of fezolinetant over 52 weeks. **Sources of Funding:** Astellas Pharma Inc. Medical writing support was provided by Sue Cooper of Envision Pharma Inc. and funded by Astellas Pharma Inc.

Table

	Placebo (n=952)	Fezolinetant 45mg (n=1100)
TEAE (%) [rate <sup>a</sup> ] <sup>b</sup>		
Overall	526 (55.3) [95.8]	692 (62.9) [75.9]
Drug-related	140 (14.7) [25.5]	171 (15.5) [18.7]
Serious	15 (1.6) [2.7]	45 (4.1) [4.9]
Drug-related serious	1 (0.1) [0.2]	5 (0.5) [0.5]
Leading to withdrawal of treatment	37 (3.9) [6.7]	47 (4.3) [5.2]
Drug-related, leading to withdrawal of treatment	24 (2.5) [4.4]	31 (2.8) [3.4]
Death (unrelated to treatment) (%)	0	1 (0.1)
Preferred Term (%) <sup>b</sup>		
Upper respiratory tract infection	78 (8.2)	85 (7.7)
Headache	73 (7.7)	90 (8.2)
COVID	39 (4.1)	67 (6.1)
TEAEs of special interest (%) <sup>b</sup>		
Liver test elevations	39 (4.1)	61 (5.5)
Bone fractures	11 (1.2)	15 (1.4)
Depression	19 (2.0)	21 (1.9)
Wakefulness	6 (0.6)	7 (0.6)
Memory	1 (0.1)	2 (0.2)
Centrally-read endometrial biopsy (%)		
Hyperplasia <sup>c</sup>	-	1 (0.3) <sup>d</sup>
Malignancy <sup>c</sup>	-	0 <sup>e</sup>

<sup>a</sup>Exposure-adjusted incidence rate per 100 subject-years; <sup>b</sup>Fezolinetant 45 mg group includes placebo subjects who were re-randomized to fezolinetant 45 mg after 12 weeks on placebo from SKYLIGHT 1 and 2 studies; <sup>c</sup>Determined by final endometrial biopsy diagnosis; <sup>d</sup>n=304 (upper limit of one-sided 95% CI 1.6%); <sup>e</sup>n=304 (upper limit of one-sided 95% CI 1.0%).

**P-44.**

**The comparison of bilateral bone mineral density in postmenopausal women**

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**Objective:** The aim of this study is to determine whether there is a difference between right and left femur bone mineral density (BMD) in postmenopausal women. **Design:** We performed a retrospective chart review of postmenopausal women who underwent bone

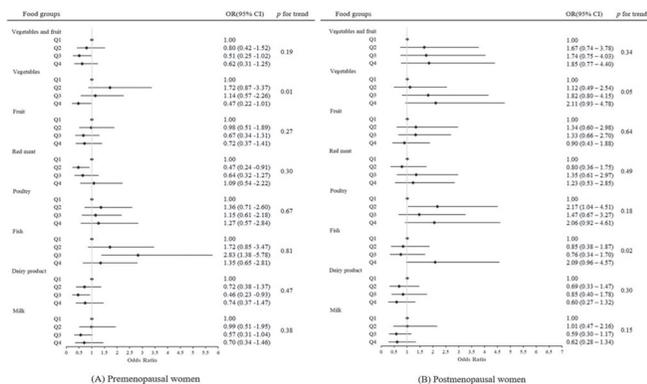
mineral density (BMD) measurement from 2010 to 2019 at a single center using dual-energy X-ray absorptiometry (DXA). Data, including BMD and T- scores of bilateral hip and lumbar spine, was gathered for all postmenopausal women above the age of 50 years. The continuous variables were expressed as means with standard deviation for normal distribution and analyzed with a two-sample t-test. Multiple regression analysis was used to test the effect of underlying medical conditions on T-score of bilateral hips. For all analyses, a p-value of <0.05 was considered significant. **Results:** 346 patients were included in the study with a mean age at imaging of 62 + 9.7 years and body mass index (BMI) of 23.4 + 6.1 kg/m<sup>2</sup>. There were no significant differences between right and left femoral BMDs in all patients. There were significant differences in BMD of both total femurs in women in their 60s and women with normal BMD. There was no difference in both femur BMDs between those taking hormone therapy and those not taking hormone therapy. In patients undergoing osteoporosis treatment, there was a difference in the BMD of both femur neck. Calcium and vitamin D intake were not associated with differences between both femur BMD. We found a significant correlation between the BMD measures at lumbar spine and both femur (p < 0.01). **Conclusion:** There were no significant differences between right and left femoral BMDs in postmenopausal women. Therefore, BMD may be measured at either hip. The correlation of bone density between lumbar spine and femur neck is shown to be statistically meaningful. Based on the knowledge of the correlation coefficients between lumbar spine and femur neck, it seems possible to predict the BMD result of one location through the measurement of another. **Sources of Funding:** None

**P-45.**

**Dietary patterns are associated with the prevalence of uterine leiomyoma in Korean Women**

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**Objective:** This study aimed to evaluate the association between dietary food group intake and the prevalence of uterine leiomyoma (UL) in Korean women who underwent pelvic ultrasonography. **Design:** A cross-sectional study was performed among 672 women aged 25–65, of which 383 (57%) were premenopausal. Dietary intake was assessed using a validated 106-item food frequency questionnaire (FFQ), and the presence of UL was evaluated by ultrasonography. Cases with UL were defined as having one or more nodules of typical leiomyoma with a largest diameter of ≥10mm in length. Only items corresponding to the ten categories (vegetables/fruit, vegetables, fruits, red meat, processed meat, poultry, fish, dairy product, milk, and alcohol) were included in the analyses. The amount of food intake was divided into tertiles or quartiles. Multiple logistic regression models were used to analyze the relationship between dietary patterns and the prevalence of UL by calculating odds ratios (ORs) and 95 % confidence intervals (CIs) with adjustment for confounding factors. **Results:** A total of 219 (32.6%) women were diagnosed with UL in our study. High intakes of fish and poultry were associated with a high prevalence of UL; ORs (95% CIs) comparing top vs. bottom quartiles were 1.70 (1.02-2.84; p trend = 0.049) for fish intake and 1.85 (1.09 -3.14; p trend = 0.07) for poultry intake. However, high intake of dairy products was inversely associated with the prevalence of UL (OR 0.59, 95% CI 0.36–0.98; p trend = 0.06). When we examined pre- and post-menopausal women separately, we found a similar increased prevalence with fish intake and decreased prevalence with dairy product intake. However, the association for poultry intake was generally limited to postmenopausal women. In premenopausal women, those with higher vegetable intake had a lower prevalence of UL (OR 0.47, 95% CI 0.22 -1.01 for top vs. bottom quartiles; p trend = 0.01). **Conclusion:** In our study of Korean women who underwent pelvic ultrasonography, we found that high intakes of fish and poultry, but low intake of dairy products, were associated with a higher prevalence of UL. Additionally, vegetable intake was inversely associated with the prevalence of UL in premenopausal women. **Sources of Funding:** None



**Figure 1. Association between dietary patterns and the prevalence of UL in subgroups according to menopausal status. Q and T represent quartile and tertile, respectively. The black circles indicate the study specific odds ratios (ORs) and the horizontal lines indicate the 95% confidence intervals (CIs).**

### P-46.

#### Characteristics of Postmenopausal Women with Low Libido Self-Referring for A Flibanserin Telehealth Visit

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**Objective:** Although only approved in the US to treat premenopausal women with hypoactive sexual desire disorder (HSDD), flibanserin has been studied in and prescribed to thousands of postmenopausal women. During the COVID-19 pandemic, telehealth emerged as a critical component of patient care and is now widely accepted. This study utilizes data from an online telehealth screening questionnaire (screener) to explore the key characteristics of postmenopausal women with low libido who self-refer for treatment with flibanserin for low libido. **Design:** A 25-question screener was used to confirm a diagnosis of HSDD and determine eligibility for treatment with flibanserin. Questions from the Decreased Sexual Desire Screening (DSDS) were included on the screener to facilitate the diagnosis of HSDD. Eligibility for flibanserin was assessed using patient responses to questions related to demographics, coexisting medical conditions, and concomitant medications. The screener provided a brief definition of menopause, and women were asked to respond "Yes," "No," or "I don't know" to the question "Have you gone through menopause?" Women who self-reported as menopausal and completed the screener, between January 1, 2022, to December 31, 2022 (study period) were automatically enrolled (study population). All patient data were captured and stored in a secure and HIPAA-compliant platform. **Results:** A total of 1246 menopausal women completed the screener during the study period and were automatically enrolled. Ninety-nine percent of the study population indicated a bothersome decrease in libido, 84% indicated that in the past, their libido was good and satisfying, and 93% indicated their HSDD-related symptoms had lasted for >6 months. Time since last wellness exam was <12 months for 1033 (83%) of the study population. Patient characteristics, including age, medical history, and concomitant medications, are summarized in the Table. **Conclusion:** It is clear that many postmenopausal women self-refer for off-label treatment with flibanserin for their low sexual desire, reflecting an unmet need for this population. Interestingly, most of the study population reported experiencing HSDD symptoms lasting > 6 months and met the DSDS criteria for HSDD. The most frequently self-reported coexisting medical conditions were related to mood disorders, and treatments for these conditions were the most prescribed concomitant medications, most notably antidepressants. Study limitations include reporter bias and lack of generalizability to other clinical settings.

**Sources of Funding:** Sprout Pharmaceuticals, Inc

**Table. Study Population Characteristics (N=1246)**

Age, mean, y	51
Weight, mean, lbs.	170
Alcohol consumption	n (%)
• Yes	863 (69%)
• No	383 (31%)
≥1 medication	n (%)
• Yes	850 (68%)
• No	396 (32%)
Most commonly reported medication classes	n (%)
• Antidepressant	280 (22%)
• Blood pressure lowering	180 (14%)
• Thyroid replacement	117 (9%)
• Hormone therapy	109 (9%)
• Anxiolytic	65 (5%)
≥1 chronic medical condition	n (%)
• Yes	428 (34%)
• No	818 (66%)
Most common medical conditions	n (%)
• Anxiety	157 (13%)
• Depression	148 (12%)
• Hypertension	85 (7%)

### P-47.

#### What do women with breast cancer take for menopause symptoms?

#### A real-world analysis of treatment utilization from the US and Europe

Sheryl Kingsberg, PhD<sup>1</sup>, Cecile Janssenswillen<sup>2</sup>, Cecilia Caetano<sup>2</sup>, Lauren Lee<sup>3</sup>, Megan Scott<sup>3</sup>, Nils Schoof<sup>6</sup>, Carsten Moeller<sup>6</sup>, Siir Su Saydam<sup>6</sup>, Lisa Halvorson<sup>2</sup>, Victoria Banks<sup>4</sup>. <sup>1</sup>Departments of Reproductive Biology, Psychiatry and Urology, University Hospitals, Cleveland, OH; <sup>2</sup>Bayer Consumer Care AG, Basel, Switzerland; <sup>3</sup>Respiratory Franchise & Women's Health, Adelphi Group Ltd, Bollington, United Kingdom; <sup>4</sup>Medical Affairs & Pharmacovigilance, Pharmaceuticals, Bayer plc, Reading, United Kingdom; <sup>5</sup>Bayer Corporation, Whippany, NJ; <sup>6</sup>Bayer Pharma AG, Berlin, Germany

**Objective:** Women receiving adjuvant endocrine therapy (AET) for hormone-positive breast cancer report high rates of menopausal symptoms including vasomotor symptoms (VMS). Treatment options for VMS in this patient group are limited due to contraindications to hormone therapy (HT). The REAL-world evidence on vasomotor and other symptoms in menopausal women (REALISE) study aimed to evaluate treatment utilization in women experiencing VMS while on AET. **Design:** The Adelphi 2020 VMS Disease Specific Program (DSP™) was a quantitative, cross-sectional, ethics board-exempt survey conducted in France, Germany, Italy, Spain, the United Kingdom, and the United States. Oncologists provided demographic, clinical, and treatment data on adult women in remission from breast cancer taking AET (tamoxifen/aromatase inhibitors) and experiencing VMS. We stratified patients by physician-reported VMS severity; analyses were descriptive. **Results:** Data were provided by 77 oncologists on 635 women (mean age 53.9 years, standard deviation [SD] 9.5; mean age at onset of induced menopause 48.7 years, SD 7.3; 80.3% White/Caucasian). Physicians reported that 60.5% of women were currently prescribed treatment for VMS related to AET (mean [SD] treatment duration 50.7 [66.7] weeks); 7.1% had previously been prescribed, and 32.4% had never received treatment. Of women receiving VMS treatment, 21.9% were prescribed one or more HT products (alone or in combination with other drugs), including bioidentical hormones; 65.9% were prescribed serotonin/norepinephrine reuptake inhibitors (SSRI/SNRI, alone or in combination); and 12.2% other treatment only (gabapentin/pregabalin/clonidine/others). Estradiol products were the most common HT (8.3%) and venlafaxine the most frequently prescribed SSRI/SNRI (25.0%) (Table). Route of administration for all HT products (n=84) included: Oral pill/tablet/capsule (63.1%), patch (13.4%), and cream/gel (11.9%). Of women with severe VMS, 81.4% were prescribed VMS treatment (19.3% received HT), while 48.3% with mild VMS received VMS treatment (22.7% HT). **Conclusion:** We found that around one-fifth of the women receiving treatment for VMS were prescribed HT (61.1% by oral route), which is in principle contra-indicated in this population. Our data highlight an unmet need in the management of VMS in women taking AET for the prevention of breast cancer recurrence.

**Sources of Funding:** Study funded by Bayer AG.

**Table. Current physician-reported treatment regimens by VMS severity**

Current treatment by category and product, n (%)	Total sample (n=384)	VMS severity: Mild (n=97)	VMS severity: Moderate (n=204)	VMS severity: Severe (n=83)
<b>CATEGORY 1:</b>				
Hormones, including bioidentical hormones*	84 (21.9)	22 (22.7)	46 (22.6)	16 (19.3)
Estradiol (Vivelle DOT, Divigel, Estrojel, others)	32 (8.3)	6 (6.2)	18 (8.8)	8 (9.6)
Premarin	10 (2.6)	5 (5.2)	5 (2.5)	0 (0.0)
Prempo & other conjugated estrogens	3 (0.8)	0 (0.0)	1 (0.5)	2 (2.4)
Medroxyprogesterone (Provera, Depo-Provera, others)	4 (1.0)	1 (1.0)	3 (1.5)	0 (0.0)
Raloxifene (Evista)	14 (3.7)	6 (6.2)	(3.4)	1 (1.2)
Progesterone (Prometrium, others)	9 (2.3)	2 (2.1)	4 (2.0)	3 (3.6)
Tibolone (Livial, Tibomax, others)	5 (1.3)	1 (1.0)	4 (2.0)	0 (0.0)
Bioidentical progesterone	4 (1.0)	0 (0.0)	3 (1.5)	1 (1.2)
Bioidentical estradiol	9 (2.3)	1 (1.0)	4 (2.0)	4 (4.8)
<b>CATEGORY 2:</b>				
SSRI/SNRI*	253 (65.9)	66 (68.0)	126 (61.8)	61 (73.5)
Paroxetine	51 (13.3)	16 (16.5)	26 (12.8)	9 (10.8)
Escitalopram	12 (3.1)	3 (3.1)	6 (2.9)	3 (3.6)
Fluoxetine	19 (5.0)	6 (6.2)	12 (5.9)	1 (1.2)
Citalopram	65 (16.9)	15 (15.5)	29 (14.2)	21 (25.3)
Sertraline	9 (2.3)	2 (2.1)	6 (2.9)	1 (1.2)
Venlafaxine	96 (25.0)	23 (23.7)	44 (21.6)	29 (34.9)
Desvenlafaxine	10 (2.6)	3 (3.1)	7 (3.4)	0 (0.0)
Duloxetine	4 (1.0)	1 (1.0)	2 (1.0)	1 (1.2)
<b>CATEGORY 3:</b>				
Other*	47 (12.2)	9 (9.3)	32 (15.7)	6 (7.2)
Gabapentin	26 (6.8)	6 (6.2)	13 (6.4)	7 (8.4)
Pregabalin	11 (2.9)	1 (1.0)	10 (4.9)	0 (0.0)
Clonidine	6 (1.6)	2 (2.1)	1 (0.5)	3 (3.6)
Other	22 (5.7)	4 (4.1)	17 (8.3)	1 (1.2)

**SSRI, serotonin-specific reuptake inhibitor; SNRI, serotonin-norepinephrine reuptake inhibitor; VMS, vasomotor symptoms. \*Product level data may not add up to the summary categories as respondents may have >1 one product within each category.**

#### P-48.

##### **Clearing the fog: Learning about menopause through the experiences of 4,578 women ages 40-65**

Benjamin Klein, Andrea Matthews, Ben Serbiak. Self Care, Johnson & Johnson Services Inc, New Brunswick, NJ

**Objective:** Studies suggest that there is a disconnect between symptoms associated with menopause and a woman's self-identification with menopause. By gaining comprehensive insight into the experiences and attitudes of women navigating the changes associated with menopause, this study aimed to better understand how women are currently identifying and managing their symptoms- all to elevate the care and experience for each woman on her individual menopausal journey. **Design:** An Attitudes and Usage study was conducted among women\* age 40-65 in the US, with 4,578 participants. This study consisted of an online survey completed over a 3-week period. The main sample included 4,046 women between the ages of 40-65, with additional representation from specific (historically under-represented) cohorts, including an additional 135 Black women and 122 Hispanic women. The study is one of the largest (likely the largest) quantitative study of women of perimenopausal/menopausal age conducted to date in the US. From a recruitment perspective, the study included women from all US regions, and had a representative split across income levels. The study included 4 modules, designed to learn about the unique experiences of each woman through both qualitative and quantitative feedback. Module 1 explored lifestyles and attitudes, with a variety of question formats. Example questions: - Numeric scale ranking (E.g., "How do you describe your energy level?") - Choice rank (E.g., Choose which best describes you: "I like to make my own health decisions" or "I strictly follow medical advice") - Open-ended (E.g., "What was the significant moment where you first began to think you were entering a different life phase?") Module 2 explored each woman's symptoms, as well as her perceived correlation between those symptoms and menopause. Example questions: - Which of the following symptoms are you experiencing, or taking steps to prevent? - In your opinion, is your [SYMPTOM] connected with menopause? Module 3 explored sources of trust. Example questions: - Where do you seek advice for [SYMPTOM], and what triggered you to seek advice for the first time? If you haven't sought advice, why not? Module 4 probed on each woman's understanding of HRT, and their openness to learning more. For those taking HRT today, satisfaction levels and feelings during the process were explored. \*We recognize that "women" is a gendered term and not all people with ovaries may identify with the gendered terms used here. **Results:** Our data suggests a disconnect between a woman's experience with menopause-related symptoms and her ability to identify them as such. Prior to age 50, the proportion of women experiencing symptoms that could be connected to perimenopause is significantly greater than the proportion who are aware they are in perimenopause. 45% of women report experiencing symptoms (avg. 8.4 symptoms experienced), regardless of if they believe to be in any stage of menopause, indicating that the perception of menopause onset is blurred. Notably, 1 in 5 respondents experiencing hot flashes and night sweats at 45 or 46 years old believe they are not yet in perimenopause. Further, most women reported reluctance to seek help, despite the impact on their quality of life. Using night sweats as an example, 39% of women either sought advice but didn't take action or meant to seek advice but didn't. Another 43% did not seek advice at all. Only 17% sought advice and addressed the symptom. The top 10 symptoms of concern are hot flashes, fatigue, night sweats, weight gain, brain fog, loss of libido, slower metabolism, memory issues, bloating, and joint pain. **Conclusion:** Through this data we can see patterns driven by mis-informed perceptions and a lack of information around symptoms that are connected to menopause onset. In many cases, women may be ignoring symptoms of perimenopause and not getting the help they need- falsely assuming that age is the scapegoat. This study revealed key opportunities: - Increasing education and support for women earlier in their journey to help close the gap in misinformation and provide women access to the help they need sooner - Improving awareness via patient/provider relationships and community to help normalize menopause experiences.

**Sources of Funding:** Kenvue, Part of the Johnson & Johnson Family of Companies

#### P-49.

##### **Botulinum Toxin (Botox®) for the Treatment of Vaginismus**

Sunbal Javaid, MD, Natalie Suozzi, BS, Michelle Nezoslosky, MPH, Michael Krychman, MD. HerMD, Cincinnati, OH

**Objective:** Vaginismus is a subset of the genito-pelvic pain/penetration disorder (GPPPD).<sup>1</sup> It is defined as the involuntary contraction of the muscles surrounding the vaginal opening.<sup>2</sup> With vaginismus, the vaginal muscles automatically tighten when something is inserted (e.g., tampons, digits, penis, dilator, or during a pelvic examination). Patients will also present with profound psychological impacts from a vaginismus diagnosis, with women often reporting shame, embarrassment, guilt, and self-deprecation. Their relationships are often considered in jeopardy, and many have seen multiple healthcare professionals seeking help with these troublesome symptoms. At least 80% of patients report one comorbid psychological disorder, which is routinely either anxiety or depressive disorder. Pacik et al. report an average duration of vaginismus of 7.8 years from time of discovery, with 70% of women noting severe vaginismus, and a mean number of 4 failed treatments in their cohort study.<sup>1</sup> While traditional treatments have included dilator therapy and counseling, many healthcare professionals have been remiss in identifying novel therapeutics that can add to the biopsychosocial treatment paradigm of this condition. Botulinum toxin, (a drug made from a toxin produced by the bacterium *Clostridium botulinum*) has been shown in select research to effectively reduce pain with intercourse and eliminate involuntary contractions of the muscles surrounding the vaginal opening in the vaginismus patient. Historically, success rates from vaginal botox have been reported at 63-75%, with Pacik reporting a return to intercourse in a large sample of 71% of patients. Unique clinical centers in the United States focused on

the specialty areas of menopause and sexual health offer these vaginal botox injections to treat the symptoms of vaginismus, with promising anecdotal results. 1. Pacik PT, Geletta S. Vaginismus Treatment: Clinical Trials Follow Up 241 Patients. In: Sexual Medicine. Vol 5. Elsevier B.V.; 2017:e114-e123. doi:10.1016/j.esxm.2017.02.002 2. Patient education: Vaginismus (The Basics). In: UpToDate. UpToDate. <https://www.uptodate.com/contents/vaginismus-the-basics> **Design:** A retrospective chart review was performed at two clinical centers to examine the safety and efficacy of vaginal botox injections for the treatment of vaginismus during the study period of December 15, 2018 through January 1, 2023. **Results:** During the study period, twenty-five (25) patients were seen at two clinical centers, with 95% of patients seen at one clinical facility and 5% seen at the other. Five patients were lost to follow up. The mean age of the individuals in the final analysis was 31.3 years (range 20-40). 90% of participants were single/other and 10% were married. The twenty analyzable patients received a total of 964 units of Botox® with a mean 48 units delivered per individual (range 36-50). Seventy percent (70%) of the individuals received 50 units of Botox®. All participants tolerated the procedure well without incidence or complaints. There were no adverse events reported. At the patients' subsequent follow-up interaction, 95% of those treated reported a positive outcome and improvement in their vaginismus symptomatology, and 88% (15/17) reported successful intercourse. **Conclusion:** Our unique clinical centers ascribe to the multimodal biopsychosocial treatment of female sexual complaints. While sexual health counseling, dilator use, and pelvic floor physical therapy remain the mainstay for vaginismus treatment, these treatment modalities are often time-consuming and have variable rates of success. Given our centers' proprietary algorithms of care and specialized medical training and clinical support, personalized treatment paradigms can effectively incorporate innovative therapeutic interventions that result in exceptional outcomes and improved symptom resolution across additional specialty centers. As demonstrated in this encouraging data, the adjunctive addition of vaginal botox to the treatment paradigm for vaginismus can be safe and effective, with encouraging results highlighting the need for additional data collection and analyses demonstrating the benefits of vaginal botox in this setting.

**Sources of Funding:** None

#### P-50.

##### **Utilizing Advanced, Innovative Technologies To Improve Symptoms Associated with Sexual Health and Menopause Conditions**

Sunbal Javaid, MD, Natalie Suozzi, BS, Michelle Nezoslosky, Michael Krychman, MD. HerMD, Cincinnati, OH

**Objective:** Clinical research has shown that systemic hormone therapy may alleviate symptoms of vaginal dryness or atrophy in approximately 75% of cases, while local therapy does so in approximately 80%-90% of cases. While hormone therapy remains one of the most effective treatment options for various gynecological and vaginal symptoms, the use of advanced technological interventions for the treatment of the genitourinary syndrome of menopause (GSM) and sexual health concerns has gained in popularity over the last decade, offering viable treatment alternatives to hormonal medications. One of the latest technological innovations in the women's health ecosystem is the EmpowerRF treatment platform, which utilizes various technological handpieces to treat a wide range of symptomatology. In the setting of vaginal and urinary symptoms, the FormaV and VTone handpieces are commonly used therapeutic interventions. The FormaV handpiece is designed to improve vaginal elasticity, pliability, and sensitivity. The VTone handpiece provides electrical muscle stimulation (EMS) to strengthen weak pelvic floor muscles, helping to alleviate symptoms of incontinence. Anecdotal reports of treatment with these interventions demonstrate improvements in GSM and urinary symptoms such as vaginal dryness, incontinence, painful intercourse, and vaginal blood flow. **Design:** A retrospective chart review examining the safety and efficacy of the FormaV and VTone handpieces in the treatment of GSM and urinary symptoms was conducted at two clinical centers focused on the specialties of sexual health and menopause between January 1, 2021 through March 1, 2023. **Results:** Across two clinical centers, forty-seven (47) women received treatment with the FormaV or VTone handpieces. A total of 148 treatments were delivered, with a mean of 3.1 treatments administered per individual. A range of 1-7 treatments were delivered, with 74.5% of treatments administered at one clinical facility and 25.5% of treatments administered at the other. The mean age of participants was 53.1 years (range 25-73) and 45% of those individuals were married. 51% of participants received 3 treatments, 25% received 4 or more treatments, and 19% received only 2 treatments. The most common diagnoses were GSM, stress urinary incontinence (SUI), and dyspareunia. **GSM-Diagnosed Group** In a subanalysis of the group diagnosed with GSM, participants received a total of 70 treatment procedures (mean 3.7 procedures; range 1-7) across two clinical facilities. The mean age of participants was 57 years (range 49-73). 58% of participants were married. The FormaV handpiece was utilized most frequently (79%), followed by the VTone handpiece (56%), and the Morpheus8 and Morpheus 8V handpieces (32%). 95% of patients reported subjective improvement in their overall GSM symptomatology. No serious adverse events were reported at the time of procedure nor at follow-up surveillance visits. **Stress Urinary Incontinence-Diagnosed Group** In a subanalysis of the group diagnosed with stress urinary incontinence (SUI), 20 participants received a total of 59 procedures with a mean of 2.96 procedures (range 1-7) for the treatment of SUI symptoms across two clinical centers. The mean age of participants was 52.7 years (range 40-63). 45% of participants were married. The FormaV handpiece was utilized most frequently (95%), followed by the VTone handpiece (65%), and the Morpheus8 and Morpheus 8V handpieces (5%). 90% of patients reported improvement in their symptoms. **Conclusion:** The EmpowerRF's FormaV and VTone handpieces are innovative and advanced technological procedures which have demonstrated efficacy and safety in treating various gynecological conditions. Given specific proprietary algorithms

of care, specialized medical education, training, and clinical support, the specialized healthcare professionals at these unique centers are able to develop unique, personalized treatment paradigms that incorporate advanced and innovative technological interventions resulting in positive outcomes and improved symptom resolution. While these data are encouraging and demonstrate the safety and efficacy of these innovative interventions, there is a need for larger, randomized, sham-controlled clinical trials to further elucidate the benefits of the EmpowerRF platform and associated handpieces in these settings.

**Sources of Funding:** None

### P-51.

**Drospirenone 4mg use in 44 premenopausal women ages 40 – 51 and its influence on bleeding patterns: Results from a phase III clinical trial**  
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**Objective:** Contraception is an essential aspect of caring for peri-menopausal women not desiring pregnancy. We performed a sub-analysis of 44 participants  $\geq 40$  years enrolled in a phase III clinical trial to evaluate the efficacy, safety, and bleeding patterns while using drospirenone 4mg as an oral contraceptive. **Design:** To be eligible for enrollment, individuals were required to have regular menstrual cycles in the past six months (unless pregnant, breastfeeding, or using hormonal contraception). Participant demographics (including age, substance use, and risk factors for thromboembolism) were collected during study enrollment. A daily e-diary recorded bleeding, medication use, and sexual activity. Adverse event monitoring was conducted via self-report at all study visits. Data were analyzed using SAS and Excel. **Results:** Of the 44 premenopausal women ages  $\geq 40$ , 13 participants (30%) had a BMI  $\geq 30$  kg/m<sup>2</sup>. No participants reported a family history of VTE or a medical disorder pre-disposing them to VTE. All participants were considered to have at least one risk factor of VTE due to age. Six participants (13.6%) were current nicotine users, 8 participants (18.1%) were former nicotine users, and 30 (68.2%) denied previous nicotine use. Moderate alcohol use was reported by 25 participants (56.8%), while the remaining 19 participants (43.2%) abstained from alcohol use. Five participants discontinued the clinical trial prematurely due to adverse events: one for a macular/papular rash; two participants discontinued the trial due to breakthrough bleeding; one participant discontinued due to mood swings and breakthrough bleeding; and one participant discontinued due to abdominal pain. There was a general trend towards less bleeding and spotting days with continued use. Reported bleeding days, spotting days, and total bleeding and spotting days are presented in Table 1. Contraceptive efficacy was not evaluated in this population. However, no pregnancies occurred in this sub-population. The FDA assigned Pearl Index in participants  $\leq 35$  years old is 4.0. In this trial, no cases of hyperkalemia occurred in participants  $\geq 40$  years old; two participants  $< 40$  years old discontinued drospirenone 4mg due to persistent hyperkalemia. There were no thromboembolic events or cardiovascular events throughout the clinical development program. **Conclusion:** Most participants ages 40 – 51 had a bleeding change while enrolled in this clinical trial. Further research is needed to determine the long-term safety profile, tolerability profile, and bleeding changes during 4mg drospirenone use in this sub-population.

**Sources of Funding:** Exeltis USA, Inc Laboratorios León Farma S. A.

Table 1. Bleeding and spotting days with Drospirenone 4mg use in premenopausal women aged  $\geq 40$  years (N=44)

		Bleeding Days	Spotting Days	Bleeding or Spotting Days
Cycle 1 (n=40)	Mean	3.9	2.6	6.5
	Median	3	1	6
	SD	4.3	3	5.8
Cycle 6 (n=33)	Mean	1.6	1.7	3.3
	Median	0	0	1
	SD	3.4	2.8	8.2
Cycle 13 (n=28)	Mean	0.6	0.3	1
	Median	0	0	0
	SD	1.3	0.8	2.1

### P-52.

**Design and verification of mobile application ‘Re-bone’ for the treatment of sarcopenia in perimenopausal women.**

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**Objective:** To design and implement ‘Re-bone’, a mobile application for middle-aged women, and confirm its effectiveness and feasibility of digital intervention targeting perimenopausal women for the treatment of sarcopenia. **Design:** 51 women who are more than 45 years old who shared similar basic characteristics (BMI, waist circumference, skeletal muscle mass etc.) were included in this study. Basic physical parameters such as height, weight, waist circumference, skeletal muscle mass, fat content was collected. Also, parameters that represent muscle strength (hand grip strength) and physical performance (5-time sit-to-stand) were collected. 25 women were allocated to 16-weeks course of complex exercise program consisting of aerobic exercise and resistance exercise provided for three times a week through the implemented mobile application, the other 26 women were instructed to exercise for three times a week without use of the mobile application. Same measurements were done after the intervention. A paired

t-test was performed after the normality test for the difference between the pre- and post-scores for each group and independent t-test was done for comparison of the parameters for two groups. **Results:** There was no significant difference in all parameters before intervention. Analysis for the application-user group shown statistically significant difference in sarcopenia-related variables before and 16-weeks after application use (grip strength  $p=0.027$ , SARC-F score  $p=0.002$ , sit-to-stand time  $p=0.029$ ). On analysis with non-‘Rebone’ users, significant difference was noted only in the subjective SARC-F score ( $p=0.038$ ), whereas objective parameters did not have significant difference (grip strength  $p=0.150$ , sit-to-stand  $p=0.071$ ). **Conclusion:** For all collected sarcopenia-related parameters, a statistically significant difference was found in application-implemented group before and after the intervention (grip strength  $p=0.027$ , SARC-F score  $p=0.002$ , sit-to-stand time  $p=0.029$ ). This mobile-based intervention is an effective modality for life-style modification and treatment for sarcopenia for perimenopausal women.

**Sources of Funding:** None

### P-53.

**Effect of black cohosh with St. John’s wort (Feramin-Q®) on breast density in Korean postmenopausal women**

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**Objective:** Black cohosh with St. John’s wort (Feramin-Q®) is one of the most widely used alternative treatment regimens for postmenopausal women who wish to avoid conventional E or E+P hormone therapy. It is widely known that dense breast is one of risk factors of breast cancer, while the effect of combined preparation of Black cohosh and St. John’s wort, Feramin-Q®, on breast is unknown. The aim of this study is to evaluate the effect of black cohosh and St. John’s wort combination treatment on breast density in postmenopausal women with climacteric symptoms. **Design:** Medical records of women who were treated with Feramin-Q® for menopausal symptoms at Seoul National University Hospital was retrospectively reviewed from January, 2012 to December, 2022. An automated volumetric breast density measurement techniques was used to calculate the breast density. Patients who underwent mammography (MMG) twice, before and after Feramin-Q® treatment, were included. Patients who had a history of breast cancer or received other hormone medications concurrently were excluded. Pearson correlation analysis was performed to analyze the correlation between duration of black cohosh and St. John’s wort combination treatment and the change of breast density. **Results:** A total of 70 patients were included. The mean duration of Feramin-Q® was  $184.25 \pm 163.58$  days, and the mean age at initiation of Feramin-Q® was  $56.3 \pm 6.00$  years. Breast density of 3 patients (4.29%) increased, and that of 17 patients (24.29%) decreased, while that of 50 patients (71.42%) remained unchanged. Two women (0.02%) experienced progression of breast lesion to BIRADS category 3 or 4. Baseline right breast density (%) was  $12.43 \pm 5.73$ , and follow up density (%) was  $10.87 \pm 5.83$ . Baseline left breast density (%) was  $12.43 \pm 6.35$ , and follow up density (%) was  $10.91 \pm 5.97$ . The change of breast density was not significantly correlated with duration of Feramin-Q® treatment (right breast;  $r = -0.008$ ,  $p = 0.526$ , left breast;  $r = -0.020$ ,  $p = 0.567$ ). **Conclusion:** Feramin-Q® seems to have no significant effect on breast density, but larger prospective study is necessary for further analysis.

**Sources of Funding:** None

### P-54.

**Association Between Menopausal Status, Menopausal Hormone Therapy, and Severe Outcomes in COVID-19**

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**Objective:** Males and females are equally susceptible to infection with COVID-19, but it has been observed that males experience higher rates of severe disease, hospitalization, and death. Several hypotheses have been suggested to explain this observation, including the immunomodulatory effects of estrogen on inflammatory cytokines which may limit the cytokine storm often responsible for respiratory failure in COVID-19. There are some data to suggest a protective effect of oral contraceptive pills in premenopausal women but reported effects of menopausal hormone therapy (MHT) in middle-aged women have been mixed. The purpose of this study is to examine the association between MHT and severe outcomes due to COVID-19 in a large epidemiological database. **Design:** A retrospective cohort study was conducted using the Rochester Epidemiological Project (REP), a comprehensive medical record linkage system for patients in 27 counties located in southern Minnesota and western Wisconsin. Data were abstracted for women aged 40-65 with documented COVID-19 infection by positive polymerase chain reaction (PCR) between March 12, 2020 – September 29, 2020. Outcomes were stratified by (1) menopausal status, (2) hormone use, and (3) a combination of menopausal status and hormone use (pre-menopausal, peri- or postmenopausal with no hormone use, and peri- and postmenopausal with systemic hormone use). Separate logistic regression models were fit with an outcome of adverse events (defined as emergency room [ER] visits, hospitalization, and/or death) for menopausal status, hormone use, and combined menopausal status/hormone use as defined above. Additional models adjusted for age, Charlson Comorbidity Index (CCI; composite score including age and 16 possible comorbidities), race (binary variable; white or non-white), and body mass index (BMI) status (underweight or normal, overweight, obese). **Results:** 1393 female patients were identified with documented COVID-19 infection. These patients were 71% white, 52% obese, and the large majority (90.4%) had symptomatic COVID-19 infection.

Median age was 51 with an interquartile range of 45 to 58. About half lived in a rural community and half in an urban community. Most (86.1%) had a Charlson Comorbidity Index of 0-2; 7.7% had a CCI of 3-4 and 6.2% had a CCI of 5 or greater. There were 184 total adverse outcomes (ER visits, hospitalizations, and/or deaths). These outcomes increased in frequency with increasing age, CCI, and BMI status. Of those with both menopausal and hormonal data available (n = 1156), 36.5% were premenopausal, 52.5% were peri- or postmenopausal with no hormone use, and 11.0% were peri- or postmenopausal with systemic hormone therapy. There was a 1.6% rate of intensive care unit (ICU) admission and a 0.8% rate of intubation. There were 7 total deaths; 2 were related to COVID-19 infection. Compared to peri- or postmenopausal women with no hormone use, peri- or postmenopausal women on MHT had a lower hospitalization/death rate (7.1% vs 10.2%) and ER visit/hospitalization/death rate (15.0% vs 15.7%). The unadjusted odds ratio (OR) for ER visit/hospitalization/death was 0.95 (95% confidence interval [CI] 0.56, 1.62) for peri- or postmenopausal women with MHT compared to peri- or postmenopausal women with no hormone use. After adjusting for age, CCI, race, and BMI status, OR was 1.07 (95% CI 0.62, 1.84) for peri- or postmenopausal women with MHT compared to peri- or postmenopausal women with no hormone use. **Conclusion:** After adjusting for age, Charlson Comorbidity Index, race, and obesity, there was no evidence that hormone therapy had a protective effect against severe outcomes related to COVID-19 in peri- and postmenopausal women. Available studies on this topic are difficult to compare due to much variation in length of observation, adjustment for confounding variables, and mixing of inpatients and outpatients. Additional studies are needed to examine the association between MHT and mortality due to COVID-19.

**Sources of Funding:** None

## P-55.

**Healthcare Usage Patterns Across the Menopausal Transition Spectrum**  
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**Objective:** Gennev.com is an online platform that provides telemedicine services for women in menopause. As part of our work in menopausal medicine we enlisted a large actuarial and data company, Milliman MedInsight, to gather de-identified billing and claims data for major commercial insurers in the United States. We reviewed usage of preventative care, cardiovascular care, overall per-member-per month (PMPM) cost, as well as pharmacy cost over the menopausal transition in women in general and in several subsets of treatment. **Design:** BRANY IRB determined this not to be human subjects research and therefore not needing a review. Validated data was received from Milliman MedInsight in pivot tables representing annual usage of services per 1000 clients and PMPM utilization numbers for the years 2020 and 2021. This represents data from private insurers over millions of women, separated into categories based on age, medical utilization patterns, diagnoses, and by treatments used. Across all age ranges, patients in treatment groups were actively using treatment at the point in time; data is not available on length of use. **Results:** Women in menopause but not using any menopause related treatments had a high overall usage of general preventative services [figure 1], high rate of mammograms [figure 2], and the lowest utilization of cardiovascular (CV) outpatient and professional services [figure 3,4]. They used the least amount of money PMPM and their pharmacy costs were the lowest [figure 5,6]. Women in menopause and using hormone replacement therapy (HRT) utilized the highest amount of preventative general services and mammography across all age groups [figure 1]. They initially had higher CV outpatient and professional usage, but this declined with age and by age 60-64 they were low users of these services [figure 3,4]. They initially had higher PMPM and pharmacy costs, but the curve changed over time with lower benefits in these areas being paid for women receiving HRT [figures 5,6]. Women in menopause using other therapies (venlafaxine, gabapentin, and/or clonidine) were high utilizers of care, and had the highest care cost [figures 3-6]. (Figures available, unable to upload due to system error) **Conclusion:** Actuarial data is limited in the conclusions that can be made given the lack of covariates. The strength of this data is the large data set size and the ability to look at rare outcomes and gauge impact of different variables. In this data set we see that the diagnosis of menopause alone with no intervention signals someone who is getting preventative services, but generally is not needing a lot of additional care. While HRT use initially drove up cost, in later years HRT users are using less health care services, with the exception of preventative care.

**Sources of Funding:** None

## P-56.

**A Systematic Review Of The Effects Of Androgens Therapy In Women With Premature Ovarian Insufficiency**

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**Objective:** Objective: To critically review and assess the literature on the use of various androgen preparations in cases diagnosed with premature ovarian insufficiency (POI). **Design:** Database search included randomized controlled trials, prospective comparative, observational, non-randomized studies, and case series of 10 or more subjects with no time limit restrictions. The word search included: spontaneous/primary premature ovarian failure/ insufficiency. Eligible trials included females below the age of 40, with amenorrhea >4 months, FSH >40 IU/L on two occasions separated by 6 weeks. Participants utilized androgens alone, with or in comparison with placebo or other hormonal preparations. **Results:** 539 abstracts were double screened,

identifying 6 eligible studies; 3 randomized prospective double blinded studies, one randomized placebo controlled, one prospective observational and one retrospective study. Discrepancies were arbitrated by a third reviewer. Androgen preparations used included DHEA, danazol and testosterone patch. Trials studied the impact of androgen supplementation on menstrual pattern, ovarian reserve markers, fertility outcomes, mood, and self-esteem as well as bone mineral density. **Conclusion:** Based on the limited evidence presented by the included studies, there was no significant effect of androgen supplementation on mood, self-esteem, or bone mineral density. Although one study demonstrated an increase in ovarian volume and antral follicular count, there was no significant change in ovarian reserve, ovarian function, fertility outcome or menstrual pattern. Further long term trials are recommended.

**Sources of Funding:** None

**Summary of the Studies included in the systematic review**

Author/Year	Country	Age (Median)	Number of participants	Type of the study	Androgen preparation used/dose	Duration of androgen use	Inclusion criteria	Conclusion	Side effects
Wong QHY/2018	Hong Kong, China	36	31	Prospective observational	DHEA 25 mg three times daily	12 months	Women < 40 years, who were diagnosed to have POI (amenorrhea or oligomenorrhea together with serum FSH levels > 40 IU/L on two separate occasions 6 weeks apart), Normal karyotype (46XX)	No significant improvement in ovarian function by 12-month DHEA supplementation in women with POI.	5 cases (16.1%) acne 2 cases of transient polycythemia
Anasti JN/1994	Maryland USA	32	46	Prospective, double-blinded, crossover	Danazol 400 mg twice daily	4 months	Patients were less than 40 years of age with higher or equal 4 months of amenorrhea and serum FSH values more than 40 mIU/mL on at least 2 occasions, at least 1 month apart.	No statistically significant benefit from the immunomodulatory and gonadotropin-suppressing effects of danazol in patients with karyotypically normal spontaneous POF.	3 cases of rash 2 cases of mildly elevated liver enzymes
Guerreri GM/2014	North Carolina USA	Not mentioned in median (31.1-5.8)	123	Randomized, placebo-controlled, parallel-design	Testosterone transdermal patch 150 ug/day	6 years	POI diagnosed by a history of at least 4 months of non-iatrogenic oligomenorrhea occurring in women less than 40 years and at least 2 determinations of menopausal Serum (FSH) (more 40 mIU/mL), and a normal 46,XX peripheral karyotype.	A 150-ug testosterone patch achieves physiologic hormone levels in women with POI. However, no significant change in baseline reports of quality of life or self-esteem and had minimal effects on mood noted when added to standard E/P therapy	2 cases skin irritation
Yeung TW/2013	Hong Kong, China	Not mentioned in median (35.9-3.26)	21	Randomized, double-blinded, placebo controlled	DHEA 25 mg three times daily	One year	Females younger than 40 years with secondary amenorrhea. And serum FSH level greater than 30 IU/liter on two occasions of at least 6 wk apart. Normal karyotype of 46XX; and negative FMR1 gene mutation	Higher AFC and ovarian volume at wk 12 and 20, in the DHEA group.	Acne: 22% (DHEA group) vs 8.3% (placebo) Non-persistent mild elevation in liver enzymes: 22% (DHEA) vs 16.7% (placebo)
Dragojevic Dikic S/2020	Belgrade Serbia	37	90	Retrospective	DHEA 25 mg three times daily	8 years	Secondary amenorrhea in POI patients below the age of 40 who wished to restore fertility.	E/P therapy combined with DHEA and melatonin could optimize fertility and lead to successful pregnancy in POI patients	Not reported
Popat VB/2014	Maryland USA	31.3	145	Randomized, double-blind, single-center, placebo-controlled	Transdermal testosterone 150 ug patch/day	3 years	POI (at least 4 months of oligomenorrhea and two FSH levels in the menopausal range, confirmed on two separate occasions at least 1 month apart before age 40 y); absence of iatrogenic cause or known chromosomal abnormality; and age between 18 and 42 years.	The addition of transdermal T replacement to E/P therapy did not provide additional benefit.	Five cases of skin irritation, redness, rash, hirsutism, and oily skin

**AFC:** Antral follicular count; **DHEA:** Dehydroepiandrosterone; **POI:** premature ovarian insufficiency; **POF:** Premature ovarian failure; **E/P:** Estrogen/Progesterone; **FSH:** Follicle stimulating hormone.

**P-57.**

**Leading causes of death among women and girls aged 10–89 years in the United States: Focus on women aged 45 and older.**

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**Objective:** The objective of this study was to examine differences in the leading causes of death among women by age group and between women and men with the National Vital Statistics System (NVSS) data (2020-2022). **Design:** The Office on Women's Health and the Office of Science and Medicine in the Office of the Assistant Secretary of Health in the Department of Health and Human Services have reviewed the leading causes of death. The study uses death certificate data for 2001 through provisional 2022 from NVSS. The queries are grouped by the ten leading causes of death, separately for women and men and by age category, based on the underlying cause of death. Underlying causes of death were coded and grouped by leading causes by CDC's National Center for Health Statistics. Mortality rates were obtained from the publicly available CDC Wonder website. Death counts were available for 5-year age bands. **Results:** The leading causes of death differed for adult women and men between the ages of 10–89 in the United States from 2020–2022. The leading cause of death for women aged 45–79 was cancer. Men aged 45 years and older died predominantly from heart disease. Heart disease was the leading cause of death for women aged 80 and older. From 2020–2022, women 45–59 years of age were more than twice as likely to die from cancer than from heart disease, with breast cancer as the leading cause of cancer death. For women ages 60–79, the leading causes of cancer death were lung and trachea cancers. Heart disease is the predominant cause of death for women 80-89. Both heart disease and cancer mortality rates have been steadily declining in all age groups of women since 2000. Steeper declines for heart disease mortality versus cancer were observed through 2019, further widening the gap in death rates between cancer and heart disease for women aged 10–89 years. Although heart disease and cancer death rates have been declining over time, a sharp increase in these rates was observed at the start of the COVID-19 pandemic in early 2020. **Conclusion:** Women and men are dying from similar causes but at different rates. By itself, the narrative that heart disease is the leading cause of death in women is misleading. Overall, cancer is the leading cause of death, followed by heart disease for women aged 10-79 years. However, causes of death change as women age, cancer leading for women aged 40-79 years, and heart disease leading for women over 80 years of age. Public health efforts should consider factors such as sex and age cohorts when developing initiatives to address causes of death for their populations of interest to have the most impact.

**Sources of Funding:** None

**P-58.**

**Evaluation of the association between the deterioration of physical function with the history of hysterectomy with or without oophorectomy and according to menopausal status in Colombian older women**

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**Objective:** To estimate the association between the deterioration of physical function, a component of quality of life, with the history of total abdominal hysterectomy accompanied by conservation or bilateral ovarian extraction, considering the menopausal status at the time of surgery. **Design:** Cross-sectional study conducted in women who voluntarily signed informed consent, aged between 60-75 years and residing in municipalities in northeastern Colombia. The participants were visited in their homes by nurses or doctors, who invited them to fill out a form that questioned sociodemographic characteristics and applied the items of the SF-36 scale, in its Spanish version. SF-36 is a generic quality of life scale that assesses in a general and summarized way the well-being and the multidimensional state of health. It is composed of eight domains, including the one referring to physical function that questions the opinion on the ability to perform vigorous and moderate activities of daily living, the ability to lift shopping bags, the limitations to climb floors of buildings, the ability to bend, the willingness to walk a km, the comfort when kneeling, the ability to walk several blocks, the ability to bathe and dress, in the last four weeks. Impairment of physical function was considered, the physical function domain score below average in the study population. The Colombian population census was used to estimate the sample size. Unadjusted logistic regression was performed: physical function [dependent variable]. Four scenarios were established as independent variables. Initially, the history of abdominal hysterectomy with preservation of the ovaries and the history of abdominal hysterectomy with bilateral oophorectomy. For both situations, menopausal status at the time of surgery was considered: before menopause and after menopause. P<0.05 statistically significant. Study approved by the Ethics Committee of the University of Cartagena **Results:** Seven hundred women were evaluated. Age: 66.9±4.8y. Age of menopause: 48.1±4.1y. Years since menopause onset: 18.9±6.3y. With 6-10 years of posmenopause: 69 (9.9%). More than 11 years of posmenopause: 631 (90.1%). Hysterectomy without bilateral oophorectomy: 184 (26.2%). Hysterectomy without bilateral oophorectomy before menopause: 125 (17.8%). Hysterectomy without bilateral oophorectomy in posmenopause: 59 (8.4%). Bilateral oophorectomy at the time of hysterectomy: 45 (6.4%). Bilateral oophorectomy at the time of hysterectomy in premenopause (surgical menopause): 30 (4.2%). Bilateral oophorectomy at the time of hysterectomy in posmenopause: 15 (2.1%). Overweight women: 257 (36.7%) and obese: 166 (23.7%). They had abdominal obesity: 368 (52.5%)

and android obesity: 410 (58.5%). The following were associated with deterioration of physical function: the history of abdominal hysterectomy with bilateral oophorectomy in premenopause (surgical menopause) and the history of abdominal hysterectomy with ovarian conservation performed in premenopause: OR: 2.8 [CI95%: 1.33-6.27] and OR: 2.0 [CI95%: 1.4-3.0], respectively, p<0.05. Abdominal hysterectomy with preservation or removal of the ovaries and performed after menopause were not significantly associated with impairment of physical function, OR:1.1 [95% CI: 0.6-2.0] and OR:2.1 [95% CI: 0.7-5.9], respectively. **Conclusion:** In a group of Colombian adult women, it was found that a history of hysterectomy with oophorectomy and even ovarian-sparing hysterectomy, performed before menopause, were significantly associated with impaired physical function. When performed after menopause, neither was significantly associated with impaired physical function.

**Sources of Funding:** None

**P-59.**

**Maturation 2.0: Menopause Group Education**

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**Objective:** The purpose of this quality improvement project is to educate individuals about the physiology of menopause and evidence-based treatment options for burdensome symptoms. More specifically, our goals are to improve knowledge, symptom perceptions, and attitudes toward menopause. If these aims are successful, then the pilot *Maturation 2.0* program would transition into a regularly scheduled virtual class and an inclusive referral system to menopause care providers. **Design:** A virtual group education program titled *Maturation 2.0* was developed to educate individuals in the menopausal transition. Twenty-two participants ages 38 to 57 were recruited via email, social media, and clinic appointments. One women's health nurse practitioner and one licensed acupuncturist and nursing scientist conducted a virtual menopause group education session. The curriculum included menopause physiology, symptoms, treatment options, and controversies. Pre-surveys, post-surveys, and eight-week follow-up surveys were distributed to participants to assess changes in knowledge, symptoms, and attitudes toward menopause as well as participant satisfaction with the program. **Results:** Post-intervention, we found that participants were highly satisfied with the intervention and rated the course a mean score of 9.2 on a scale of 1 to 10 for their likelihood to recommend the course to a family member or friend. Participant knowledge was assessed via a five-question quiz, and scores increased after the course, demonstrating an improvement in knowledge, which persisted eight weeks later. Menopause-Specific Quality of Life scores decreased, but this did not reach statistical significance (p-value=0.914). Attitudes, which were assessed via Attitude Toward Menopause sub-scales, also improved following the intervention. **Conclusion:** Our menopause group education QI project demonstrated that group education can improve knowledge, symptoms, and attitudes toward menopause among mid-life women. The course will change current practice and continue to be offered on a regular basis via live virtual format. By providing group education, our health system will more efficiently educate women in a group setting rather than provide baseline knowledge during individual clinic visits, which may not yield adequate time in many settings.

**Sources of Funding:** University of Utah Educational Resource Development Council (ERDC)

**P-60.**

**Specific epidemio-clinical characteristics of the menopause in Tunisian women**

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**Objective:** The aim of this study is to clarify the epidemiological features of the menopause in Tunisian women and to identify the clinical and biological aspects in women with a confirmed menopause. **Design:** This is a prospective study conducted in department D of the Tunis maternity and neonatology centre over a 6-month period from January 2023 to June 2023. We included women with clinically confirmed menopause who agreed to take part in the study. We carried out a meticulous interview by the same investigator and we completed by a biological assessment (lipid assessment, fasting glycaemia, hormonal assessment) and a bone densitometry. **Results:** our study involved

85 patients. the average age of the women was 56.7 with extremes ranging from 42 to 72 years. the average age at menopause was 53.2 years with extremes ranging from 41 to 62 years. all the women had amenorrhoea of at least one year. 78.3% of women suffered from hot flushes. 28.6% of women were very bothered by hot flushes. The average number of hot flushes was 12.3, with extremes ranging from 3 to 21 flushes. 62% of women reported the occurrence at least once of an attack of tachycardia with or without lipothaemia. 52% of women with hot flushes confirm that symptomatic treatment does not improve their symptoms. 23% of women feel that these attacks are a handicap and prevent them from carrying out their work. The rate of days off work due to hot flushes is estimated at 0.9%. Lipid status was disrupted in 16.3% of cases. The most common anomaly is increased triglyceride levels. the fasting blood glucose test made it possible to diagnose diabetes in 0.8% of cases and to discover a prediabetic condition in 0.3%. The interrogation found no cases of fatigue fracture or spinal fracture. Osteodensitometry showed a decrease in fracture threshold in 6.8% of cases. Bone density was reduced 16.1% of the time, the diagnosis of osteoporosis was made in 3.9% of patients. **Conclusion:** Menopause is a physiological state of every woman's life. That is a public health concern in our country. Complications due to this physiological condition are common but underestimated. Large-scale studies are needed to better evaluate the situation and to be able to map out our national strategy to combat the complications of menopause.

**Sources of Funding:** none

## P-61.

### Similarities and Differences between US and International Responses to Menopause Needs Assessment

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**Objective:** The purpose of this study is to assess menopause education, including existing and desired resources, with a comparison of survey responses from national and global educators. **Design:** An IRB-approved web-based Qualtrics survey was designed with 15 total questions: 5 regarding program demographics, 6 assessing current menopause resources and training, and 4 assessing menopause curricular needs. The survey was electronically distributed to US ObGyn residency program directors as well as global educators at the 2022 International Menopause Society (IMS) conference and through regional listservs of the Council of Affiliated Menopause Societies (CAMS). 99 US program directors completed the survey and 12 international responses were collected: 3 from Australia, 2 each from Afghanistan and the UK, and 1 each from Albania, Andorra, Canada, Jordan, and Hungary. Recognizing significant variations in patient populations, a subgroup of the US responses was also analyzed, looking specifically at the 39 responses that indicated that half or more of patients served were peri- or post-menopausal. Descriptive statistics were performed along with Fisher's Exact Test for statistical significance of observed differences. **Results:** 39% of US based respondents indicated that half or more of patient served were peri- or post-menopausal, compared to 100% of Global respondents. Global respondents were significantly more likely to endorse having a dedicated menopause curriculum, with 75% (9 of 12) doing so compared to 31% (31 of 99) of US respondents,  $p = 0.008$ , and 31% (12 of 39) of US subgroup respondents,  $p = 0.0163$ . 85% of US respondents, including the subgroup, and 90% of Global respondents identified a need for more menopause education, and over 90% of all groups would use standardized training materials for a menopause curriculum, with 89-90% of all groups indicating that they would be likely or very likely to use self-paced menopause modules in particular. A significant discrepancy was noted in the percent of respondents who would use mock oral exam questions on menopause. Only 44% (4 of 9) in the Global group indicated they would be likely or very likely to use this resource, significantly less than the 77% (75 of 97) of US based respondents ( $p = 0.045$ ) and 92% (35 of 38) of US subgroup respondents ( $p = 0.004$ ) who indicated the same. When evaluating satisfaction with their current menopause training and perceived effectiveness at preparing trainees to care for menopausal patients after training, US based respondents averaged 38% on a 100% scale and Global respondents averaged a 41%, indicating sizable perceived room for improvement among all study groups. **Conclusion:** Large majorities of both US and Global respondents to the Menopause Needs Assessment identified a need for more menopause education and a desire for standardized materials, especially self-paced menopause modules. US based respondents were more likely to desire mock oral exam question resources compared to Global respondents, reflecting the importance of customizing resources to individual countries. Finally, despite an identified need for improved menopause education among all groups, Global respondents were more likely to endorse an existing menopause curriculum, reflecting the value of organizations such as the North American Menopause Society (NAMS) in promoting menopause education in the US.

**Sources of Funding:** None

## P-62.

### Characterizing the Spectrum of Distress Symptoms in Midlife Women: A Preliminary Study

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**Objective:** Perimenopause is a time of increased risk for depression, which is a common source of functional impairment. Despite the prevalence of this condition, efforts to describe the clinical symptomatology in this population have focused primarily on depressed mood and insomnia. Identifying the range of symptoms may improve screening and inform novel and efficacious treatment approaches. We therefore aimed to preliminarily

characterize the spectrum of affective symptoms associated with perimenopausal-onset major depressive disorder (PO-MDD), as well as to identify clinical correlates (e.g., temperament) that may predispose women to experience distress during perimenopause.

**Design:** Participants were women in the late-perimenopause (by STRAW -1 criteria) ages 44-55 (N=90) enrolled in studies examining the effects of estrogen on brain activation. Presented here are baseline data collected prior to estrogen treatment for the purpose of clinical characterization of the women with PO-MDD (n=51) and a comparison group of perimenopausal women without MDD ("controls"; n=39). The Structured Clinical Interview for DSM-IV (SCID) was used to confirm presence or absence of PO-MDD diagnosis. Clinical symptomatology was characterized using the Inventory of Depression and Anxiety Scale (IDAS), a 64-item scale containing a depression composite scale and 11 symptom scales, including dysphoria, lassitude, insomnia, suicidality, appetite gain/loss, ill temper, anhedonia, social anxiety, panic, and traumatic intrusions. The Schedule for Non-Adaptive and Adaptive Personality (SNAP) was used to examine temperament, with extreme scores (high or low) representing maladaptive traits of either negative temperament (NT, e.g., mistrust, aggression, manipulativity) or positive temperament (PT, e.g., exhibitionism, entitlement, impulsivity). Student's T tests were used to describe between group differences and controlled for multiple comparisons. Pearson correlations were used to describe the association between IDAS depression composite scores and anxiety symptoms scales. **Results:** PO-MDD had higher scores than euthymic controls not only on the depression-related IDAS scales (dysphoria, insomnia, lassitude, anhedonia, and appetite gain), but across anxiety domains as well (ill-temper, panic, and social anxiety), all  $p$ 's < .001. Correlations between the depression composite score and the anxiety scales ranged from  $r=0.20$  (traumatic intrusions) to .77 (ill-temper). Although neither group endorsed temperament scores that fell outside of the SNAP clinical cutoffs, PO-MDD had significantly higher negative temperament and lower positive temperament compared with controls. Elevated negative temperament in PO-MDD was driven by elevations in mistrust and eccentric perceptions compared with controls ( $p$ 's < .001). **Conclusion:** Findings in this descriptive secondary data analysis show a broad range of perimenopause-onset distress symptoms beyond depression, including anxiety (i.e., social anxiety and panic) and psychosis-related maladaptive traits (i.e., mistrust and eccentric perceptions) not traditionally thought to be associated with the menopause transition. Moreover, low to moderate correlations between depression composite scores and anxiety scale scores suggest that these symptoms can be intertwined and highlights the importance of screening for anxiety related distress, in addition to depression, in this population.

**Sources of Funding:** K23 MH105569 (CS) Foundation of Hope (CS)

## P-63.

### Effect of fezolinetant on moderate-to-severe vasomotor symptoms according to time of day: pooled data from two randomized phase 3 studies

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**Objective:** Fezolinetant is a nonhormonal agent in development for the treatment of vasomotor symptoms (VMS; hot flashes and night sweats) due to menopause. The efficacy of fezolinetant vs placebo in reducing the frequency and severity of VMS and improving sleep was demonstrated in two phase 3 studies (SKYLIGHT 1 and 2; NCT04003155 and NCT04003142). These and the 52-week SKYLIGHT 4 safety study (NCT04003389) confirmed the safety profile of fezolinetant. Night-time moderate-to-severe VMS can impact quality of life through a significant impact on sleep. To further explore the effect of fezolinetant on night-time VMS episodes post hoc analyses using pooled data from SKYLIGHT 1 and 2 were undertaken. **Design:** SKYLIGHT 1 and 2 were double-blind, placebo-controlled studies with the same design. Women aged  $\geq 40$ – $< 65$  years with moderate-to-severe VMS (minimum average  $\geq 7$  hot flashes/day) were randomized to once-daily placebo, fezolinetant 30 mg or fezolinetant 45 mg (1:1:1) for 12 weeks. Post hoc analyses assessed the frequency and severity (range 1–3 with 3 being the worst) of VMS between 06:00 and 23:59 (daytime; 18 h), and between 00:00 and 05:59 (night-time period; 6h). **Results:** The pooled dataset comprised 1022 participants who took  $\geq 1$  dose of study medication: placebo, n=342; fezolinetant 30 mg, n=339; fezolinetant 45 mg, n=341. Reductions in the frequency and severity of daytime and night-time VMS were observed with fezolinetant compared with placebo. These improvements were seen each week from weeks 1 to 12 apart from one (night-time frequency at week 1 for fezolinetant 45 mg). At week 12, the least squares mean differences vs placebo were numerically greater with fezolinetant 45 mg than with fezolinetant 30 mg (Table). Data at baseline and week 12 are shown in the Table. Improvement for fezolinetant vs placebo is indicated by a least squares mean difference of  $< 0$ . Further post hoc analyses assessing the relationship between reduction in night-time VMS frequency and severity and improvement in outcomes such as sleep are in progress. **Conclusion:** This pooled analysis demonstrates that fezolinetant 30 mg and 45 mg reduced both the frequency and severity of moderate-to-severe daytime and night-time VMS compared with placebo. SKYLIGHT 1 and SKYLIGHT 2 found that fezolinetant reduced the frequency and severity of VMS compared with placebo in the overall populations, and this post hoc analysis shows consistency of effect at night as well as during the day.

**Sources of Funding:** Astellas Pharma Inc. Medical writing support was provided by Becky Ayles of Envision Pharma Inc. and funded by Astellas Pharma Inc.

Table

	Statistics	Placebo (n=342)	Fezolinetant 30 mg (n=339)	Fezolinetant 45 mg (n=341)
Frequency of moderate-to-severe VMS at week 12 based on pooled data				
Day (18 h)	Mean (SD) at baseline	9.12 (3.96)	9.14 (4.19)	9.17 (5.15)
	Mean (SD) at week 12	5.33 (5.10) n=281	3.53 (3.92) n=268	3.20 (3.77) n=294
	LS mean difference vs placebo (95% CI)	–	–1.89 (–2.46, –1.31)	–2.11 (–2.67, –1.54)
Night (6 h)	Mean (SD) at baseline	1.95 (1.33)	1.81 (1.27)	1.96 (1.77)
	Mean (SD) at week 12	1.26 (1.54) n=281	0.89 (1.07) n=268	0.91 (1.25) n=294
	LS mean difference vs placebo (95% CI)	–	–0.31 (–0.47, –0.14)	–0.36 (–0.52, –0.19)
Severity of moderate-to-severe VMS at week 12 based on pooled data				
Day (18 h)	Mean (SD) at baseline	2.39 (0.35)	2.38 (0.34)	2.38 (0.35)
	Mean (SD) at week 12	1.87 (0.66) n=281	1.63 (0.72) n=268	1.58 (0.78) n=294
	LS mean difference vs placebo (95% CI)	–	–0.26 (–0.37, –0.14)	–0.29 (–0.40, –0.18)
Night (6 h)	Mean (SD) at baseline	1.99 (0.80)	1.94 (0.84)	1.94 (0.76)
	Mean (SD) at week 12	1.37 (0.94) n=281	1.10 (0.98) n=268	1.04 (0.91) n=294
	LS mean difference vs placebo (95% CI)	–	–0.24 (–0.37, –0.11)	–0.31 (–0.43, –0.18)

LS=least squares; VMS=vasomotor symptoms

#### P-64.

### Needs Assessment: Menopause Education at Two Obstetrics and Gynecology Residency Programs in Southern Louisiana

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**Objective:** Based on the 2020 United States Census, an estimated 860,000 postmenopausal people live in Louisiana.<sup>1</sup> This large patient population dictates that resident physicians, particularly obstetrics and gynecology residents, need comprehensive education on menopause and the associated health concerns that present during this phase of life. Needs assessment surveys pertaining to menopause education have been conducted in the past and include data from residency programs of several states, but not Louisiana.<sup>2</sup> The purpose of this study is to assess self-identified knowledge of menopause medicine and perceptions on the current curriculum pertaining to menopause amongst residents, fellows, and faculty members at two obstetrics and gynecology residency programs in Southern Louisiana. **Design:** A needs assessment survey was designed and administered through a web-based data collection service to assess resident (n=39), fellow (n=2), and attending physician (n=30) self-reported knowledge on menopause management at Louisiana State University Health Sciences Center Obstetrics and Gynecology departments in New Orleans and Baton Rouge, Louisiana. The primary outcomes for both surveys were self-assessed knowledge and comfort with menopause, related health concerns, and management options. Secondary outcomes included resident preferred learning modalities and attending physician exposure to menopause education during residency. Since all responses were categorical, variables were summarized by reporting counts and percentages. **Results:** Of 39 residents who were surveyed, 17 residents (43.6%) responded. Four PGY-1, six PGY-2, four PGY-3, and three PGY-4 residents participated in the survey. Amongst residents from all postgraduate years, 1 (5.9%) felt very well prepared, 5 (29.4%) felt adequately prepared, 9 (52.9%) felt somewhat prepared, and 2 (11.8%) felt not at all prepared to manage patients experiencing menopause at this time. Of note, 64.7% of resident respondents ranked menopause as being the number one or number two topic area in which they had the most experience. Of the 32 attending/fellow physicians who were surveyed, 11 (34.3%) responded. The results showed that the majority of faculty members who responded felt “comfortable” or “very comfortable” managing menopause and its symptoms. Faculty also overall felt “comfortable” (45.5%) or “very comfortable” (54.5%) guiding residents through the management of these patients. **Conclusion:** As a core learning objective for obstetrics and gynecology residency programs, education on menopause remains a priority for residents. Most faculty respondents feel comfortable managing patients with menopause and teaching about this management to residents. However, it is difficult to say if this is a result of residency training or experience working in the field. Meanwhile, many residents feel “adequately prepared” or “somewhat prepared” to work with this population. As researchers continue to explore ways to improve menopause education for residents, it would be beneficial to assess resident knowledge on menopause at the beginning of residency. A subsequent survey to assess knowledge at the end of four years of training would help to determine effective learning modalities and strategies. References: 1. US Census Bureau. Louisiana Population Pyramid: Population by Age and Sex in Louisiana. 2020. <https://data.census.gov/viz/widget?g=040XX00US22&infoSection=Age+and+Sex>. Accessed 28 April 2023. 2. Christianson MS, Ducie JA, Altman K, Khafagy AM, Shen W. Menopause education: needs assessment of American obstetrics and gynecology residents. *Menopause*. 2013 Nov; 20(11):1120-1125. doi: 10.1097/GME.0b013e31828ced7f. PMID: 2362655.

**Sources of Funding:** None

#### P-65.

### Dyspareunia as a Symptom of Urinary Tract Infection

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**Objective:** UTI's has been undiagnosed across the spectrum, as clinician are increasingly relying on urinalysis rather than the symptomatology. The presence of dyspareunia is rarely inquired during evaluation of the patient and may not be found along with the classical symptoms of UTI. Our First Objective aimed at informing clinicians that dyspareunia is a common symptom of urinary tract infections in almost 80 % of the cases especially in pre-menopausal women, being found more frequently than pollakiuria, urodynea, dysuria and urgency. By increasing awareness of the association between UTI's and dyspareunia, clinician will include it in the assessment of patient, rather than relying solely on a urinalysis. Our second Objective aimed at educating the patient population about dyspareunia as an abnormal symptom, but a medical condition that needs to be investigated and resolved. **Design:** In 2010, in the annual meeting of the Society for the Scientific Study of Sexuality (SSSS), in Las Vegas, Nevada, we presented a study of 3000 women trying to describe the attitude and sexual behaviors of the female Spanish population in South Florida. We realized that dyspareunia was present in association with UTI's in around 80 % of the cases. Since then, in a prospective way, we have confirmed the relationship in more than 2500 additional cases. **Participants** Study population: 5500 patients presenting to the Miami Center for Obstetrics Gynecology and Human Sexuality. Age range of study participants: 17 to 72 years old. Since 2007 up to this date, we have continued to follow thousands of women seen in our centers regarding the presence of dyspareunia as a symptom of UTI. **Results:** In 83% of the UTI cases studied over the years, dyspareunia was endorsed as a symptom. Of these, approximately 94% of cases responded positively to treatment with antibiotics. In the post-menopausal women, the addition of local vaginal estrogen was necessary in around 45% of the cases in which recurrent UTI was the diagnosis, secondary to hypoestrogenism. Additionally, the dyspareunia gradually disappeared with the treatment of the UTI. We also found that 80% of women of reproductive age presenting with complaints of dyspareunia had an undiagnosed UTI. During the perimenopausal and postmenopausal years, dyspareunia is more often associated with genitourinary syndrome of menopause rather than UTI associated symptoms. **Conclusion:** Our data confirmed that Dyspareunia has been described as one of the symptoms of interstitial cystitis but has never been implicated as a significant symptom of regular uncomplicated or complicated UTI. We have found that this symptom is extremely important as part of the symptomatology of the UTI, frequently found along with the classical symptoms of UTI. Why has something so clear, so frequently present, never been described? The answer is simple, physicians and patients do not talk about sex, despite dyspareunia being more a clinical symptom than a sexual one. Medical schools and residency programs in all areas, especially in obstetrics and gynecology, urology, and psychiatry have been neglecting the education of physicians-in-training in this important aspect of human health. In conclusion, this is prove of how medicine, has sometimes been influenced by religion, culture, and social norms far away from science.

**Sources of Funding:** NONE

#### P-66.

### Sexual Emergencies in Pre/Post-Menopausal Women

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**Objective:** Our objective is to provide a comprehensive understanding of the scope of sexual emergencies in women on a national and international level. We aim to highlight how these emergencies can differ depending on location, culture, and societal norms. Additionally, we seek to explore the various methods of diagnosing and treating the wide array of conditions that can arise. Our hope is that this knowledge will lead to better management strategies and ultimately improve survival rates for patients experiencing these emergencies. **Design:** The study aimed to review and present the magnitude, variety, and diversity of sexual emergencies specifically in women pre- or post-menopausal ages. To achieve this, a comprehensive literature review was conducted, and relevant cases seen in our medical facility that involved female patients were analyzed. The review was focused on the following aspects: Common coital emergencies in female patients, including cases in neurology, cardiology, gynecology and immunology. Common autoerotic emergencies in female patients, including cases in gastroenterology and related cases. Identification of body packings. Sexual assault in female patient. Sexual dysfunction in female patients, including hyperactive arousal disorders and related suicide attempts. Sociosexual issues in female patients, such as killings, infidelity, and castration. The data collected was analyzed and presented in a structured manner to highlight the epidemiology, diagnosis, and treatment of these sexual emergencies specifically in women. The study also aimed to identify the variations in these pathologies across different countries, cultures, and populations of female patients. **Results:** The Review includes: The common coital emergencies in neurology (benign coital headache, subarachnoid hemorrhage, intracerebral bleeding, subdural hemorrhage, cerebral vascular accidents), in urology: ureterovesical foreign

bodies, obstructive uropathies; cardiology (sudden cardiac death, myocardial infarction), gynecology (vaginal laceration and/or eversion with/without previous gynecological surgeries), obstetrical (postpartum dyspareunia secondary or not to episiotomy or vaginal lacerations); postcoital preterm labor), immunological and infectious diseases (local or systemic, anaphylactic allergic reactions to latex of condoms, to sperms, and tampons). Common autoerotic emergencies in gastroenterology (foreign objects in rectum, vagina, oropharyngeal/mandibular lesions), as well as “body packers” cases (swallowed latex balloons for smuggling in the GI tract, rectum, or vagina) Sexual assault, Sexual dysfunction: Hyperactive arousal disorders (compulsive hunt for orgasms with/without attempt or real suicide, hypersexuality related to SSRI use). Sociosexual issues: Killings for jealousy during sex, infidelity, castration like Lorena Bobbitt case. **Conclusion:** The review and presentation of cases in this study reveal that sexual emergencies are more prevalent than commonly thought and encompass a wide range of pathologies that are critically significant. This highlights the importance of physicians being prepared to address these cases. Sexual emergencies are frequently encountered in emergency departments and extend beyond complications related to sexual activity and autoerotic behaviors. Other factors such as sexual assault, sexual dysfunction, and sociosexual issues unique to different cultures also contribute to the spectrum of sexual emergencies. Therefore, it is imperative for healthcare professionals to have a comprehensive understanding of the diagnosis and management of these conditions.

**Sources of Funding:** None

### P-67.

#### **Vaginal Obliterations in Post-Menopausal Women.**

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**Objective:** From December 2018 to July 2022, our centers diagnosed, assessed, and managed six instances of vulvovaginal fusion (obliteration). Our analysis of medical literature reveals that less than 30 cases have been reported so far. All the cases had common characteristics, including a period of more than 20 years without sexual activity or masturbation, no hormone replacement therapy, and a record of persistent urinary tract infections. Provide information on six cases of a rare genitourinary disorder, including diagnosis, medical and surgical management, follow-up, and resolution. Identify vulvovaginal obliteration or labial fusion as one of the most severe consequences of untreated genitourinary syndrome of menopause. Emphasize the importance of local estrogen use for women going through menopause and highlight the significance of maintaining penetrative sexual activity among older women. This can be achieved naturally or with the use of dilators and sexual toys. **Design:** We've analyzed 8 Cases with vulvovaginal obliteration that presented to our facilities. Case 1: 92 Year old woman, 25 years without sexual intercourse or HRT. Case 2: 90 year-old woman; had partner but was not sexual active or on HRT. Case 3: 90 year old woman, 30 years without sexual intercourse or HRT Case 4: 77 year woman with partial obliteration; treated with only estrogens and dilators. Case 5: 90 year old woman, 30 year with sexual intercourse or HRT. Case 6: 86 year old woman; 25 years without sexual intercourse or HRT. Case 7: 73 year old woman; who was the least affected of these cases. Case 8: 64 year old woman with incomplete vaginal obliteration, with more that 25 years without intercourse. (Pictures of the cases will be used in the presentation if the abstracts if accepted for presentation)\*\* **Results:** Upon analyzing the 8 cases, it was found that: Out of the 8 cases, in 3 instances, patients experienced vaginal obliteration resulting in urinary retention. Their main complaint was an inability to urinate due to a fused labia obstructing the urethral outlet. The most severe case involved a patient who had not engaged in penetrative sexual activity for more than 30 years; this 92-year-old patient presented with her labia completely fused. An ultrasound revealed fluid retention in her bladder and bilateral megaloureters. She had to be urgently taken to the surgical unit to have over 2000 cc's of fluid drained from her bladder. She was discharged on the same day with estrogen vaginal cream. The age range of the patients in our facility was between 64 to 94 years old. **Conclusion:** Vulvovaginal obliteration, whether total or partial, is a rare condition that has not been extensively documented. However, by considering the sexual history of each patient and utilizing geriatric gynecology practices, we have been able to diagnose this disorder. Although not commonly associated with genitourinary syndrome of menopause, vulvovaginal obliteration, also known as labial fusion, is one of the most severe complications. Preventative and treatment measures include the use of local estrogen and educating patients on the importance of maintaining penetrative sexual activity to prevent genitourinary atrophy and maintain functionality. This can be achieved with a partner, penetrative dilators, or sexual toys.

**Sources of Funding:** None

### P-68.

#### **Body Composition and Bone Mineral Density in Postmenopausal Women with Advanced Knee Osteoarthritis Undergoing surgical treatment**

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**Objective:** This study sought to demonstrate bone mineral density (BMD) conditions and body composition in postmenopausal women with knee osteoarthritis (OA) undergoing surgical treatment such as total knee arthroplasty (TKA), Osteotomy, meniscectomy. **Design:** 254 women with OA aged 50 who underwent surgical treatment were enrolled in the study. Body composition (fat mass (FM), lean mass and bone mineral component (BMC)) and BMD of the lumbar spine, both femoral neck and total hip were measured using dual-energy X-ray absorptiometry (DXA). Appendicular muscle mass (AMM) and

appendicular mass index (AMI) were calculated. The criteria of the The Asian Working Group for Sarcopenia (AWGS) 2019 consensus were used for low muscle mass and sarcopenia. Osteoporosis was determined in accordance with WHO criteria. **Results:** The mean age of patients underwent operation due to advanced knee osteoarthritis was 70.09 ± 7.2 years (p=0.455). When analyzing bone mineral density, normal patients were 7.5%, osteopenia was 48.8% and osteoporosis was 43.3%. Performing paired t test for BMD in the area with knee pain, there was a significant difference between the two sides, and the pain-treated side had significantly lower results than normal side. Based on the skeletal muscle index, the prevalence of sarcopenia observed in the OA patient group who underwent surgical treatment was 53.1%. When obesity defined based on BMI over 25, the prevalence of obesity in patient group was 59.8%. In the case of the android gynoid ratio (A/G ratio), which is the standard for evaluating the risk of visceral fat, high risk group greater than 1 was observed in 81.9% for these patients. Prevalence of sarcopenic obesity was 22% in advanced OA group with surgical treatment. When subdivided into obesity, the prevalence of sarcopenia in the non-obese OA group was 77.5%. (p<0.001). In addition, the non-obese OA group showed significantly lower BMD than the obese group (p=0.02), and a significant decrease in femur neck t-score under -2.0. **Conclusion:** Our study suggests that more attention should be paid to identify and treat osteoporosis and obesity in postmenopausal women with advanced knee OA undergoing surgical treatment.

**Sources of Funding:** none

### P-69.

#### **The Female Longevity Factor**

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**Objective:** Discuss the genomic, epigenetic, metabolic, hormonal and mitochondrial biological advantages and susceptibilities that are unique to women and confer an aging advantage. From telomere length to mitochondrial vitality, women are born with a longevity advantage but one that is more vulnerable to lifestyle, behaviours and environmental exposures. We are the first generation of women who can expect to live twice as long as their reproductive lifespan. The health status and lifestyle of women in their middle years predicts their neurocognitive reserve and physical function in their 80s. Harnessing the new science of regenerative medicine, it is possible to future proof health and reprogram youth to live longer better. **Design:** A detailed presentation of the emerging science of regenerative medicine and longevity describing key biological advantages that translate into women's longevity. From longevity genes, to longer telomeres, from epigenetic risks, hormones, mitochondrial function and more, women have a longevity advantage that can be harness and protected from environmental risks. This engaging talk will present the emerging science with an action oriented approach to help clinicians translate the science into therapeutic treatment plans to help their patients age their best. **Results:** A detailed scientific review and presentation will lead into a discussion of pearls for clinical practice. From lifestyle to nutrition, from stress management to sleep, from hormones to metabolic health, there is so much that can be done for our patients to help them age their best. **Conclusion:** The female longevity factor refers to the biological advantage that women have at birth including genomics, epigenomics, hormonal, metabolic, telomere and mitochondrial profiles. An individualized female centric care plan can augment these advantages and mitigate the risks with a lifestyle based approach. The audience will leave inspired to use this functional medical model to facilitate regenerative, wholistic care.

**Sources of Funding:** none

### P-70.

#### **Correlation between equol production and intestinal microbiota after treatment with isoflavone alone or associated with probiotic and hormonal therapy in postmenopausal women: a randomized clinical trial.**

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**Objective:** To correlate urinary excretion of equol with intestinal microbiota in response to the use of isoflavone alone or associated with probiotics and compare to hormone therapy in postmenopausal women. **Design:** A randomized clinical trial was conducted in sixty postmenopausal women aged 40-60 years, randomly assigned to receive oral isoflavone (dry extract of glycine max 150mg) or isoflavone plus probiotic (*Lactobacillus acidophilus*, *Lactobacillus casei*, *Lactococcus lactis*, *Bifidobacterium bifidum*, and *Bifidobacterium lactis*) or hormone therapy (estradiol 1mg/ norethisterone acetate 0.5mg). Bacterial DNA was extracted from fecal samples and equol and equol intermediary were measured by gas chromatography coupled to mass spectrometry in the baseline and after 16 weeks of treatments. The fecal samples were processed for analysis of the 16S ribosomal ribonucleic acid (16S rRNA) by the Helixxa Genomic Services. The Illumina MiSeq Platform was used to extract bacterial DNA from 47 fecal samples. Stool DNA Isolation Kit (Cat. 27600) (Norgen Biotek Corporation, Thorold, Canada) with MiSeq 2x300 cycles was used. Spearman's correlation (r) was used to establish the relation between the intestinal microbiota and the production of equol and equol intermediary. The Consolidated Standards of reporting Trials 2010 statement (CONSORT) were observed, and the protocol was approved by the Human Research Ethics Committees by the Research Ethics Committee (CEP, acronym in Portuguese) (CAAE/process number 56751216.7.0000.5404) and registered on the Brazilian Clinical Trials Registry (ReBEC; RBR-83vwpx). **Results:** The mean age of the women was 52.4 years, while the mean age of menopause was 48.8 years, and the time of menopause was 43.2 months. In the isoflavone group, an increase of *Proteobacteria* and *Fusobacteria* phylum were related to an increase of equol, with no increase of genus related with the production of equol and

it's intermediate. In the isoflavone plus probiotic group, an increase of *Verrucomicrobia* phylum and *Lachnospira* genus were related to an increase of equol intermediary. The increase of *Cyanobacterium* phylum, *Catenibacterium*, *Clostridium*, *Barnesiella*, and *Oscillospira* genus were related to increase of equol and equol intermediary, while an increase of *Bacteroidetes* phylum, *Bacterioides* and *Prevotella* genus were related to an increase of equol intermediary in HT group. **Conclusion:** We found that equol and equol intermediary urinary concentration were directly related with modification in the composition and activity of the intestinal microbial community, and we were able to correlate the phylum and genus bacterial responsible for the increase in these isoflavone metabolites. Isoflavone associated with probiotic was able to increase the number of bacteria responsible for isoflavone metabolism; however it was more evident in the group using HT, evidencing the importance of estrogens in the microbial population of postmenopausal women.

**Sources of Funding:** This research was funded by The São Paulo Foundation for the Support of Research (Fundação de Amparo à Pesquisa do Estado de São Paulo - FAPESP), grant # 2016/08089-9

## P-71.

### Is age associated to prevalence and severity of premenstrual syndrome? Results from a Brazilian population-based survey.

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**Objective:** To evaluate the relationship between premenstrual syndrome and age, analyzing the prevalence and severity of psychoemotional and physical symptoms in a representative sample of Brazilian women. **Design:** An observational and retrospective study was carried out analyzing data from 5,121 Brazilian women aged 20 to 49 years old from all the five regions of the country who claimed to have premenstrual symptoms. The participation consisted of answering a questionnaire adapted from the Brazilian validated version of the Premenstrual Symptoms Screening Tool (PSST), with their respective scores. The prevalence and severity of the symptoms were evaluated. The PSST is a self-applied recall tool that reflects the International Society for Premenstrual Syndrome/Disorders criteria, translating its criteria into a scale with degrees of severity, in addition to assessing the functional impact. Data were analyzed through Pearson's Chi-Square test and Bonferroni multiplicity correction. The protocol for the study was approved by the Research Ethics Committee under registration number 33794520.1.0000.8098 **Results:** A total of 23,104 women claimed to have premenstrual symptoms, of which 38.91% (n=8,990) reported that these symptoms caused functional impairment. Finally, 5,121 participants agreed to answer the symptoms questionnaire, distributed in the following age groups: 20-29 years old (46.7%), 30-39 years old (38.3%) and 40-49 years old (15%). The most prevalent and severe physical symptoms of participants aged 20 to 29 years old were acne/oily skin. Headache was the most prevalent and severe physical symptom reported by women aged 30 to 49 years old. Participants aged 40 to 49 years had headaches (90.5%), followed by weight gain (89.5%) and, ultimately, breast tenderness (87.4%). Of the symptoms observed, the most severe was headache (48.2%). Based on the data presented, a trend towards an increase in the prevalence of most physical symptoms can be observed with increasing age and approaching menopause transition, except for acne/oily skin. In the evaluation of psychoemotional symptoms, the most prevalent in the 20-29 years old group and 40-49 years old group was anxiety/tension while for the 30-39 group the most prevalent symptom was irritability/anger. In all groups, irritability/anger was the most severe symptom. On average, 74% of participating women would be willing to take hormonal oral contraceptives for symptoms relief, mainly in younger groups. **Conclusion:** Age is one of the factors having the most influence on women's reports of premenstrual symptoms. The physical symptoms related to premenstrual syndrome vary according to age, but through this study, we could note that the psychoemotional symptoms are more intense, with irritability/anger and anxiety being the most severe in Brazilian women of reproductive age. There is a higher willingness to take contraceptives as a treatment for PMS in younger women but overall, most participants (74%) would like to take oral contraceptives as a treatment for premenstrual symptoms. So, it is important this data when counselling contraception for women with PMS. The physician's proactive attitude in the investigation of PMS and the appropriate therapeutic approach can bring great benefits to the patient, in addition to improving her family, social and work environment. **Sources of Funding:** This study has received financial support from Libbs Farmacêutica, São paulo, Brazil.

## P-72.

### Prevalence of Premenstrual Dysphoric Disorder in Brazilian women: a national cross-section survey

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**Objective:** Estimate the prevalence of women with Premenstrual Dysphoric Disorder (PMDD) through self-report of somatic and psycho-emotional symptoms. The secondary objectives were to estimate the prevalence of the symptoms according to age group and perform a correlation analysis between psycho-emotional and somatic symptoms. **Design:** This was a cross-sectional, retrospective, population-based study. Data from women from the five Brazilian regions, aged between 20 and 49 years, attended in 303 private health services were analyzed. The women answered the adapted Brazilian

version of the Premenstrual Symptoms Screening Tool (PSST) on the prevalence and intensity of somatic and psychoemotional premenstrual symptoms. The sample size calculated to obtain an intended level of statistical significance was 1022 women. A total of 11,943 with premenstrual syndrome agreed to voluntarily answer the questionnaire. Of these, 1,614 had diagnostic criteria for PMDD, according to the International Society of Premenstrual Syndrome. Statistical analysis was performed using Pearson's chi-square test, Bonferroni multiplicity correction and Poisson regression. The protocol for the study was approved by the Research Ethics Committee under registration number 33794520.1.0000.8098. **Results:** The prevalence of PMDD was 13.5% (95% CI; 12.9%; 14.1%). Psychoemotional symptoms were more prevalent than somatic symptoms, with anxiety (99.9%) and irritability (99.8%) being more prevalent and of greater intensity in the older age group (40-49 years). Regarding somatic symptoms, weight gain (92.5%) and edema (92.1%) were the most prevalent, with no correlation with age. The correlation of psychoemotional symptoms such as anxiety occurred independently of somatic symptoms and headache occurred independently of psychoemotional symptoms. Binge eating was related to weight gain, acne, and immunoallergic exacerbations, increasing the likelihood of these symptoms occurring by 19.5%, 17.1%, and 12.5%, respectively.

**Conclusion:** The prevalence of PMDD in this sample of Brazilian women was high, with psychoemotional symptoms being more prevalent than somatic symptoms. This demonstrates the impact of premenstrual symptoms on women's mental health. Knowing the epidemiology of PMDD, as well as the symptomatological profile in different age groups, can help in the design of more effective and specific diagnostic and treatment protocols for each population

**Sources of Funding:** This study has received financial support from Libbs Farmacêutica, São paulo, Brazil.

## P-73.

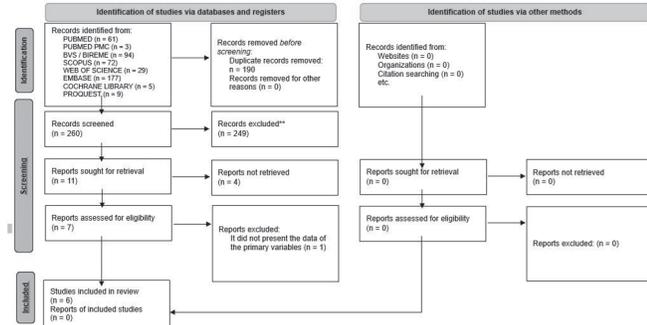
### Prolactinoma in post-menopausal women: a systematic review

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**Objective:** Evaluate the evolution of prolactinomas after menopause: to identify data on growth, prolactin serum levels, clinical treatment, symptoms, and relapses **Design:** a systematic review with inclusion of observational prospective or retrospective studies and clinical trials of prolactinoma in the post-menopause period considering providing a pooled estimate of treatment response: growth, serum prolactin levels, symptoms, and recurrence of prolactinomas in post-menopause women. The following database: PubMed, BVS, EMBASE, Scopus, Web of Science, COCHRANE, PROQUEST, and grey literature were included, without language and date restrictions. Search strategy with mesh terms was: "Prolactin (PRL)-secreting tumors", "prolactin adenoma", "Adenoma" and "Prolactin", "Hyperprolactinemia", "Prolactinoma", "Climacteric", "Menopause", "Postmenopause", until May 2022. Two researchers independently screened records for inclusion. A third author judged disagreements between the reviewers. The papers were selected and judged using the Intelligent Systematic Review (RYYAN). Data were extracted from the articles after reading them in full. The risk of bias will be assessed using the NIH quality assessment tool (NIH) for the observational study. Data were synthesized narratively on the association between changes in prolactinoma and women in the post-menopause period. A meta-analysis was not realized considering the study design included. **Registration number:** CRD42022364079. **Results:** From searches in the databases, 260 articles were retrieved that, after analyzing the title and abstract, in addition to applying filters, left 6 for a full reading. The data are summarized according to the flowchart below (Figure 1). After analysis of the risk of bias in the studies, it was identified that 5 studies presented fair quality and 2 studies as good. A total of 158 patients were included. Part of these women was analyzed during menacme, menopause, and post-menopause, with, and without treatment. We could observe the description of 109 included women with microprolactinomas and 47 with macroprolactinomas. Considering the diagnosis in the post-menopause period, there is a greater prevalence of macroprolactinomas (n= 40) against microprolactinomas (n=25), which show a reduction in tumor size with the use of a dopamine agonist, the most commonly used as Cabergoline, as well as a reduction in prolactin levels and symptoms associated with the adenoma. In the follow-up period, the behavior of the tumor and, prolactin levels, maintain stable. **Conclusion:** Microadenomas diagnosed before menopause can be followed without treatment. When the tumor is diagnosed after menopause, macroadenomas are the most frequent. Cabergoline is still the medical choice, if symptoms of mass effect. We recommend at least one follow-up for year in despite that the ideal postmenopausal follow-up time has not been defined.

**Sources of Funding:** None

Figure 1. Summary of articles identified in the databases for this systematic review



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. Doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

## P-74.

### Cardiovascular Disease in Menopausal Incarcerated Women

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**Objective:** Midlife and older women have an increased risk of cardiovascular disease (CVD). Since women who are 55 or older are the fastest-growing age group in prison, CVD is a major health concern for them. Data suggest that of newly admitted women prisoners to maximum-security prisons, 34% have CVD. Several adverse determinants of health that menopausal women face in the correctional system may increase this risk of their developing CVD. **Design:** On PubMed, “((women) AND (prison)) AND (cardiovascular disease)” were searched. Six articles written in English met the inclusion criteria of addressing CVD among incarcerated women in the criminal justice system. **Results:** Of the six articles found, three discussed risk factors for CVD, and three discussed potential interventions. In addition to postmenopausal incarcerated women being more vulnerable to CVD due to an increased prevalence of comorbid conditions, including hypertension, diabetes mellitus (DM), high cholesterol, and obesity, socioeconomic disparities prior to incarceration increase their risk of comorbidities and CVD as well. Aspects of the prison environment also contribute to the increased prevalence of CVD. Those who are incarcerated may have decreased access to adequate optimal health care. Furthermore, prison itself can be defined as a high-stress environment. Incarcerated postmenopausal women may experience sexual harassment, solitary confinement, maternal guilt, and loss of ability to move freely. HIV also is prevalent in those incarcerated and can increase CVD risk. Those incarcerated may have limited exposure to sunlight, leading to vitamin D deficiency, which is associated with CVD, as well as osteoporosis. Regarding prevention of CVD in the criminal justice system, is crucial, but scant data exists. A study hypothesized that lifestyle factors would improve cardiovascular health in prison. A 2016 study proposed an intervention involving indoor biking and education on diet, activity, weight, stress, and smoking, but no data regarding its effectiveness has been published. Other research suggests that a CDC program on heart intervention should be implemented in prisons to decrease CVD risks. **Conclusion:** CVD is a significant problem for postmenopausal women in the criminal justice system. The New Jersey Reentry Corporation (NJRC) advocates and collaborates to implement health and wellness interventions, including the addressing of CVD. For example, one educational tool that was created for incarcerated and reentry women to improve health education was an animated video geared to teaching about ways to prevent CVD. These animations present the material in an easy to understand and embracing way to reduce health barriers for individuals, including those with low health literacy. There is a need for more research and interventions for CVD, as prevention and risk reduction of CVD would play a crucial role in the lives of older women in the criminal justice system.

**Sources of Funding:** None

#### Determinants for CVD in Prison



## P-75.

### Impact of Travel Time to Menopausal Follow Up Care, Symptom Burden, and Acceptance of Hormone Therapy

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**Objective:** Barriers to access to menopause care lead to increased patient and societal burden of menopausal symptoms, with significant impact on patient quality of life. This study evaluated access, defined as the travel time from a patient's residence to a menopause specialty clinic at an urban university-affiliated academic medical center. We explored the association between travel time and the number of follow-up visits, symptom burden, and types of therapy accepted. **Design:** Eligible patients with menopausal symptoms (both vasomotor and genitourinary) who presented to an in-person menopause specialty care clinic between July 2018 and December 2022 were included. Data were extracted from retrospective medical record reviews. Travel time was calculated using Google Maps as the average of two times over clinic operating hours from patients listed home addresses on initial registration to clinic. Average travel time was calculated One-way ANOVA and post-hoc analyses were used to examine the association between travel time and therapy type and number of follow-up visits. Student's t-test was used to examine the association between symptom burden and average travel time. **Results:** A total of 119 individual patients were included in this study. Median travel time was 22.2 minutes, and median travel distance was 15.8 miles. Women who accepted both local and systemic hormone therapy traveled significantly less time (17.3 ± 7.2 minutes, p < 0.001), compared to women who accepted lifestyle modifications only (28.4 ± 8.3, p < 0.001). Women who visited the clinic once (30.6 ± 10.4 minutes, p = 0.009) had significantly more travel time to clinic compared to those who visited the clinic twice (23.7 ± 11.3 minutes, p = 0.002) and three or more times (16.6 ± 8.6, p < 0.001). Women who reported vasomotor symptoms, genitourinary symptoms, and decreased libido had significantly longer average travel times compared to women without these symptoms [24.5 vs 18.7 minutes (p = 0.005), 24.7 vs 21.6 minutes (p = 0.041), and 25.2 vs 20.7 minutes (p = 0.046), respectively]. **Conclusion:** Longer travel times to our menopause clinic are a barrier to accessing care, which was found to be associated with less follow-up care, increased symptom burden, and decreased acceptance of hormone therapy for menopausal symptoms. We highlight an access to care barrier that providers should consider. Ultimately patient time is valuable and any increase in travel time might be impactful on their health.

**Sources of Funding:** None

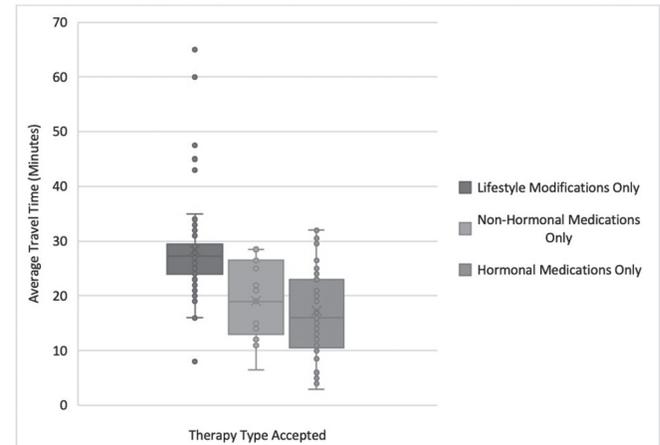


Figure 2. Association of Travel Time and Type of Therapy Accepted

## P-76.

### Vaginal Orgasms: Do They Really Exist in Menopause?

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**Objective:** In 1948, Alfred Kinsey's investigation of female and male sexuality found that 80% of women reached orgasm mainly through non-coital sexual experiences, such as oral and physical manipulation of the genitals or through sex toys. Many peer-reviewed studies - as well as what we observed in our practice - confirmed these findings. However, the question remains: what happened with the other 20% that reached orgasm through vaginal penetration? Hence, the goal of this study was to examine the relationship between sexual partner history, timing of sexual initiation, and orgasmic responsiveness in post-menopausal women who primarily reach orgasm through vaginal penetration. The study aimed to provide a deeper understanding of the sexual experiences and response patterns in this population, with the ultimate goal of improving female sexual health and well-being. **Design:** The study was conducted in a medical center and involved the collection of sexual histories from over 3,000 post-menopausal women. Both retrospective and prospective questionnaires were used to gather data on the participants' sexual experiences, partner history, and timing of sexual initiation.

The questionnaires were administered by trained healthcare professionals to ensure accurate and reliable data collection. In addition, medical records were reviewed to confirm the reported information and to obtain additional relevant data. The data was analyzed using descriptive statistics to examine the prevalence of sexual partner history and timing of sexual initiation among the participants, and to identify correlations between those variables and orgasmic responsiveness. To ensure the privacy and confidentiality of the participants, all data was securely stored and de-identified before analysis. **Results:** The epidemiological sexual characteristics of this specific group of women who reach orgasm through vaginal penetration are: 75% have had only one sexual partner in their lives; 20% of them have had two sexual partners in their life; 5% of them have had more than two. It has been very scantily found that women with a history of multiple sexual partners enjoy sexual penetration. The orgasmic response resulting from coital sex was more persistent and presently found while the number of sexual partners was lower. Increased orgasmic responsiveness was also present when the initiation of sexual activity with the partner occurred earlier in life. This highlights the importance of a stable sexual relationship in a woman's sexual response. The results also indicate that the women with a history of multiple sexual partners had a lower likelihood of enjoying sexual penetration, further emphasizing the significance of a stable sexual environment for a woman's sexual satisfaction. The study found that the orgasmic response resulting from coital sex was more persistent and present in women with fewer sexual partners. Furthermore, increased orgasmic responsiveness was observed in women who initiated sexual activity earlier in life, suggesting that a woman's sexual development plays a crucial role in her ability to respond to sexual stimulation and reach orgasm through vaginal penetration. The results also show that the orgasmic response was more attainable and persistent when penetrative stimulation was the main form of stimulation, reinforcing previous findings that a woman's sexual response is directly related to the type and quality of sexual stimulation she receives. **Conclusion:** The findings of this study provide valuable insights into the sexual characteristics of post-menopausal women who reach orgasm through vaginal penetration. The results support the idea that a stable and supportive sexual environment is crucial for a woman's sexual satisfaction and overall health. As healthcare providers, we must consider these findings in our approach to sexual health and well-being. When the sexual development of a woman is allowed to mature in the presence of a lifelong partner, her response to penetrative vaginal stimuli is better and the obtention of sexual pleasure and orgasm reinforces this response, which persists throughout her life and is more attainable over any other form of vaginal stimulation.

**Sources of Funding:** None

**P-77.**

**Ameliorating Menopausal Symptoms: The Role of Dance**

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**Objective:** Menopause may affect middle-aged cisgender women by causing hot flashes, pain during sex, mood changes, irritability, and depression. Often accompanying these changes that occur with menopause is an increased level of psychological distress, which can manifest in different ways. For example, in a cross-sectional study of 300 women, 85% of post-menopausal women and 47% of peri-menopausal women reported symptoms of physical and mental exhaustion, compared to 20% of pre-menopausal women. This can have a significant impact on the well-being of these women—some may even decide to discontinue activities, including work and hobbies, earlier than they had planned. Research remains divided on whether the increased psychological distress seen in menopausal women stems from biology, societal schemas, or a combination of both. While it is documented that hormonal changes occur in menopause, it is unclear whether this contributes to mental health dysregulation in some. On a societal level, Western countries often convey menopause as a major sign of aging and loss of sexuality in women, creating societal pressure that may lead some women to develop unrealistic expectations and therefore experience increased stress. Regardless of the reason for the increase in psychological stress, stress management modalities may be one way to improve the menopausal woman's quality of life. Dance Movement Therapy (DMT) is an emerging strategy for reducing psychological stress. Since early human history, many cultures have used dance as a healing ritual for ills and maladies. Today, dance has been used as a complementary therapy to standardized Western medicine to promote greater muscle strength and to positively influence mental health. This review explores the use of dance to ease menopause-related stress. Previous research has revealed the benefits of physical activity in women undergoing menopause. However, in this review the role of dance is explored, and whether it is superior to other forms of physical activity as well as whether it has additional benefits of improving self-image and self-esteem. **Design:** A literature review was conducted using PubMed. Keywords included "menopause," "dance," "stress," "emotional," "movement," "self-esteem." Research was focused into two groups: impact of menopause on stress levels and the impact of dance on stress reduction. **Results:** Menopause has been shown to be a contributor to increasing stress levels and depressive symptoms in some aging women, likely due to societal schemas surrounding the concept of womanhood combined with sudden hormonal changes. Available data suggest that 12 weeks of DMT increases serotonin and decreases dopamine levels, stabilizing the sympathetic nervous system. This would likely be beneficial for menopausal patients, who may experience mood disturbances due to the biochemical disruption of serotonin production as a result of fluctuating estrogen and progesterone levels. Similarly, there are data that suggest DMT reduces depressive symptoms in individuals of all ages. This could also be advantageous to those with menopause-induced mood changes due to both biological and societal causes. In addition, the physical benefits experienced through dance may help women maintain

their independence, which is, in turn, associated with increased feelings of wellness. This could counteract the depression and exhaustion experienced by some menopausal women. Finally, because low self-esteem and loss of personal value have been associated with menopausal changes, DMT could also address this issue as it has been shown to increase self-esteem, again improving the mental wellness of menopausal women. **Conclusion:** Despite the historical association between dance and healing, dance is currently underutilized as a management modality for many individuals, including those undergoing menopause. Additionally, dance is an inherently social activity, providing built-in social support to individuals and encouraging a form of camaraderie. Further research is needed to directly evaluate the relationship between dance and stress reduction in women experiencing menopause as well as the perceived benefit of increased social support through dance classes and events.

**Sources of Funding:** None

**P-78.**

**Impact of Demographic and Sociocultural Factors on a satisfying sexual life. A Cross-Sectional Survey on Menopausal Mexican Women.**

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**Objective:** To identify if demographic, and socio-cultural factors among menopausal women, are associated with an active and satisfactory sexual life. **Design:** Cross-sectional online surveys about sexual life, demographic and sociocultural factors, were conducted from March 9-26 2023, using Google forms platform. Obtained responses were analyzed using GraphPad Prism version 8.4.2 for Windows. Central tendency measures were used for the descriptive analysis and for comparison we used Fishers exact test. **Results:** A total of 100 Mexican eligible women, answered completely and consistently the survey. Table 1 depicts the demographic variables and the relationship with an active sexual life, in which no statistical significance was observed, except for marital status. More than half patients have an active sexual life, of which, 80% reported living a satisfactory sexual life (SSL). Regarding treatment, 76% were with hormone replacement therapy (HRT), but using hormones neither represented a difference between have SSL or not. For 84% of women surveyed, it is difficult to talk about sexuality, we organized the reasons into cultural and social aspects, 70% was cultural embracing shame and taboo, 20% was social, which mainly included "education", 17% included both aspects, and 3% did not answer. An attempt was made to relate it to the time of menopause without finding statistical significance OR 0.6865 (CI 0.2143 – 2.056). The patients who do not have an active sexual life, referred as main cause, decreased desire, vaginal dryness and sexual pain. **Conclusion:** Our results indicate that demographic factors are not directly related with an SSL. Be married or live with a partner seems to influence in having sexual activity. Contrary to the expected, been in menopause longer, or not being on HRT, does not affect in achieving a SSL. Among the main factors that influenced not achieving a SSL were symptoms related to lack of estrogen and sociocultural barriers.

**Sources of Funding:** None

Table 1. Comparison of demographic characteristics and an active sexual life.

Variable	Overall (N=100)	Active sexual life (N=59)	No Active sexual life (N=41)	P
Age, mean (SD)	57 (5.2)	58 (54-60)	57 (55-61)	0.79
Marital Status, n(%)				0.001
Single	8%	2 (3%)	6 (15%)	
Married/ Living with partner	68%	49 (83%)	19 (46%)	
Widowed	6%	7 (12%)	11 (27%)	
Divorced/ Separated	18%	1 (2%)	5 (12%)	
Education, n(%)				0.06
Elementary	3%	0	3 (7%)	
High School	5%	4 (7%)	1 (3%)	
Professional degree	82%	47 (80%)	35 (85%)	
Graduate	10%	8 (13%)	2 (5%)	
Employment Status, n(%)				0.66
Unemployed	37%	22 (37%)	16 (39%)	
Full/part-time employed	62%	37 (63%)	25 (61%)	
Month Household Income, n (%)				0.22
\$500-\$599	30%	14 (24%)	16 (39%)	
\$600-\$1,599	28%	19 (32%)	9 (22%)	
\$1,600 +	42%	26 (44%)	16 (39%)	
Religion, (n%)				0.38
Catholic	84%	52 (88%)	32 (78%)	
Christian	12%	5 (9%)	7 (17%)	
Non-practicing	4%	2 (3%)	2 (5%)	
Sexual Preference, n (%)				>0.99
Heterosexual	95%	56 (95%)	39 (95%)	
Homosexual	5%	3 (5%)	2 (5%)	

P-79.

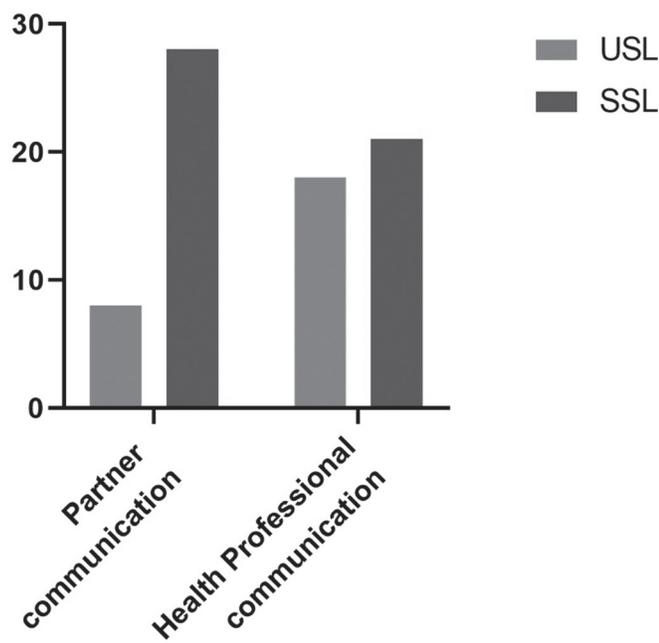
### Let's talk about sex: The role of communication in sexual satisfaction during menopause.

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**Objective:** Identify if the communication with the partner is more important than the communication and advices from their professional physician to reach a satisfactory sexual life. **Design:** Cross-sectional online surveys about sexual life in menopausal women were conducted from March 9 to March 26 2023. Surveys were delivered to participants through Google forms platform, responses were recorded on a Microsoft Excel spreadsheet and analyzed using GraphPad Prism version 8.4.2 for Windows. The communication with sexual partner or the professional physician and the relation with having a satisfactory sexual life were assessed with Fisher's exact test. P-values <0.05 were considered statistically significant. **Results:** A total of 106 Mexican women were approached and 100 answered completely the survey. The mean age of the participants was 57 years old. When comparing the patients' self-perception of a satisfied sexual life, the patients with a satisfied sexual life, have communication with their partners, including their concerns, doubts, annoyances or desires, in contrast to those who have an unsatisfied sexual life ( $p=0.003$ ) (Figure 1). Among the women who don't have communication with the partner, the main reasons given were lack of time, distrust, and fear of being judged. An interesting point about professional physicians was that of the patients who talk with them, 18% reported still having doubts, and 15% considered that their doctor was not qualified to provide information on sexual health. **Conclusion:** For our community, communication with the partner proved to be more significant than the information provided by a health professional in order to live a satisfied sexual life. There is an area of opportunity among professional physicians to acquire more knowledge about sexuality, and improve on how to transmit it to patients.

**Sources of Funding:** None

**Figure 1.- Relationship between communication and self-perception of Satisfactory Sexual Life (SSL) or Unsatisfactory Sexual Life (USL)**



P-80.

### Health disparities in prevalence of diagnosed vasomotor symptoms in women of menopausal age

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**Objective:** Most women experience vasomotor symptoms (VMS), including hot flashes and night sweats, at some point during the menopausal transition. This study aimed to estimate the prevalence of diagnosed VMS among US women aged 40–64 years and to assess diagnosis disparities based on sociodemographic characteristics. **Design:** In this retrospective study, claims data from IQVIA's PharMetrics Plus (PMTX+) database were used to estimate the prevalence of diagnosed VMS, and patient-level data from IQVIA's

Consumer Attributes (Cx) database were used to identify sociodemographic covariates (study period: 7/1/2016–12/31/2021; selection period: 1/1/2017–12/31/2020). Women aged 40–64 years with any enrollment data in PMTX+ that were linked to Cx during each of the calendar years 2017–2020 were included. Women with Medicare Risk, Medicare Cost, or State Children's Health Insurance Program coverage, or with data quality issues, were excluded. VMS diagnosis was defined by a medical claim with ICD-10-CM diagnosis codes in any position for (1) natural or surgical menopausal/female climacteric states or (2) flushing or hyperhidrosis and  $\geq 1$  claim with a diagnosis code associated with natural menopause or a procedure/diagnosis code for surgical menopause on the same date or in the prior 12 months. Prevalence (per 1000 women) for each calendar year and for the overall cohort (combined years) stratified by age, race/ethnicity, income, region, rural vs urban residence, and education level were calculated and projected to estimate the burden of diagnosed VMS in the US population (2020 US census data). Multivariable logistic regression was performed to examine the factors associated with diagnosed VMS from the latest non-COVID year (ie, 2019). **Results:** For each calendar year (2017–2020), nearly 5 million women were eligible for inclusion in the annual prevalence cohort. For the 4-year period combined, a total of 7.4 million unique women were included in the overall prevalence cohort. Projected prevalence of diagnosed VMS for 2017–2020 was 79.07 per 1000, with the annual prevalence highest in 2019 (41.06 per 1000) and lowest in 2020 (37.90 per 1000). Upon stratification by age group, women aged 51–54 years had the highest projected prevalence (133.24 per 1000) and those aged 40–44 years had the lowest (21.48 per 1000). Women aged 51–54 years with enrollment data in 2019 had >5 times higher odds of diagnosed VMS than those aged 40–44 years (OR [95% CI]: 5.31 [5.19–5.43];  $P<0.001$ ). Among racial/ethnic groups, projected prevalence was highest among White women (82.47 per 1000) and lowest among Asian women (64.51 per 1000). The odds of diagnosed VMS were significantly lower among Asian (OR [95% CI]: 0.69 [0.67–0.71];  $P<0.001$ ), African American (0.82 [0.81–0.84];  $P<0.001$ ), and Hispanic (0.87 [0.85–0.89];  $P<0.001$ ) women than among White women. The prevalence of diagnosed VMS was higher among women with higher median household income (105.32 [ $\geq$ \$250,000] vs 63.48 [\$20,000–\$34,999] per 1000); women with median household income  $\geq$ \$250,000 had 70% higher odds of diagnosed VMS than those with median income \$20,000–\$34,999 (1.67 [1.63–1.71];  $P<0.001$ ). The odds of diagnosed VMS were 20% higher among women in urban areas than among those in rural areas (OR [95% CI]: 1.18 [1.13–1.23];  $P<0.001$ ), and women in the South had twice the odds of diagnosed VMS than women in the Northeast (2.03 [2.00–2.06];  $P<0.001$ ). **Conclusion:** Using US claims data linked with consumer data, this study elucidated differences in prevalence of diagnosed VMS among women aged 40–64 years by age, race/ethnicity, income level, and area of residence. This study revealed lower prevalence of diagnosed VMS among vulnerable populations, such as those with low income and racial minorities, highlighting unmet need among these patients. Further research is needed to understand the source of healthcare disparities among women with VMS.

**Sources of Funding:** The study was sponsored by Astellas Pharma, Inc. (Northbrook, IL). Writing support provided by LeeAnn Braun, MPH, MEd, of Peloton Advantage, LLC, an OPEN Health company, was funded by Astellas.

P-81.

### Ability of anthropometric indices to discriminate metabolic syndrome in women in different stages of climacteric

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**Objective:** To evaluate the ability of anthropometric indices to discriminate the metabolic syndrome in women in different stages of climacteric conditions. **Design:** This is a cross-sectional epidemiological study of the analytical type conducted in units of the Family Health Strategy (FHS) in urban and rural areas of Montes Claros, Minas Gerais, Brazil. Data collection included sociodemographic data and lifestyle habits. Metabolic syndrome (MS) was assessed according to the criteria of the International Diabetes Federation, 2006, and body mass index (BMI), abdominal circumference (AC), Body Roundness Index (BRI), A Body Shape Index (ABSI), and visceral adiposity index (VIA) were calculated. Descriptive statistics, chi-square test, binary logistic regression, ROC curve, and the Youden index were used for data analysis. **Results:** The sample consisted of 874 climacteric women aged 40 to 65, out of which 399 (45.6%) were classified as premenopausal and 475 (54.4%) were postmenopausal. The premenopausal women had higher education levels ( $p<0.001$ ), higher employment rates ( $p<0.001$ ), and were more active ( $p<0.001$ ). Among the anthropometric indices evaluated, only the BRI ( $p=0.006$ ) and the ABSI ( $p<0.001$ ) showed significant differences between the two climacteric stages. The prevalence of MS was 60.9%, predominantly affecting postmenopausal women (66.1%). After the adjustment for alcohol consumption, smoking, and level of physical activity, an association was observed between all anthropometric indices evaluated and the MS, both in pre and postmenopausal women; the VIA was the index that was related to a higher number of alterations in the components of the syndrome in both stages of the climacteric period. The measures that showed greater strength of association were the BRI and the ABSI in pre and postmenopausal women. In premenopausal women, an increase in BRI was associated with a 1.77-fold increased chance of developing MS (OR: 1.775; 1.533–2.057), while an increase in ABSI was associated with a 2.40-fold increased chance of having MS (OR: 2.406; 1.741–3.324). In postmenopausal women, an increase in BRI was associated with a 1.55-fold increased chance of MS (OR: 1.556; 1.362–1.777) and ABSI with a 2.18-fold increased chance (OR: 2.189; 1.590–3.012). When analyzing the anthropometric indices, the VIA obtained

better accuracy in identifying the MS, both in the pre (ACR=0.821; 0.779-0.862) and postmenopausal (ACR=0.812; 0.769-0.854) periods, with the highest value of area under the ROC curve. Despite showing a smaller area, AC and BRI were considered reasonable in discriminating the MS in pre (ACR CA=0.794; ACR BRI=0.792) and post (ACR CA=0.728; ACR BRI=0.727) menopause. The markers with smaller areas under the curve were ABSI and BMI in pre (ACR ABSI=0.663; ACR BMI=0.697) and postmenopausal (ACR ABSI=0.640; ACR BMI=0.666). As for sensitivity, the values ranged from 46.33% to 87.16% in premenopausal and from 24.90% to 96.50% in postmenopausal. The BRI showed greater sensitivity to discriminate the MS both in premenopausal (87.16%) and postmenopausal (96.5%) compared to BMI, AC, ABSI, and VIA, from the cutoff points identified in the ROC curve (Youden index). BMI obtained the lowest sensitivity value for premenopausal women (46.33%) and AC for postmenopausal women (24.90%). Regarding specificity, the values ranged from 49.72% to 83.43% for premenopausal women, with the highest value referring to BMI and the lowest to ABSI. For postmenopausal women, the values ranged from 42.86% to 69.57%, with the VIA presenting the highest specificity value and the BRI the lowest. **Conclusion:** The VIA was the anthropometric index that obtained the highest area under the ROC curve in pre and postmenopausal women. With a lower accuracy power, the AC and the BRI were considered good at tracking MS in climacteric women, particularly the BRI, which achieved high sensitivity. However, BMI and ABSI did not prove helpful in the studied population.

**Sources of Funding:** None

## P-82.

### Mobile application for screening metabolic syndrome in climacteric women.

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**Objective:** To describe the development process of an application aimed at primary care physicians, designed to facilitate the identification of climacteric women predisposed to develop the metabolic syndrome (MS) from the calculation of an appropriate anthropometric index. **Design:** This is applied research initially composed of a planning stage, with the definition of the Body Roundness Index (BRI) and the Visceral Adiposity Index (VIA) as the most appropriate anthropometric measures to be used, according to a study that evaluated the ability of anthropometric indices to discriminate the MS in climacteric women. After defining the cutoff points of the BRI and the VIA, the application architecture was designed, containing the navigation and user interaction screens, with a brief explanation about the objectives, as well as the forms for selecting the variables and entering the anthropometric measurements needed to calculate the BRI and VIA. After defining the application's design, we researched the best tool to build it. Based on emerging technologies, it was decided to use a mobile application development kit created by Google called Flutter, which eases the creation of applications and uses Dart programming language, also created by Google. **Results:** The mobile application developed was named ClimatMed. It is available for free on the Google Play Store Platform and can be installed on smartphones with the Android system. The initial screens of the application contain a brief introduction, with an explanation of the theme and the objective, and present the partner institutions of this project. When clicking on the "learn more" option, the person has access to the diagnostic criteria for MS according to the International Diabetes Federation - IDF (2006), in addition to the concepts of the anthropometric measurements used (BRI and VIA). On the initial screen, by clicking the "Start" button, the application displays a screen so the woman can define the climacteric period in which she is (pre- or postmenopause) and the variables that were adjusted (level of physical activity, alcohol consumption, and smoking). To assess the level of physical activity, we used the International Physical Activity Questionnaire (IPAQ), developed and validated by Craig et al. (2003). This questionnaire classifies women as very active/active, irregularly active, and sedentary through questions related to physical activity performed in the last week for at least 10 continuous minutes before answering the questionnaire. Then, the measurements required to calculate the BRI can be entered (abdominal circumference and height). As a result, the application provides the probability of developing MS. This probability is calculated by the logistic regression models obtained from the database created. After this, one can close the application or continue adding the anthropometric measurements required to calculate the VIA, triglycerides, and HDL. Then, it automatically calculates the index and the probability of the patient developing MS. The application also allows the storage of the history of the results, which eases the monitoring and improves the system. **Conclusion:** The insertion of computer technology into the medical consultation of climacteric women brings numerous contributions, especially to the public health system, because it allows cost savings, besides being simple and accessible to the professional. Additionally, the identification of this population predisposed to develop MS helps in the prevention of chronic cardiovascular diseases. As future work, ClimatMed will be made available for the IOS system and a version for Web browsers.

**Sources of Funding:** None.

## P-83.

### Predictors of Quality of Life in Postmenopausal Women

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**Objective:** The study aimed to examine the prediction of quality of life in postmenopausal women based on the use of some body composition, socio demographic and menopause related variables. **Design:** A descriptive cross-sectional research was conducted on 131 postmenopausal women, aged 42-72 years and stratified according time since menopause (63 in early postmenopause and 68 in late postmenopause). Menopause-Specific Quality of Life Questionnaire (MENQOL) was used to assess menopause related symptoms and fat mass (FM), visceral fat level (VFL) and skeletal muscle mass (SMM) were measured with the bioimpedance InBody 120. Some sociodemographic variables were explored (age, education). The cut-off points for obesity, high visceral fat and low muscle mass were respectively FM $\geq$ 35%, LVF $>$ 9 points and SMM $<$ 15 kg. The MENQOL variables was categorized into two groups, based on the mean values identified in the sample (vasomotor and sexual domains:  $\leq$ 2 and  $>$ 2; total scale, psychosocial and physical domains:  $\leq$ 3 and  $>$ 3). Binomial logistic regressions were developed to predict the presence of lower or higher MENQOL values as a function of categorical independent variables (age, education, adiposity, hormone therapy and stage of reproductive aging). The ROC curves were developed and a p value lower than 0.05 was accepted as significant. **Results:** The mean of the total MENQOL scale was 3.30 ( $\pm$ 1.26), with the psychosocial and physical (Phyd) domains exhibiting the highest mean values. Most participants revealed a natural menopause (93.1%), the non-use of hormone therapy (HT) and at least the high school graduation. Elevated levels of total (76.3%) and central (80.9%) adiposity were also identified but all the women exhibited a normal muscle condition. The models developed for the vasomotor, psychosocial, and sexual domains did not prove to be statistically significant. The logistic regression model developed for the Phyd was significant ( $\chi^2=22.55$ ,  $p<0.01$ ), explained 21.4% of the variance and correctly predicted 89% of participants with Phyd $\leq$ 3. The HT proved to be a significant predictor ( $\beta=2.623$ ,  $p<0.01$ ) and the area under the ROC curve (AUC) was 0.74 (95% CI, 0.66 to 0.83). For the MENQOL total scale ( $\chi^2=13.19$ ,  $p=0.04$ ), the sensitivity was 45.7% and specificity was 84.6%, but the ROC curve analysis revealed poor discrimination (AUC=0.67; IC95%, 0.72 to 0.89). Being younger and using HT increased the odds of a better quality of life by 3.08 and 3.43, respectively. **Conclusion:** The results suggest that the use of HT provides greater chances to postmenopausal women to present a better quality of life, namely regarding the physical domain. Younger women are also more likely to have better values on the MENQOL scale.

**Sources of Funding:** None

## P-84.

### Quality of Life in Postmenopausal Women: Influence of Physical Activity and Adiposity Levels

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**Objective:** This study aims to explore the influence of physical activity and anthropometric indicators of obesity in quality of life of postmenopausal women. **Design:** A cross-sectional study was conducted on 98 women aged 44-72 years. The Menopause-Specific Quality of Life Questionnaire (MENQOL) was used to assess menopause related symptoms and standard procedures for anthropometry were followed, including weight, height and waist circumference (WC). The socio demographic data were obtained by questionnaire. Triaxial accelerometers wGT3X-BT were used to measure the moderate-vigorous physical activity (MVPA) and steps/day. Cut-off points for MVPA and steps/day were 150 min/week and 10000, respectively, and obesity risk was identified for values of body mass index (BMI)  $\geq$  25.5 kg/m<sup>2</sup> and WC  $\geq$  80 cm. Student t tests or Mann-Whitney test were applied and stepwise multiple regressions were conducted to evaluate explanatory factors associated with MENQOL using continuous variables (BMI, WC, age, steps/day, MVPA) and dummy variables (number of children, education, hormone therapy and stages of reproductive aging). A 5% degree of statistical significance was considered. **Results:** Most of the participants had a late postmenopause (54.1%), natural menopause (91.8%) and did not document the use of hormone therapy. The mean of the total MENQOL scale was 3.44 points ( $\pm$ 1.30), with higher values in the physical and psychosocial domains. Many of the participants displayed obesity and especially central obesity (85.7%). Most of the sample was physically active (MVPA $\geq$ 150min/week) but only 22.4% performed at least 10000 steps/day. No differences were observed in the various MENQOL domains according to the established adiposity and physical activity groups. Age was the only predictor selected for the total MENQOL scale ( $\beta=-0.29$ ,  $p=0.03$ ) and psychosocial domain ( $\beta=-0.25$ ,  $p=0.02$ ), explaining respectively 3% and 5% of its variance. Increased BMI was associated with higher values in the physical domain ( $\beta=0.25$ ,  $p=0.01$ ). **Conclusion:** The results suggest no differences in the

quality of life of postmenopausal women according to the groups considered for BMI, WC, MVPA, and steps/day. However, women with higher levels of adiposity seem to exhibit better scores in the physical domain, regardless of menopausal characteristics.

**Sources of Funding:** None

#### P-85.

##### **Sedentary behavior and associated factors in climacteric women.**

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**Objective:** To evaluate sedentary behavior in climacteric women and associated factors. **Design:** This is a population-based epidemiological study with a cross-sectional design, in the Municipality of Montes Claros, Minas Gerais, Brazil. Data were obtained through questionnaires, anthropometric evaluation, and collection of peripheral venous blood for biochemical parameters analysis. The data were typed and stored in the statistical software SPSS. Initially, an exploratory, descriptive analysis was performed, with the frequency distribution of the study variables according to sedentary behavior. The Random Forests (RF) classification technique was used, which listed the variables in order of predictive importance and selected the variables as input for the final classification model. To understand sedentary behavior related to the exposure variables, multivariate analysis was performed using the Decision Tree (DT) method. The DT method, with the Classification and Regression Tree (C&RT) algorithm, was used to investigate predictor variables of sedentary behavior as an alternative to the logistic regression method, given the limitations of these models available for analysis.

**Results:** A total of 873 climacteric women participated in the study, with a mean age of 51.0±7.08 years. Regarding education, 65.7% of women had ≤ 8 years of education, most had non-white skin color, with a steady partner, and family income averaged 1,362.91±977.52 reais (Brazilian currency). Regarding reproductive variables, most women reported having had menarche at regular age, < 3 vaginal deliveries, ≤ 1 cesarean delivery, were classified in the pre/perimenopausal period, had natural menopause, did not use hormone replacement therapy (HRT), and had mild climacteric symptoms. Regarding behavioral characteristics, most interviewees reported not being smokers and alcohol drinkers. However, regarding sedentary behavior, 65.8% of the women were above the threshold (≥ 171 min/day). Regarding eating habits, a relevant group of women reported not eating meat with fat, not adding salt to food, and consuming ≤ 02 fruits a day. As for the clinical variables, most women have compromised sleep quality, lack of daytime sleepiness, absence of metabolic syndrome, intermediate cardiovascular risk, no urinary incontinence, gout disease, rheumatoid arthritis, low back pain, and cancer. Concerning depressive and anxiety symptoms, a significant share of the population had mild symptoms and a positive perception of health status. The following variables were selected for input into the final classification model: skin color, menarche, diastolic blood pressure (DBP), low back pain, waist circumference, total cholesterol, HDL-cholesterol, and triglycerides. The decision tree indicated that the variables total cholesterol, diastolic blood pressure, body mass index (BMI), and triglycerides were associated with sedentary behavior. Those women with total cholesterol ≥ 236.5 are more prone to sedentary behavior when compared to women with total cholesterol < 236.5. Regarding diastolic blood pressure, women with DBP < 75mmHg formed a group more prone to sedentary behavior when compared to women who had DBP ≥ 75mmHg. Women with BMI ≥ 30.02 were more inclined to sedentary behavior when compared to women with BMI < 30.02. In addition, women with triglycerides ≥ 157.5 were also more likely to possess sedentary behavior. The metrics used to evaluate the quality of the results of the Decision Tree model showed the following results: Accuracy = 0.6632; Recall = 0.8171; Precision = 0.7128; and Fscore = 0.7614. **Conclusion:** The present study showed an elevated prevalence of sedentary behavior, which was associated with high total cholesterol levels, low diastolic blood pressure, obesity, and high triglyceride levels.

**Sources of Funding:** None.

#### P-86.

##### **Investigating the effect of exposure to a novel digital menopause-focused education, care, and community platform on mid-life women**

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**Objective:** The menopause experience is influenced by numerous factors, including physiological symptoms, cultural perceptions, available resources, and education on the menopause transition. Access to evidence-based, menopause-focused educational resources and personalized menopause counseling outside of a clinical setting is limited. However, digital tools can help to mitigate issues of limited access. Prior research has demonstrated that exposure to a digital-based menopause-focused intervention has increased health-directed behaviors and decreased menopause-related symptom severity [1]. Building on this, the University of Rochester and Elektra Health are undertaking a new study to evaluate the impact of Elektra's novel digital menopause-focused education, care and community platform on reported menopause-associated symptom severity and menopause preparedness in menopausal women. **Design:** This single-center prospective

cohort study included a sample of women aged 40-65 with reported internet access via computer or smartphone. Pregnant participants were excluded. Age, race, use of hormone replacement therapy (HT), and a diagnosis of anxiety or depression were obtained from the participant's medical records. Baseline demographic and medical history data were abstracted from the medical record. Participants completed pre- and post-exposure clinically validated questionnaires, including Menopause Rating Scale (MRS) to assess menopause symptoms, anxiety (GAD2), depression (PHQ2) and non-validated menopause preparedness questionnaires, relating to mindset, work, and productivity. Once enrolled, subjects had 60 days of access to digital resources, including menopause-focused webinars, written articles, one-to-one coaching by menopause trained nurses or doulas, and virtual discussion groups. Engagement was assessed by activity, completion of educational modules and counseling sessions. **Results:** Data collection is ongoing. The study is projected to be completed by September 2023. A total of 50 subjects aged 40 to 65 were consented and enrolled in the study. Enrollment began on May 22nd and was complete by June 27th. The mean age was 54.6 years with twenty-seven (54%) participants identified as postmenopausal. Seven (14%) participants are receiving HT. Thirty-two (64%) participants scheduled a virtual individual session with a menopause guide and 7 calls have been completed to date. **Conclusion:** Menopause preparedness is multifaceted and time-intensive from the provider perspective. Common barriers in receiving high quality menopause care and counseling include provider knowledge gap and visit time constraints. The results of this study will garner data that will meaningfully further the current understanding of how digital health interventions can help to mitigate constraints, and thereby improve quality of life for menopausal patients. Specifically, they will provide additional information on the effectiveness of utilizing an integrated menopause-focused digital health platform in women with menopause. Digital platforms may prove to be a powerful tool in ensuring women have access to accurate educational resources, high quality menopause care and management, and a supportive community. References 1. Yeganeh, L., et al., *Positive impact of a co-designed digital resource for women with early menopause*. Menopause, 2022. 29(6): p. 671-679.

**Sources of Funding:** None

#### P-87.

##### **Characterizing treatment pathways for endocrine therapy-related menopausal symptoms in the US**

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**Objective:** Over 80% of women receiving endocrine therapy (ET) for breast cancer may experience menopausal symptoms including vasomotor symptoms (VMS), which can impact quality of life and lead to ET discontinuation and reduced cancer survival. Effective treatment options for ET-related menopausal symptoms are limited as hormone therapy (HT) is contraindicated in women receiving ET. There is little evidence on utilization patterns of prescription medications for ET-related menopausal symptoms. This study aimed to describe treatment pathways for ET-related menopausal symptoms in the US.

**Design:** This large retrospective cohort study was conducted across administrative claims databases from the US, standardized to the Observational Medical Outcomes Partnership Common Data Model. Data from IBM<sup>®</sup> MarketScan<sup>®</sup> are reported (study period: January 2009 to June 2020). The study analyzed the sequence and combination of treatments prescribed to women aged 18–65 years following initiation of ET for breast cancer or for a condition considered high risk for breast cancer. Treatment classes of interest were HT, non-HT (as per the NAMS 2015 position statement) and benzodiazepines. A gap of less than 30 days between prescriptions indicated a treatment combination while a gap of 30 days or more indicated a change of line of treatment. Only treatment pathways with over 250 women are reported. **Results:** Overall, 239,486 women received a first prescription of ET with a diagnosis of breast cancer or at high risk for breast cancer; median follow-up was 2.1 (interquartile range 1.1–4.0) years. The majority (71.0%) were aged over 50 years. The most common non-oncological comorbidities were hypertension (n=32,842, 13.7%), osteoarthritis (n=23,621, 9.9%), anxiety (n=23,369, 9.8%), and depression (n=19,387, 8.1%). Treatments of interest were recorded in 86,165 women (36.0%); 75,039 (31.3%) followed a treatment pathway with over 250 women. Pathways with only one line of treatment were reported in 65,079 women (86.7%); benzodiazepines, venlafaxine and gabapentin were most prescribed. Two lines of treatment were reported in 9,960 women (13.3%); benzodiazepines, venlafaxine and gabapentin were the most prescribed first-line and combinations of benzodiazepines with gabapentin or venlafaxine were the most common second-line treatments (Table 1). Pathways that featured HT were reported in 9,312 women (12.4%), of whom 8,413 (90.3%) had HT prescribed first-line. Estrogens were prescribed in 6,605 women (70.9%), progestogens in 1,163 (12.5%), raloxifene in 867 (9.3%) and combination estrogen and progestogen in 677 (7.3%). **Conclusion:** In this study, which included all women initiating ET for breast cancer or high breast cancer risk, without criteria for ET-related menopausal symptoms, only one-third of women received a treatment of interest. This suggests that menopausal symptoms often go unrecognized and untreated. Almost 90% of women had only one reported line of treatment; benzodiazepines were most prescribed. Depression and anxiety were among the most common comorbidities; thus, usage may not be solely for menopausal symptom management. The most prescribed pathways with more than one line of treatment always included the combination of another medication with the first-line treatment, which may indicate that the initial medication was insufficient to control symptoms. Over 12% of reported pathways included HT, despite HT being contraindicated in this population, although there are no route of administration data so patients may have received vaginal

HT for local symptoms, a common practice in menopause clinics. This contraindicated use of HT highlights the unmet treatment need for women experiencing ET-related menopausal symptoms.

**Sources of Funding:** Bayer AG

Table 1. Top five treatment sequences by number of lines of treatment

Total number of women	Total number of women with reported treatment pathway	Lines of treatment	First-line treatment	Second-line treatment	Number of women	Percentage (of all women with reported treatment pathways)
239,486	75,039	One	benzodiazepines	NA	22,176	29.6%
			venlafaxine	NA	10,786	14.4%
			gabapentin	NA	10,144	13.5%
			estrogens	NA	5,088	6.8%
			citalopram	NA	3,571	4.8%
		Two	benzodiazepines	benzodiazepines + gabapentin	1,545	2.1%
			venlafaxine	venlafaxine + benzodiazepines	1,455	1.9%
			gabapentin	gabapentin + benzodiazepines	1,198	1.6%
			venlafaxine	venlafaxine + gabapentin	1,040	1.4%
			benzodiazepines	benzodiazepines + venlafaxine	811	1.1%

**P-88.**

**Characterizing treatment pathways for natural menopausal symptoms in US women**

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**Objective:** Menopausal women may experience a range of symptoms that can impact their quality of life, including vasomotor symptoms (VMS), sleep disturbances, and mood changes. Available effective treatments for menopausal symptoms include hormone therapy (HT) and nonhormonal treatments (non-HT). Despite paroxetine being the only non-HT approved for VMS in the US, antidepressants and anticonvulsants are often prescribed to menopausal women and are recommended by menopause experts. There is limited evidence on longitudinal HT and non-HT utilization patterns for symptoms of menopause. This study aimed to describe treatment pathways used to manage symptoms of natural menopause in the US. **Design:** This large retrospective cohort study was conducted across administrative claims databases from the US, standardized to the Observational Medical Outcomes Partnership Common Data Model (study period: January 2009 to June 2020). Data from IBM® MarketScan® are reported. We analyzed the sequence and combination of treatments prescribed to women aged 40–65 years following a first recorded diagnosis of natural menopause. Treatment classes of interest were HT, non-HT (as per the NAMS 2015 position statement on nonhormonal management of VMS) and benzodiazepines. A gap of less than 30 days between prescriptions indicated a treatment combination while a gap of 30 days or more was considered a change of line of treatment. Only treatment pathways with over 500 women are reported. **Results:** Overall, 1,263,336 women diagnosed with natural menopause were included in the cohort with a median follow-up of 2.3 (interquartile range 1.2–4.1) years. The majority (57.3%) were aged 50–59 years, 21.6% were aged 40–49 years, and 21.1% were aged 60–65 years. The most common comorbidities were osteoarthritis (n=92,761, 7.3%), hypertension (n=90,692, 7.2%), and hypothyroidism (n=52,071, 4.1%). Treatments of interest were recorded in 454,726 (36.0%) women; 411,765 (32.6%) followed a treatment pathway with over 500 women. In total, 345,796 women (84.0%) had only one reported line of treatment; estrogens, benzodiazepines and gabapentin were most prescribed. Two lines of treatment were reported in 65,208 women (15.8%); estrogens and benzodiazepines were the most prevalent first-line treatments, with a combination of these being the most common second-line treatment (Table 1). Three lines of treatment were reported in 761 women (0.2%); all had first-line estrogens, second-line addition of benzodiazepines, third-line addition of gabapentin. Pathways including combinations of estrogen and progesterone were reported in 26,060 women (6.3%), but none of these pathways were among the most common. Paroxetine was prescribed to 8,797 women (2.1%) with a treatment pathway reported. **Conclusion:** Two-thirds of women with a diagnosis of natural menopause did not receive a treatment of interest, suggesting a significant undertreatment of menopausal symptoms. Most women had only one reported line of treatment; estrogens were most prescribed. Paroxetine was prescribed to fewer women than other non-HT, despite being the only non-HT approved for VMS. Benzodiazepines and off-label antidepressants were highly prescribed (although these may also be used for non-menopausal symptoms). The most common pathways with more than one line of treatment involved medications added to the first-line treatment, rather than a treatment switch, with estrogen and benzodiazepine combinations being most prescribed. Taken together, this indicates that the first-line treatment was insufficient to manage menopausal symptoms for some women (with likely more severe symptoms) and may reflect an unmet need for management of sleep disturbances or mood changes, in addition to VMS.

**Sources of Funding:** Bayer AG

Table 1. Top five treatment sequences by number of lines of treatment

Total number of women	Total number of women with reported treatment pathway	Lines of treatment	First-line treatment	Second-line treatment	Number of women	Percentage (of all women with reported treatment pathways)
1,263,336	411,765	One	estrogens	NA	119,762	29.1%
			benzodiazepines	NA	100,818	24.5%
			gabapentin	NA	29,651	7.2%
			sertraline	NA	12,478	3.0%
			venlafaxine	NA	11,237	2.7%
		Two	estrogens	estrogens + benzodiazepines	12,849	3.1%
			benzodiazepines	benzodiazepines + estrogens	6,606	1.6%
			estrogens	estrogens + gabapentin	4,840	1.2%
			benzodiazepines	benzodiazepines + gabapentin	4,741	1.2%
			gabapentin	gabapentin + benzodiazepines	3,135	0.8%

**P-89.**

**Vaginal and sexual health in patients with ER+/HER2- metastatic breast cancer (mBC)**

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**Objective:** Vaginal/sexual health concerns are common but often understudied in women with breast cancer (BC) being treated with endocrine therapy (ET). The objective of this survey was to better understand these concerns in ER+/HER2- mBC patients (pts). **Design:** The 50-question, online EQUALS 2 (ESR1 QUALITY of Life Survey 2) survey was emailed to US subjects from the Cure Media Group and authors' contacts, and was also posted on private Facebook groups of pts with mBC in March and April 2023. Subjects were eligible if they had ER+/HER2- mBC. Pts received a \$10 gift card at survey completion. Survey answers were descriptively summarized. **Results:** 200 pts completed the survey and were almost equally distributed (22%–29%) to 4 age subgroups (<47, 47–55, 55–60, >60 y). The majority were White (85%), and had higher education (73%) and a female oncologist (78%). Most (84%) pts were very concerned that their mBC was impacting their family. Prior ET for early-stage BC was used by 79% of patients and negatively impacted the sexual health of 62%. Current treatments for mBC included aromatase inhibitor±CDK4/6 inhibitor (38%), antibody-drug conjugate/chemotherapy (33%), fulvestrant±CDK4/6 inhibitor (16%), antiestrogen+everolimus or alpelisib (3%), and elacestrant (3%). Pts were on 1<sup>st</sup> (29%), 2<sup>nd</sup> (17%), 3<sup>rd</sup> (23%), or 4<sup>th</sup> (28%) therapy line for mBC. Vaginal symptoms were experienced in 61% of pts and associated with BC treatment for a mean of 4.8 y. Most bothersome symptoms were vaginal dryness (33%), painful intercourse (14%), vaginal itching (10%), and vaginal irritation (5%). Limited enjoyment of sexual activity (39%) was the most reported impact of vaginal dryness since starting treatment, followed by painful intercourse (33%) and vaginal burning/itching (32%). Top interventions used to alleviate vaginal symptoms were vaginal moisturizers/lubricants (45%), natural oils (33%), topical vaginal estrogens (27%), and supplements (21%); only 9% did not try any intervention. Therapies most frequently considered helpful were natural oils (91%), vaginal moisturizers/lubricants (77%), topical vaginal estrogens (74%), supplements (67%), and laser therapy (67%). About half (54%) of pts never or almost never felt sexual desire/interests in the past month, particularly those whose sexual health was negatively impacted by prior ET (61%); 56% felt bothered by low sexual desire. The vaginal/sexual side effects of BC treatment were a concern for most pts (80%), negatively impacting the frequency of sexual intercourse (61%) and their self-esteem (64%), and making 51% feel isolated. Most (78%) felt that BC negatively impacted their body image. About a third of pts felt poorly informed by their medical team (MT; 38%) and not comfortable talking with their MT (31%) about vaginal/sexual side effects; 33% also felt poorly equipped to improve these side effects. Pts were more likely to feel well informed by their MT (54% vs 27%) or more comfortable talking with their MT (59% vs 44%) about these side effects if they had a female vs male oncologist. Pts more frequently discussed vaginal/sexual side effects with their gynecologist (33%) than their oncologist (15%); similarly, they more frequently obtained information on these side effects from their gynecologist (33%) rather than oncologist (8%). The majority (93%) of pts showed interest in trying a treatment if it was effective in treating BC, FDA approved, and well tolerated, and could also improve vaginal/sexual health. **Conclusion:** In this survey of pts with ER+/HER2- mBC, >60% experienced vaginal symptoms and felt their sexual health was negatively impacted by prior ET. Pts were concerned about the vaginal side effects from their BC treatment, which negatively impacted their self-esteem and made them feel isolated. About a third of pts felt poorly informed or uncomfortable discussing these side effects with their MT. These data highlight unmet needs for improving vaginal/sexual health while treating BC, and better patient/oncologist communication about vaginal/sexual concerns.

**Sources of Funding:** Sermonix Pharmaceuticals

**P-90.**

**Patient experience and management of vasomotor symptoms due to menopause: voices from the PatientsLikeMe community**

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**Objective:** Vasomotor symptoms (VMS) due to menopause cause significant burden and distress. Many women do not report symptoms to healthcare providers or seek treatment for various reasons including shame and discomfort. Some women join online communities to share with others their experiences with VMS, treatment outcomes, and ways to improve care through peer-to-peer interactions. About half of women who report symptoms have delayed seeking treatment for >6 months. This study aimed to describe women's experiences with VMS and approaches to symptom management. **Design:** Mixed-methods research was performed through database analysis of posts and in-depth interviews with members of the PatientsLikeMe (PLM) online community. PLM posts were searched using keywords such as hot flashes and sleep disturbance. Relevant text was extracted and screened to limit data to US females aged 40–65 years. Qualitative text analysis methods categorized and explored themes. Semi-structured interviews were then conducted with a convenience sample from PLM. Eligible participants were females aged 40–65 years who were experiencing VMS and were fluent in English. Interview moderators asked open-ended questions and prompted conversation about menopause. Interviews were recorded, transcribed, and themes identified. **Results:** Database analysis revealed the most common symptom was “experiencing hot flashes and night sweats.” Women described wide-ranging severity of symptoms that could last many years. Women's posts reported that symptoms negatively affected mental health, quality of life, and ability to work. Interviews were conducted with 14 PLM members with VMS due to menopause. Participants had a median age of 53.5 years; median age of symptom onset was 47 years, and median symptom duration was 8 years. Common concepts, themes, and patient quotes are presented in Table 1. **Conclusion:** Women reported diverse experiences with VMS due to menopause. For some women, symptoms impaired physical and mental well-being and negatively affected social activities, employment, and quality of life. Women also reported various approaches to managing VMS, including medication and lifestyle modification.

**Sources of Funding:** The study was sponsored by Astellas Pharma, Inc. (Northbrook, IL). Writing support by Nicole Boyer, PhD, MPH, and LeeAnn Braun, MPH, MEd, of Peloton Advantage, LLC, an OPEN Health company.

Table 1. Experiences of women with vasomotor symptoms: results from semi-structured interviews (n=14)

Themes	Concepts	Quotes
Symptom type/frequency	<ul style="list-style-type: none"> <li>Most common symptoms (number of mentions): night sweats (n=13), hot flashes (n=12), insomnia and anxiety (n=11)</li> <li>Frequency and symptoms varied</li> </ul>	<ul style="list-style-type: none"> <li>“Daytime, nighttime, waking up with my entire head soaked, my clothes. I’ve even had bedding soaked. It doesn’t really matter what time of the day, but the night’s worse.”</li> <li>“I suddenly had a lot more trouble falling asleep... I just have such a hard time.”</li> <li>“... perimenopause has been incredibly tough for the duration, but hot flashes and night sweats and increased anxiety have been the worst of it.”</li> </ul>
Impact on quality of life	<ul style="list-style-type: none"> <li>Primary concerns were physical discomfort and compromised emotional/mental state impacting social life and work productivity</li> </ul>	<ul style="list-style-type: none"> <li>“... you can’t do things the same. I mean, not many people have to wake up and change and... it’s embarrassing.”</li> <li>“I felt miserable... it’s very difficult for me to have a normal life. I feel like I’m not myself and [not functioning at my usual] work level.”</li> <li>“It’s inconvenient in your day-to-day life and it’s frustrating...”</li> </ul>
Symptom management	<ul style="list-style-type: none"> <li>Over-the-counter medication (eg, Estrogen)</li> <li>Prescription medication (eg, antidepressants, oral contraceptives, hormone-replacement therapy)                             <ul style="list-style-type: none"> <li>Canabidiol</li> <li>Black cohosh</li> <li>Vitamin D</li> <li>Exercise</li> <li>Meditation</li> </ul> </li> <li>Temperature regulation (eg, air conditioning)</li> </ul>	<ul style="list-style-type: none"> <li>“I did try both bioidentical hormones and synthetic hormones... bioidentical hormones did nothing to change my hot flashes and night sweats... synthetic hormones didn’t do anything either, but they caused really, really bad anxiety.”</li> <li>“Last year I got the antidepressants from my primary care doctor, but they had me feeling really depressed... they were supposed to help with hot flashes.”</li> </ul>

**P-91.**

**Demographic and Behavioral Predictors of Bothersome Hot Flashes and Night Sweats**

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**Objective:** Hot flashes (HF) and night sweats (NS) are common and bothersome symptoms during the menopausal transition, occurring in approximately 85% of women. In the literature, HF and NS are often combined into one variable: vasomotor symptoms (VMS). However, some data show that predictors as well as the impacts of HF and NS are not the same. Additionally, while many studies focus on frequency of VMS, the bothersomeness of VMS may be a more important variable for health and well-being. In this study, we explore whether the bothersomeness of HF and NS are predicted by the same demographic and behavioral variables. **Design:** Our sample was drawn from a study of brown adipose tissue and HF. Women aged 45–55 living in Western Massachusetts (n=274) were interviewed about their demographics, health, and menopausal experience. As part of the survey, women were asked about symptom severity, and HF and NS were coded as not bothersome (not at all or a little) or bothersome (somewhat or a lot). Binary logistic regressions were run separately for HF and NS in relation to financial comfort, marriage status, sexual orientation, self-reported health, smoking status, alcohol consumption, employment status, total symptom experience (excluding VMS), and parity.

Both models were adjusted for menopausal status. **Results:** Among all participants, 46% reported bothersome HF, and 43% reported bothersome NS. Postmenopausal status increased the odds of both HF and NS. Higher self-rated health scores were associated with an increase in risk for bothersome NS (Good Health: OR 2.64, 95% CI 1.08–6.48, Excellent Health: OR 2.97, 95% CI 1.11–7.98), but not for bothersome HF (OR, CI, ns). Higher alcohol consumption reduced the odds of bothersome HF and NS (HF: OR 0.50, 95% CI 0.29–0.86, NS: OR 0.50, 95% CI 0.29–0.86). Higher total symptom experience was associated with higher risk of HF and NS (HF: OR 1.07, 95% CI 1.03–1.11, NS: OR 1.08, 95% CI 1.04–1.12). **Conclusion:** We found that HF and NS were predicted by the same demographic and behavioral factors, with the exception of self-reported health. Alcohol consumption was associated with lower incidence of bothersome HF and NS, but total alcohol consumption in our sample was low (average 0.46 drinks per day). Higher total symptom experience may reflect a higher sensitivity to physical and emotional experiences, thus increasing the bothersomeness of both HF and NS. We suggest that future analyses examine HF and NS separately to further elucidate the differences between the two symptoms.

**Sources of Funding:** NSF BCS-1848330

**P-92.**

**Brown adipose tissue activity increases the risk of bothersome hot flashes**

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**Objective:** Hot flashes (HF) are experienced during the menopausal transition as sudden, uncomfortable, sensations of heat. Declining levels of estrogen result in a narrowing of the thermoneutral zone – between the temperatures that provoke shivering and sweating – and this narrowing contributes to an increased likelihood of HF. Even small changes in the core body temperature (Tc) can induce sweating responses, and small increases in Tc have been documented prior to HF occurrence. This study was prompted by peri-menopausal women asking, “How can I be hot and cold at the same time?” We posited that brown adipose tissue (BAT) activation could increase Tc within a narrowed thermoneutral zone, and this could be a cause of HF. BAT is a specialized fat tissue that plays a role in inducing non-shivering thermogenesis. The objective of this study was to test the hypothesis that women with more BAT activity would have more evidence of HF experience during the coldest months of the year (October through April) in western Massachusetts. **Design:** To date, 269 women aged 45 to 55 years participated in semi-structured face-to-face interviews, anthropometric measures, and bio-electrical impedance analysis (BIA). Hot flashes during the past two weeks were queried as “not at all,” “a little,” “somewhat,” or “a lot.” For this analysis, hot flashes were defined as not bothersome (“not at all” or “a little”) or bothersome (“somewhat” or “a lot”). BAT activity was estimated from the difference in supraclavicular skin temperature measured by infrared thermography before and after the participant placed her hand in cold (17°C) water for five minutes. Sternal temperature measures were used as a control. Body mass index (BMI) was computed as kg/m<sup>2</sup>, and percent body fat (%BF) was computed from BIA. Menopausal status (pre-, peri-, post-) was based on changes in menstruation per STRAW+10 categories. Education (high school or less; some college or degree; some post-graduate work or degree) and financial comfort (“struggling,” “OK,” “comfortable,” or “well-off”) were also included in analyses. Logistic regression analysis was applied to examine bothersome hot flashes in association with BAT activity while adjusting for menopausal status, adiposity (BMI or %BF), and socioeconomic status (education or financial comfort). BMI and %BF were highly correlated, as were education and financial comfort; one of each pair was included in separate models. **Results:** Within the total sample, HF during the past two weeks were fairly evenly described as “not at all” (29.8%) “a little” (25%), “somewhat” (22.1%), or “a lot” (23.2%). These were divided into not bothersome (54.8%) and bothersome (45.2%) categories. Supraclavicular BAT activity ranged from 0 to an increase of 1.6°C relative to control with a mean of 0.3°C. BMI ranged from 18.1 to 54.0 kg/m<sup>2</sup> with a mean of 28.3 kg/m<sup>2</sup>, and %BF ranged from 17% to 54% with a mean of 37%. Participants were most often peri- (43.2%) or post- (38.3%) menopausal; 52% had post-graduate work or earned a post-graduate degree; and most described themselves as financially “OK” (35.6%) or “comfortable” (47.4%). In all logistic regression models, estimated BAT activity was significantly associated with an increase in the odds of bothersome HF. In the logistic regression model with estimated BAT activity, menopausal status, BMI, and financial comfort, BAT activity almost tripled the likelihood of bothersome HF (OR 2.85, 95% CI 1.25–6.52). **Conclusion:** To our knowledge, this is the first study of BAT activation and HF. Our hypothesis was supported: estimated BAT activity increased the likelihood of bothersome, subjectively reported HF in the past two weeks. In addition to considering the role of BAT in lipid and glucose metabolism, diabetes, and obesity, we encourage further examination of the role of BAT in relation to HF, especially in cool ambient temperatures.

**Sources of Funding:** NSF BCS-1848330

**P-93.**

**Screening for Detection of Ovarian Cancer Among Average Risk Postmenopausal Women**

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**Objective:** Ovarian cancer is one of the gynecologic cancers with the highest mortality that usually presents with nonspecific symptoms, often resulting in late diagnosis. Data note that only ~20% of ovarian cancers are found at an early stage. However, when found early, 94% of women live longer than 5 years after diagnosis [1]. According to the American Cancer Society, half of all ovarian cancers are found in women 63 years or older, making this population especially vulnerable. Prior studies focus on screening

recommendations for high-risk women, which includes those with BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, STK11, MUTYH and EPCAM mutations, and/or have family cancer history including ovarian, breast, and colon. This review assesses current literature regarding early detection of ovarian cancer via routine screening measures for average risk postmenopausal women. **Design:** A literature review was conducted using Rutgers Libraries QuickSearch Database. Keywords included “postmenopausal”, “ovarian cancer” and “screening”. **Results:** The consensus of numerous studies is that the use of transvaginal ultrasonography, tumor markers such as CA-125, and bimanual pelvic examination conducted alone or in combination does not reduce mortality and may pose more harm than benefits in non-high-risk women. Specifically, these measures lead to unnecessary or invasive diagnostic testing, false-positives, and overall distress for a woman [2]. The UK Collaborative Trial of Ovarian Cancer Screening, one of the largest ovarian cancer screening trials to date found that neither multimodal nor transvaginal ultrasonography screening reduced ovarian cancer mortality vs. no screening in average risk postmenopausal woman [5]. Given the difficulty of finding an appropriate screening test, other modalities have been explored. The ovarian cancer symptoms (Goff) index was created that assesses specific symptoms in conjunction with their frequency and duration which was found useful in identifying women with ovarian cancer earlier. It included: pelvic/abdominal pain, urinary urgency/frequency, increased abdominal size/bloating, and difficulty eating/feeling full when they were present for <1 year and occurred >12 days per month [3]. **Conclusion:** These data suggest that there are no current screening measures suitable for the early detection of ovarian cancer. Furthermore, most current literature focus on high-risk populations, which includes women with genetic predispositions or family history. These results highlight the importance of studying early detection methods of ovarian cancer in average-risk postmenopausal women, who make a large percentage of ovarian cancer cases. Additional research should investigate the efficacy of educational interventions by clinicians. That is, patients should be made aware of the most common earliest presenting signs and symptoms of ovarian cancer as found by the ovarian cancer symptom (Goff) index. Future direction includes studying if instituting these interventions when a woman becomes postmenopausal followed by annual symptom monitoring questionnaires improves detection, mortality, and stage of diagnosis among this specific population.

**Sources of Funding:** None

#### P-94.

##### **Association of primary ovarian insufficiency with depression in US women: a national population-based study**

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**Objective:** Higher frequency of depressive-like symptoms was reported in women with primary ovarian insufficiency (POI). However, few studies have investigated depression in women with POI in a nationwide survey. We aimed to investigate the association of depression with POI. **Design:** This cross-sectional study is based on the National Health and Nutrition Examination Survey (NHANES) in the United States. We analyzed the national representative data on women with natural menopause in the United States aged 19-79 years from the NHANES from 2007 to 2018. POI was defined when the study participant had experienced the last menstrual period before age 40. Depression was defined by the patient health questionnaire-9 (PHQ-9). The weighted prevalence of infertility and access to infertility care and 95% confidence intervals (CIs) were calculated. The association was determined using multivariable logistic regression and zero-inflated negative binomial regression with complex survey analysis. **Results:** A total of 1,592 women reported natural menopause, representing an estimated population of 10,575,535 postmenopausal women accounting for the complex sampling and weighting methods used. Women with POI were more likely to be younger, lean, Hispanic, less educated, and have a lower ratio of family income to poverty compared to women without POI. Women with POI had similar odds for having depression determined by PHQ-9 (odds ratio 0.88, 95% CI 0.37-2.11) after controlling for all potential confounders. Additionally, women who reported POI had a similar PHQ-9 score compared to those who reported natural menopause after the age of 40 years. **Conclusion:** There was no significant difference in the prevalence of depression determined by PHQ-9 between women with and without POI in this nationally representative study of postmenopausal women. The association was not different after adjustment for potential confounders.

**Sources of Funding:** This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korean government (MSIT) (No. 2023R1A2C1005003).

#### P-95.

##### **Supplement Use Among a Diverse Sample of Peri-Menopausal and Menopausal Women in Rural Hawaii**

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**Objective:** In the United States, 80% of women over the age of 60 use one or more dietary supplements. This widespread use may reflect an unmet medical need among this population and suggests people in this age group may be at increased risk for adverse drug interactions. Ethnically diverse populations may have different motivations for and patterns of supplement use. This study aims to explore supplement use among peri-menopausal and post-menopausal individuals living on rural Hawaii Island. **Design:** This study is a cross-sectional survey of peri-menopausal and menopausal

women presenting to an outpatient women's health clinic on rural Hawaii Island. A validated survey was modified to include common supplements from East Asian and the Pacific Islands. Non-pregnant women over the age of 40 were eligible to participate. Recruitment consisted of flyers posted in an academic women's health clinic. Paper and web-based surveys were used to collect data concerning the prevalence of supplement use, types of supplements used, the motivations for taking each supplement, and the cost of supplement use. Descriptive statistics and a one sample t-test were used to analyze the resulting data. **Results:** From May to June 2023, 75 people participated in this study. The majority of this sample identified as Asian (47%), White/Caucasian (35%), or Native Hawaiian (15%). Mean age of participants was 62 (range: 41 to 91; standard deviation: 11). Ninety-six percent of survey respondents reported using at least one supplement in the previous 6 months, which is higher than previously reported rates for the rest of the United States (p<0.01). Participants used an average of 5 different supplements (range: 0 to 22; standard deviation: 4.5). The most commonly used supplements include vitamin D (59%), calcium (49%), multivitamins (41%), vitamin C (31%), caffeine (29%), green tea (28%) and fish oil (27%). Mean monthly cost of supplements was \$55 (standard deviation: \$88). Thirty-three percent of participants report experiencing one or more side effects from supplement use. The most commonly reported sources for supplement recommendations were health professionals (71%), family members (33%), and friends (28%). **Conclusion:** Supplement use is common among this sample of peri-menopausal and menopausal women in rural Hawaii. This population looks to health professionals for advice and guidance concerning supplements. Understanding the type of supplements used and the reasons for taking these medications could allow for more effective counseling by clinicians.

**Sources of Funding:** None

#### P-96.

##### **Leveraging the Experience of Patients with Cystic Fibrosis: A Model to Advance the Study of Menopause in Chronic Illness**

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**Objective:** Context: Women with cystic fibrosis (CF) who seek primary and specialty healthcare consider menopause concerns essential to their overall health and well-being. However, menopause research and knowledge are absent for this and other chronic disease populations. Here we report findings from a four-year patient engagement project to empower women with CF to generate research questions and articulate their priorities about menopause to remedy gaps in scientific knowledge and inadequacies in CF and menopause clinical care. More broadly, this effort identified a methodological approach to advance menopause research and clinical care for women with chronic illness. **Objective:** To leverage the expertise of adult women with a chronic disease, CF, to advance menopause research and care. **Design:** With four CF patient-partners, three two-hour sessions focused on patient-centered research generation on CF and menopause. Additional meetings covered other CF-sexual and reproductive health (SRH) topics. We held meetings online to uphold infection control guidelines. We recruited adult women with CF through community-based social media platforms, clinic teams, and via community newsletters. We compensated attendees and the patient planning team for their time, participation, and knowledge. On average, 14 women attended each meeting to contribute their voices to directions in CF-menopause research. At each meeting, an expert presented a one-hour overview of existing research for educational purposes. Confidential patient-only breakout sessions in the second hour allowed attendees to share their experiences, discuss pre-set facilitation questions, identify research gaps, and formulate research questions. At the end of the meeting, attendees ranked their top 2-3 research questions for each session in a Google poll to share with researcher-partners for translation into research studies. Investigators then created an online, transdisciplinary community of researchers and patients to promote team science on CF-SRH research, including menopause. We divided this cohort into research pods of 3-4 researchers, each tasked with designing a study, developing a patient engagement and dissemination plan, and creating a visual map of potential funders and next steps. We shared the menopause questions with a team of CF/menopause researchers who chose two questions, designed a research study, and submitted a letter of intent for a foundation grant. The research team is now awaiting a response about their application. **Results:** Women with CF generated eight patient-driven research questions on menopause and CF during the project, including: What does menopause look like for women with CF? Do CF patients enter menopause earlier than the general population? and Is hormone replacement therapy (HRT) safe for women with CF? Our model of harnessing women's expertise to generate research ideas and establishing research teams to pursue those priorities proved highly effective in reaching its goals. **Conclusion:** Women with CF propose highly innovative and relevant research questions precisely because of their proximity to, and expertise about, their illness experience. These questions are relevant and meaningful to the female patient community, potentially making recruiting them into research studies easier. Our framework for generating and leveraging patient-engaged research questions can be applied to other chronic disease populations to forward menopause research agendas responsive to those groups' priorities and needs.

**Sources of Funding:** Funders for this project include the Cystic Fibrosis Foundation and the Patient-Centered Outcomes Research Institute (PCORI).

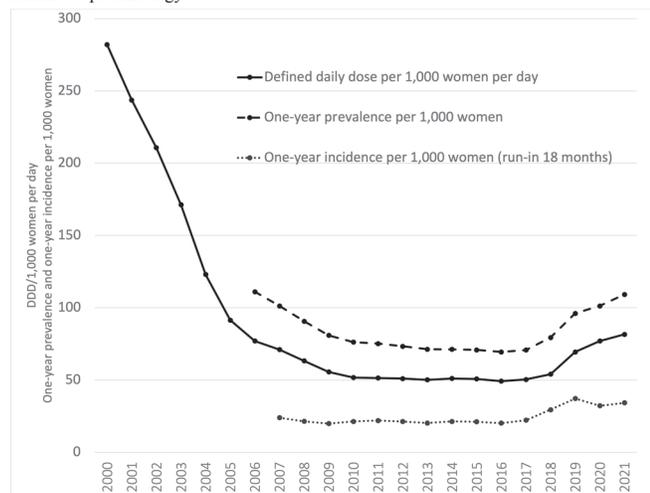
## P-97.

### Trends in the incidence, prevalence and sales volume of menopausal hormone therapy in Sweden from 2000 to 2021

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**Objective:** To describe the trends in use of menopausal hormone therapy (MHT) in Sweden, 2000–2021 and to analyse the impact of different lengths of run-in periods on the incidence. **Design:** Dispensation data were retrieved from the national mandatory Swedish Prescribed Drug Register. Aggregated sales volumes of MHT in Defined Daily Dose (DDD) were available from 2000 to 2021 and described as DDD per 1,000 women per day. Individual-level data on MHT dispensations for 2.5 million women 45–69 years of age were analyzed from 2006 to 2021 to describe the one-year prevalence and incidence proportion. The predictive values for incidence representing first-ever use of MHT were calculated for different run-in periods, which is a defined period without dispensations. A run-in period of 18 months was used to describe the incidence of MHT use. **Results:** Both the DDD, from 2000, and the prevalence, from 2006, decreased by over 80% in women aged 50–54 years, until 2010 when the use of MHT stabilized. The predictive value for incident users to be first-ever users was 88% in women aged 50–54 years, with a run-in of 18 months, in 2021. The incidence was stable between 2007 and 2016. From 2016 to 2017 an increase in the incidence by 10% was first identified among women aged 50–54 years, but not in other age-groups. Between 2017 and 2018 a further increase with 33% was seen in women 50–54 years and also an increase for 45–49 and 55–64 years. In 2020, the first year of the covid-19 pandemic, the incidence decreased for all studied age intervals. At the same time, the amount in DDD and the prevalence continued to increase, although at a somewhat slower rate than in the preceding two years. **Conclusion:** MHT use decreased significantly after the turn of the century, but has increased since 2017, mainly in the ages close to menopause. A run-in period of 18 months was found suitable and reliable for defining incident users of MHT in the age intervals closest to menopause. Incidence seems to be a more sensitive measure than prevalence or DDD for detecting early changes in prescription trends of MHT.

**Sources of Funding:** The Medical Research Council of Southeast Sweden (FORSS-646401, FORSS-746391). The NEPI foundation – the Swedish Network for Pharmacoepidemiology.



Menopausal hormone therapy in Sweden, women aged 50–54 years. Volume in Defined Daily Doses (DDD)/1,000 women per day, one-year prevalence and incidence (with an 18-month run-in) per 1,000 women and year.

## P-98.

### Nutrition Counseling in Postmenopausal Women: A Standard of Practice

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**Objective:** The postmenopausal time period can bring many unwanted physical changes, including weight gain, as well as an increased risk for various diseases such as diabetes, osteoporosis, arthritis, cardiovascular disease, metabolic syndrome and cancer. Postmenopausal women as compared to men are much more likely to be affected by weight related health complications. Providing universal preventive measures, such as nutrition counseling, could potentially positively affect the health of postmenopausal women and may lower their risk for mortality and morbidity. **Design:** The PubMed database was utilized, with inclusion criteria including English language articles that were published within the last five years. Key terms used were “post-menopause”, “nutrition”, “weight gain”, “nutrition counseling”, “weight”, “obesity”, “metabolism”, “postmenopausal women” and “nutrition education.” **Results:** Four relevant publications

were found: two randomized controlled trials, one controlled clinical trial, and one qualitative study. Two of these publications assessed the effect of nutrition education in reducing the risk of osteoporosis. One study found that participants receiving counseling reported increased intake of milk, calcium and vitamin D along with reduced total fat intake to support bone health. Similarly in the other study, participants receiving counseling reported increased intake of calcium, phosphorus and magnesium to support bone health but additionally reported improved BMI, serum lipids and systolic blood pressure. This suggests that nutrition education may also mitigate the development of cardiovascular disease. One publication specifically assessed community based nutrition education rather than the classroom/curriculum approach used in other studies. Participants receiving counseling reported increased calcium intake and benefited from reduced bone loss compared to the control group. Participants gained additional benefit from the community based approach which included weekly group discussions. This promoted collaboration among the participants and allowed nutrition experts to confirm participant understanding. One publication assessed the efficacy of virtual teaching kitchens to provide nutrition education. The use of a virtual format allowed participants to engage with the material from their own kitchens and follow along in real time. Study participants reported lower BMIs and improved dietary habits. The results suggest that virtual kitchens may be an effective intervention to promote health in the menopausal transition. These data suggest that nutrition education may be an effective intervention to mitigate postmenopausal health consequences and may prevent the development of chronic conditions. **Conclusion:** There are limited data evaluating the efficacy of nutritional counseling to optimally maintain or improve BMI in postmenopausal women. Given the prevalence of women impacted by postmenopausal weight gain, nutrition education may be an effective intervention to combat the health consequences. Future research is needed to assess the potential benefits and long term efficacy of nutrition education in promoting the health of postmenopausal women.

**Sources of Funding:** None

## P-99.

### Higher Habitual Physical Activity Reduces Vascular Endothelial Dysfunction in Healthy Peri-Menopausal People

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**Objective:** The risk for cardiovascular disease (CVD) in women increases as they transition through menopause. Vascular endothelial dysfunction is an early indicator of CVD and is measured via brachial artery flow-mediated dilation (FMD). FMD is mediated by the bioavailability of nitric oxide, a vasodilator released by endothelial cells in response to changes in shear stress. FMD decreases in healthy women as they progress from pre- to post-menopause with the greatest change during the peri-menopause. Habitual physical activity (PA) is known to be an influential factor in endothelial health in a variety of populations. However, the role of habitual PA in relation to endothelial health during the peri-menopause remains unclear. Therefore, the aim of this analysis was to test the hypothesis that endothelial function is better in higher- vs. lower-habitually active healthy peri-menopausal people. **Design:** Thirty-three peri-menopausal people aged 43–54 were included to date. Peri-menopause was defined via STRAW+10 guidelines. Exclusion criteria included a history of chronic menstrual irregularities, surgical menopause, menopausal symptom treatment, pregnancy or lactating, oral contraceptives in the past six months, and menopausal hormone therapy. Other exclusions were high blood pressure, BMI, cholesterol (TC, LDL-C), triglycerides, fasting plasma glucose, and low HDL-C. Self-reported habitual PA was determined by the International Physical Activity Questionnaire. The higher-PA group (High) criteria were >3days/wk of vigorous PA of at least 1500MET-min/wk or 7days/wk of any activity of at least 3000MET-min/wk, and the lower-PA group (Low) criteria were <150min/wk of moderate PA or <75 min/wk of vigorous PA. Endothelial function was assessed via ultrasonography of the brachial artery with an occlusion cuff placed distal to the probe. The FMD protocol consisted of 2 minutes of baseline measurement, 5 minutes of cuff inflation (200 mmHg), and 4 minutes of hyperemic response. Blood flow and diameter were continuously tracked throughout the 11-minute study (Cardiovascular Suite, version 4.0) and used to measure the baseline diameter, peak diameter, absolute FMD response, relative FMD response, shear rate stimulus, and time to peak dilation. Participant characteristics and FMD outcome variables were compared between groups using a two-tailed, independent t-test ( $\alpha < 0.05$ , Rstudio, version 2023.03.0+386). The Mann-Whitney U test was used to test the difference between outcome variables that did not meet the Shapiro-Wilk normality assumption test. **Results:** There were no differences between activity groups for BMI, blood pressure, total cholesterol LDL-C, HDL-C, triglycerides, or fasting plasma glucose. As designed, groups differed by physical activity (High=5390±2183MET-min/wk, Low=934.4±477.2MET-min/wk,  $p < 0.001$ ). Absolute FMD was significantly higher in the High-PA compared with the Low-PA group (High=0.18±0.08mm, Low=0.12±0.07mm,  $p = 0.043$ ). Relative FMD was not significantly different between groups (High=5.00±3.09%, Low=3.57±3.16%,  $p = 0.20$ ). Baseline diameter trended toward significance with a greater diameter in the higher PA group (High=3.40±0.36mm, Low=3.18±0.34mm,  $p = 0.088$ ). Maximum diameter was significantly larger in the higher-PA group (High=3.57±0.35mm, Low=3.29±0.31mm,  $p = 0.015$ ). Shear rate maximum (SRmax) trended toward significance with higher SRmax in the Low-PA group (High=869.3±246.3s<sup>-1</sup>, Low=1020.0±239.0s<sup>-1</sup>,  $p = 0.085$ ). Time to peak was not significantly different between groups (High=41.06±14.54s, Low=54.44±28.00s,  $p = 0.25$ ). **Conclusion:** Our preliminary results support our hypothesis and suggest that higher levels of habitual PA can maintain a more sensitive and responsive vasculature in healthy peri-menopausal people. Limitations include sample size and the cross-sectional design. Future work will include continued data

collection. Higher habitual PA may be important to reduce the decline in vascular endothelial function associated with menopause and optimize cardiovascular health as women transition to post-menopause.

**Sources of Funding:** Smith College McKinley Honors Fellowship Program (Tha Ra Wun), Smith College Student Research in Departments Program (Buszkiewicz), NHLBI R15 Grant 1R15HL145650-01A1 (Witkowski).

### P-100.

#### Trabecular Bone Scoring and effects on Diagnosis Change in Menopausal Women in a Specialty Women's Health Center.

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**Objective:** Osteoporosis is a common problem in postmenopausal women. Menopausal risk assessment needs to include risk for Osteoporotic fracture. The FRAX risk assessment tool discriminates against women under age 60, and those with lower spine T-scores as younger persons under age 60 and spine bone loss as opposed to hip T-scores are used to calculate the 10 year risk for any Osteoporotic fracture and the 10 year risk for hip fracture. Better assessment of bone risk is needed in menopausal women undergoing Central Dual-Energy X-absorptiometry (DXA). The newer technology of Trabecular Bone Scoring (TBS) assesses Bone Architecture which adds information to the Bone Mineral Density testing via DXA and gives additional information about fracture risk. **Design:** Data on all DXA scans performed in the calendar year 2022 for women scanned in the Center for Specialized Women's Health (a referral tertiary care center.) were reviewed and categorized into "Diagnosis not changed" or "Diagnosis changed" by TBS. The percent of patients who had a changed Diagnosis on TBS were further scrutinized to see if the diagnosis worsened or improved. Only one ISCD certified densitometrist (author) interpreted all scans as per ISCD protocol. TBS software is only currently validated on females (and males) within certain age and weight ranges and only for Caucasian and Asians. Thus age, weight and race affect whether a patient can have TBS assessment based on the software company validation studies. All eligible newly scanned patients who underwent ordered DXA in the Center had TBS performed at the same time and serial scans of the author's existing patients who presented for serial repeat DXA had TBS done. **Results: Of the 1277 DXA scans performed in 2022; 432 included TBS=34 % of scanned patients received TBS analysis** 13/432 went from a Diagnosis of Normal to Osteopenia 3% 35/432 went from Osteopenia to Osteoporosis 8% **So 11% of the TBS scanned patients received a WORSE diagnosis** 18/432 improved from Osteopenia to Normal 4% 7/432 improved from Osteoporosis to Osteopenia 1.6% **So over 5 % improved equaling a total 16% diagnosis were changed in women undergoing TBS in our Center for Specialized Women's Health.** 108/432 were Normal 25% with diagnosis unchanged 167/432 were Osteopenia 38.6% with diagnosis unchanged 83/432 were Osteoporosis 19% with diagnosis unchanged **So 83% of scanned TBS patients at A10 Center for Specialized Women's Health did NOT have a changed diagnosis.** One of the patients had Normal central TBS but Osteopenia was the ISCD diagnosis as Osteopenia stood based on T-score or the 1/3 forearm. TBS T-scores are provided for Lumbar Spine, Total Hip, Femoral Neck but not for distal 1/3 forearm. **Conclusion:** Osteoporosis is a major problem in postmenopausal women and is under recognized and under treated. Bone density assessment and fracture risk assessment is a key component in Menopausal risk assessment and 16% of TBS scanned women had the DXA diagnosis changed. Intensity of prevention and treatment strategies are affected by fracture risk assessment and shared decision making between the patient and her physician. We are the first and only site in our health system to offer TBS as this is an extra expense and not uniformly reimbursed by insurers. The TBS T-score is affected by the bone architecture and thus the TBS T-score give a more precise fracture risk assessment in untreated patients, and may also help reflect response to treatment in treated patients. Since the majority of women who present for menopausal risk assessment are under age 60, those women who have a DXA Diagnosis of Osteoporosis their individual 10 yrs FRAX risk may still be under 20% and 3 % respectively. Decisions to use menopausal hormone therapy are broader and more inclusive of several factors compared to the decision to only institute osteoporosis prevention or osteoporosis treatment. **The conclusion is that TBS provides meaningful additional information in the menopausal risk assessment, changing 16 % of women's diagnosis who were eligible for TBS and thus provided additional bone assessment which is key in this special group of patients.**

**Sources of Funding:** NONE

### P-101.

#### A Phase 1/2, Open-label, Parallel Group Study of the Safety and Pharmacokinetics of DARE-HRT1 (80 µg Estradiol/4 mg Progesterone and 160 µg Estradiol/8 mg Progesterone Intravaginal Rings) Over 12 Weeks in Healthy Postmenopausal Women

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**Objective:** Primary objectives were to evaluate the local and systemic safety and systemic plasma pharmacokinetics (PK) of DARE-HRT1, an ethylene vinyl acetate (EVA) intravaginal ring (IVR), which releases 17β-estradiol (E2) with progesterone (P4) for 28 days in healthy postmenopausal women over a 12-week study period. **Design:** Randomized, open-label, 2-arm, parallel group study in 21 healthy non-hysterectomized

postmenopausal women conducted at two sites in Australia. The study was approved by the ethics boards at each study site (Central Adelaide Local Health Network Human Research Ethics Committee 2021HRE00421) and registered at ClinicalTrials.gov (NCT05367973). Volunteers provided written informed consent prior to the performance of study procedures. Once eligibility was determined, women were randomized (1:1) to either DARE-HRT1 IVR1 (E2 80 µg/day with P4 4 mg/day) or DARE-HRT1 IVR2 (E2 160 µg/day with P4 8 mg/day). Women used the assigned IVR for three 28-day cycles. Safety was measured by treatment emergent adverse events (TEAEs) and changes in systemic laboratories and the endometrial bilayer width. Baseline adjusted plasma PK of E2, P4 and estrone (E1) was described. **Results:** Twenty-one volunteers (median age 59 years) were screened and randomized to either DARE-HRT1 IVR1 (n=11) or DARE-HRT1 IVR2 (n=10) and 19 women completed all three cycles. Both DARE-HRT1 IVRs were safe. All TEAEs were mild or moderate. Two participants in the DARE-HRT1 IVR2 group discontinued the study due to TEAEs (breakthrough bleeding, nipple tenderness and depressed mood). At baseline, the mean (SD) endometrial thickness was 2.40 (1.26) and 2.11 (0.71) mm for IVR1 and IVR2, respectively. At end of treatment, the mean (SD) endometrial thickness was 3.03 (1.86) and 2.50 (0.98) for IVR1 and IVR2 respectively. All endometrial thickness measurements were ≤ 4.8 mm. The baseline adjusted, month 3 mean (SD) steady state plasma E2 concentrations (C<sub>ss</sub>) achieved with the 160 µg/day E2 dose (IVR2) (38.97 ± 10.79 pg/mL, range of 20.68 – 53.45 pg/ml) (Table 1), put all participants in the normal, pre-menopausal early follicular phase range. On the contrary, the mean (SD) baseline adjusted, month 3 C<sub>ss</sub> plasma E2 achieved with the 80 µg/day E2 dose (IVR1) (22.17 ± 4.47 pg/mL, range of 17.67 – 29.52 pg/mL) kept some IVR1 users in the menopausal range for plasma E2. Baseline adjusted plasma P4 C<sub>ss</sub> for both IVRs were in the normal, post ovulatory, luteal phase range, > 1 ng/mL, (Table 2), which supports the *in vivo* release of P4 would protect the endometrium from the proliferative effects of exogenous E2. **Conclusion:** Safety and PK data support further development of DARE-HRT1 for the treatment of menopausal symptoms. This would be the first combination E2/P4 IVR to treat vasomotor symptoms in healthy postmenopausal women with an intact uterus.

**Sources of Funding:** None

Table 2 Baseline Adjusted Plasma Progesterone (ng/mL) Pharmacokinetic Parameters

Progesterone	Cycle 1		Cycle 2		Cycle 3		
	IVR1	IVR2	IVR1	IVR2	IVR1	IVR2	
N (Unless Specified)	11	10	11	9	10	8	
C <sub>ss</sub> (ng/mL)	N	11	9	11	8	10	7
	Mean	1.10	1.89	1.12	1.70	1.25	1.80
	SD	0.28	0.49	0.31	0.23	0.34	0.28
	Median	1.10	1.88	1.14	1.72	1.19	1.89
C <sub>max</sub> (ng/mL)	Mean	5.57	8.95	2.56	3.50	2.83	3.40
	SD	2.44	3.38	0.94	0.55	0.87	0.34
	Median	4.62	8.01	2.52	3.30	2.81	3.51

Table 1. Baseline Adjusted Plasma Estradiol (pg/mL) Pharmacokinetic Parameters

Estradiol	Cycle 1		Cycle 2		Cycle 3		
	IVR1	IVR2	IVR1	IVR2	IVR1	IVR2	
N	11	10	11	9	10	8	
C <sub>ss</sub> (pg/mL)	Mean	23.00	38.11	23.10	37.35	22.17	38.97
	SD	8.49	8.45	5.27	8.96	4.47	10.79
	Median	22.28	35.28	23.93	36.26	20.73	38.16
C <sub>max</sub> (pg/mL) Maximum Concentration	Mean	70.90	113.98	43.59	70.10	45.33	75.37
	SD	19.35	38.95	15.66	22.19	9.52	25.99
	Median	74.00	113.7	40.80	64.9	42.95	77.27
t <sub>max</sub> (hours) Time to C <sub>max</sub>	Mean	24.2	47.09	48.48	47.95	47.26	47.26
	SD	19.921	32.077	17.534	30.649	17.328	31.511
AUC D1-D29 (hours*pg/mL) Area Under Curve Day 1 to Day 29	Mean	5.865	7.634	5.167	8.316	2.981	9.225
	SD	19.690	31.255	17.519	28.723	15.798	29.932
	Median						

### P-102.

#### A Phase 1/2, Open-label, Parallel Group Study to Evaluate the Preliminary Efficacy and Usability DARE-HRT1 (80 µg Estradiol/4 mg Progesterone and 160 µg Estradiol/8 mg Progesterone Intravaginal Rings) Over 12 Weeks in Healthy Postmenopausal Women

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**Objective:** The exploratory objectives of this study were to evaluate the usability and preliminary efficacy of DARE-HRT1, an intravaginal ring (IVR) which releases 17β-estradiol (E2) with progesterone (P4) over 28 days. **Design:** DARE-HRT1-002 was a randomized, open-label, 2-arm, parallel group study in 21 healthy postmenopausal women (median age 59 years), conducted at two sites in Australia. The study was approved by the ethics committee at each study site and registered at ClinicalTrials.gov (NCT05367973). Women were randomized (1:1) to DARE-HRT1-IVR1 (E2 80 µg/day with P4 4 mg/day) (n=11) or DARE-HRT1-IVR2 (E2 160 µg/day with P4 8 mg/day) (n=10). They used the assigned IVR for three 28-day cycles. Preliminary local vulvovaginal atrophy (VVA) treatment efficacy was estimated by measuring changes from baseline in vaginal pH, vaginal maturation index (VMI) and patient-reported severity of genitourinary VVA symptoms. Preliminary systemic vasomotor symptom (VMS) efficacy was measured by changes in responses to the menopause quality of life (MENQOL) questionnaire. Acceptability was assessed by product experience surveys. **Results:** Twenty-one participants were randomized and 19 women completed all study visits.

Table 1 demonstrates significant improvement in vaginal pH, VMI and vaginal cytology with use of either DARE-HRT IVR. At baseline, 14 of 21 participants indicated that vaginal dryness was their most bothersome genitourinary symptom (MBS). Among this subset (8 from IVR1 cohort, 6 from IVR2 cohort), their median (interquartile range, IQR) reported vaginal dryness severity score was 2.0 (1, 3) at baseline and decreased to median (IQR) of 0 (0, 0) by end of treatment (EOT) with their respective IVRs (p < 0.01). These 14 women also had a significant decrease in dyspareunia severity from a median (IQR) of 1 (0, 2) at baseline to a median (IQR) of 0 (0, 0) at EOT (p < 0.01). There were significant decreases from baseline, indicating improvement in all MENQOL domains, for both DARE-HRT1 IVRs (all p values < 0.01), with the largest improvement in the MENQOL sexual domain. Based on MENQOL responses, the most commonly reported and most severe VMS at baseline was night sweats. With use of DARE-HRT1 IVR1, there was significant improvement in hot flashes and night sweats (p values 0.02 and 0.01 respectively), while there were no significant changes in sweating (p = 0.28) as 6/11 IVR1 users did not complain of this symptom at baseline. Among DARE-HRT1 IVR2 users, there was significant improvement in the severity of hot flashes, night sweats and sweating (all p values < 0.03). Most women agreed or strongly agreed that the study product was comfortable to wear, convenient to use and worked with their lifestyle. Most women reported that they were likely or very likely to use an IVR for treatment of women's health and other health conditions. **Conclusion:** This combination E2 and P4 IVR was acceptable and demonstrated preliminary efficacy for VMS and VVA treatment.

**Sources of Funding:** None

Table 1. Preliminary Markers of Local Estradiol Impact on Vaginal Epithelium

	Baseline Pre-Treatment			End of Treatment Cycle 3 or Early Termination			Wilcoxon Signed Rank Sum P Value
	Mean	SD	Median	Mean	SD	Median	
DARE-HRT1 IVR1 (E2 80 µg/day with P4 4 mg/day) (n=11)							
Vaginal Cytology							
% Superficial Cells	0.20	0.42	0.0	14.3	11.68	15.0	<0.01
% Intermediate Cells	47.30	44.56	30.50	85.73	11.68	85.00	<0.01
% Parabasal Cells	52.40	44.54	69.50	0.00	0.00	0.00	<0.01
Total VMI (%)	23.85	22.33	15.25	57.14	5.84	57.50	<0.01
Vaginal pH	5.40	0.63	5.30	4.67	0.09	4.70	<0.01
DARE-HRT1 IVR2 (E2 160 µg/day with P4 8 mg/day)							
Vaginal Cytology							
% Superficial Cells	7.6	12.40	0.5	12.2	11.30	9.5	<0.01
% Intermediate Cells	42.05	37.92	50.75	87.20	11.33	89.50	<0.01
% Parabasal Cells	50.35	44.07	37.50	0.60	1.90	0.0	<0.01
Total VMI (%)	28.63	26.24	31.50	55.80	5.79	54.25	<0.01
Vaginal pH	5.26	0.38	5.30	4.93	0.53	4.70	<0.01

### P-103.

#### Pharmacokinetics, Safety and Preliminary Pharmacodynamic Evaluation of DARE-VVA1: A Soft Gelatin Vaginal Tamoxifen Capsule for the Treatment of Vulvovaginal Atrophy

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**Objective:** Safety, systemic pharmacokinetics (PK) and preliminary assessment of treatment efficacy were measured among healthy postmenopausal women with moderate-to-severe vulvovaginal atrophy (VVA) in this first-in-woman study of DARE-VVA1, a soft gelatin vaginal tamoxifen capsule. **Design:** This was a randomized, placebo-controlled, double-blind, study of DARE-VVA1, vaginal tamoxifen, in 4 doses (1 mg, 5 mg, 10 mg and 20 mg). Women used study product daily for 14 days and then twice weekly for 6 weeks. **Results:** We screened 45 women and enrolled 17 (mean age 61 years); 14 women completed the study at two Australian clinical sites. Three participants (1 placebo, 2 in 5 mg group) were discontinued due to protocol violations. All treatment emergent adverse events (TEAEs) were mild or moderate in severity and were similarly distributed between active and placebo dosing groups. Endometrial thickness measurements were normal at baseline and end of treatment, with all < 4.0 mm. Systemic tamoxifen and metabolite concentrations were highest among 20 mg users, but maximum mean (SD) plasma tamoxifen concentrations (C<sub>max</sub>) on day 1 (2.66 ± 0.85 ng/mL) and day 56 (5.69 ± 1.87 ng/mL) were < 14% of C<sub>max</sub> measured after a single oral tamoxifen (20 mg) dose (40 ng/mL) (Table 1). Similarly, the first metabolite of tamoxifen, N-desmethyl tamoxifen (NDT) had mean (SD) C<sub>max</sub> plasma concentrations on day 1 (0.20 ± 0.17 ng/mL) and day 56 (8.13 ± 2.90 ng/mL), which were < 2% of that steady state NDT concentrations (353 ng/mL) with oral tamoxifen use. Plasma tamoxifen concentrations were negatively correlated with vaginal pH (R = -0.51, p < 0.01) and % vaginal parabasal cells (R = -0.53, p < 0.01), and were positively correlated with % vaginal superficial cells (R = 0.45, p < 0.01), % vaginal intermediate cells (R = 0.45, p < 0.01) and total VMI (R = 0.62, p < 0.01). Women reported vaginal dryness or dyspareunia as their most bothersome genitourinary symptom at baseline. The severity of these symptoms decreased significantly with active study product use (p = 0.02 for both), while placebo users had no significant changes in the severity of these symptoms (p values 0.17, 0.33 vaginal dryness and dyspareunia respectively). **Conclusion:** These data support that DARE-VVA1 is safe and results in minimal systemic exposure to tamoxifen or its metabolites compared to orally administered tamoxifen. Preliminary efficacy data support the clinical development of DARE-VVA1 to effectively lower vaginal pH and improve VMI and treat bothersome genitourinary symptoms.

**Sources of Funding:** None

Table 1: Plasma PK Parameters for Tamoxifen

		DARE-VVA1 1 mg	DARE-VVA1 5 mg	DARE-VVA1 10 mg	DARE-VVA1 20 mg
		(n=3)	(n=4)	(n=3)	(n=3)
Tamoxifen					
Day 1 C <sub>max</sub> (ng/mL)	Mean	0.04	0.49	2.08	2.66
	SD	0.06	0.20	0.51	0.85
Day 1 T <sub>max</sub> (hours)	Median	0	0.57	2.17	2.97
	Mean	4.98	15.96	2.00	2.43
	SD	4.98	5.00	2.00	2.02
Day 1 AUC 0-24 hrs. (hours*ng/mL)	Median	4.98	24.08	2.00	4.00
	Mean	0	9.22	25.05	39.08
	SD	0	4.44	11.89	12.27
Day 56 C <sub>max</sub> (ng/mL)	Median	0	10.84	20.26	44.60
	Mean	0.19	2.03	3.31	5.69
	SD	0.06	0.87	0.38	1.87
Day 56 AUC <sub>0-τ</sub> (hours*ng/mL)	Median	0.17	2.03	3.47	4.63
	Mean	3.55	45.17	68.61	113.00
	SD	1.09	22.09	8.21	21.81
Day 56 T <sub>1/2</sub> (hours)	Median	3.25	45.17	70.71	102.00
	Mean		182.21	109.29	190.80
	SD		16.70		
	Median		182.21	109.29	190.80

TABLE 2. Vaginal pH and Vaginal Cytology

	Baseline Pre-Treatment (Day 1)			Day 56 (End of Treatment)			Wilcoxon Signed Rank Sum P Value
	Median	Mean	SD	Median	Mean	SD	
Vaginal pH							
Placebo (n=4)	5.3	5.6	0.6	5.3	5.4	0.5	>0.99
DARE-VVA1 All Actives (n=10)	5.3	5.6	0.5	5.0	5.3	0.4	0.04
Vaginal Maturation Index (VMI)							
Placebo	2.0	2.0	1.7	10.3	10.3	14.5	0.85
DARE-VVA1 All Actives	43.5	15.9	14.7	54.3	51.3	30.4	0.32
Superficial Cells (%)							
Placebo	0	1.0	2.0	0	0	0	>0.99
DARE-VVA1 All Actives	0	2.4	3.1	11	20.9	27.9	0.11
Parabasal Cells (%)							
Placebo	96.5	97.0	2.2	79.5	79.5	29.0	>0.99
DARE-VVA1 All Actives	75.0	60.8	41.2	1.0	11.4	22.9	0.04

### P-104.

#### The New, Undescribed, and Lethal Symptoms in the GSM and Advanced Menopause.

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**Objective:** This study endeavors to highlight new symptoms observed in patients with GSM and advanced menopause—not heretofore associated with the condition—including mortality risk: Total Vulvovaginal Obliteration (TVO), with possible secondary renal damage as well as, in those without Hormone Replacement Therapy (HRT), undiagnosed recurrent Urinary Tract Infections (rUTIs), which may be accompanied by secondary sepsis, pneumonia, and mortality. Abnormal false pap smears are an additional—albeit non-lethal—consequence of GSM. The study will also outline a newfound association between decubitus ulcers and the lack of HRT. **Design:** This multi-method longitudinal study took place within a multidisciplinary healthcare facility and nursing homes over the course of 10 years. The sample population included menopausal and postmenopausal women with and without HRT. A comprehensive review of current medical literature was conducted to identify new findings associated with GSM not traditionally reported. Patients with GSM symptoms were diagnosed and treated according to established protocols. Current outlined identifications were used along with new findings such as: false abnormal pap smears, TVO, and undiagnosed rUTIs. Demographic and clinical data were collected for each patient including age, HRT status, and diagnosis. Patients were followed up regularly to monitor their progression and ensure the effectiveness of respective treatments. **Results:** Through the treatment of newly associated symptoms of menopause and GSM, this study resolved abnormal pap smears with local estrogens in more than 1500 cases, and successfully managed 8 cases of TVO with surgery, dilators, increased penetrative sex, and local estrogen. Descriptions of a dozen rUTI patients whose conditions progressed to sepsis, pneumonia, and even death were also seen and evaluated in home care facilities by the primary care provider. Women over 55 have a higher incidence of rUTIs. UTI risk factors differ between pre- and postmenopausal women. Younger women are more likely to experience UTIs linked to sexual intercourse and vaginal infections; older women are more likely to experience them from hypoestrogenism and secondary to vaginal decrease of their immunological response. For this reason, there may be multiple unnecessary antibiotic treatments, antibiotic prophylaxis, and altered patterns of resistance due to a lack of awareness of the association between the rUTI and GSM. Generally, menopausal and vaginal symptoms are satisfactorily resolved with systemic and local HRT and the appropriate antibiotic therapy. Though not associated with GSM, we have found also that in nursing homes, women who have not been in HRT more frequently develop decubitus ulcers. Frequently this—combined with the comorbidities of diabetes mellitus, severe immobility, and geriatric age (centenarians)—increases mortality risk. **Conclusion:** This study finds GSM symptoms may include several beyond the usually considered scope

of the disease—some of which are accompanied by mortality risk. These symptoms—false abnormal pap smear results, TVO, and undiagnosed rUTIs—ought to be considered and checked for in GSM patients. Physicians should note that risk factors for rUTIs differ for pre- and postmenopausal women, to reduce the risk of multiple unnecessary antibiotic treatments, antibiotic prophylaxis, and antibiotic resistance—that may arise from an incomplete understanding of the association linking rUTIs and the GSM. The implications of these findings are particularly salient for urologists, primary care, internal medicine, OB/GYN physicians, geriatricians, and infectious disease specialists, who should consider the expanding list of GSM symptoms in the treatment of their menopausal and postmenopausal patients, ensuring regular screening, monitoring, and the timely identification of new symptoms. Further research, and monitoring of current GSM patients, is needed to ensure up-to-date understandings of GSM and its constellation of associated symptoms and—more urgently—the best possible standard of care for patients.

**Sources of Funding:** 1Miami Center for Obstetrics Gynecology and Human Sexuality 2American University of Antigua

### P-105.

#### The Effect of Estetrol (E4) on Patient-Reported Outcome Measures in Postmenopausal Women – Results From a Phase 3 Trial

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**Objective:** Estetrol (E4) is a native estrogen in development for menopausal vasomotor symptoms (VMS) in postmenopausal (PM) women. A previous phase 2 trial found that E4 was effective for the treatment of VMS, genitourinary syndrome of menopause (GSM) symptoms and quality of life (QoL), with a favorable safety profile. Moreover, E4 had minimal impact on hemostasis and had potentially beneficial effects on lipids, carbohydrate metabolism, and bone turnover. Data from two Phase 3 trials demonstrated a significant reduction in the frequency and severity of moderate to severe VMS. Here, we present the patient-reported outcomes from a Phase 3 trial (E4Comfort 1), which was conducted at 151 enrolling sites in 14 countries in Europe, Latin America, Russia, and North America. **Design:** In this randomized, placebo-controlled, double-blind phase 3 trial, 640 PM women 40–65 years of age were randomized to receive E4 15 mg (n=213), E4 20 mg (n=213), or placebo (n=214) daily for 12 weeks. To ensure endometrial protection all non-hysterectomized (NH) women received progesterone 200 mg once daily for 14 days after completion of E4 treatment. Secondary efficacy endpoints including QoL, clinical meaningfulness, and GSM symptoms were measured by validated patient-reported outcome questionnaires. For QoL, the Menopause-Specific Quality of Life (MENQOL) questionnaire was completed at baseline and at week 12 and consisted of 29 items: vasomotor (3 items), psychosocial (7 items), physical (16 items), and sexual (3 items). Items pertaining to a specific symptom were rated as present or not present, and if present, how bothersome on a zero (not bothersome) to six (extremely bothersome) scale. The Clinical Global Impression questionnaire was completed at baseline and at weeks 4 and 12 to evaluate clinical meaningfulness of VMS reduction. Participants answered the following question: “Rate the total improvement, whether or not in your judgment it is due entirely to drug treatment. Compared to your condition at admission to the study, how much has it changed?” Potential responses included “very much improved”, “much improved”, “minimally improved”, “no change”, “minimally worse”, “much worse”, or “very much worse.” “Very much improved” and “much improved” were included in the rating of clinical important (meaningful) difference. GSM symptoms were self-assessed at baseline and at week 12 and involved vaginal dryness, vaginal and/or vulvar irritation/itching, dysuria, vaginal pain associated with sexual activity (dyspareunia) (scored as 0 [none], 1 [mild], 2 [moderate], or 3 [severe]), and vaginal bleeding associated with sexual activity (scored as 0 [absent] or 1 [present]). Statistical analyses on changes from baseline were performed using analysis of covariance. **Results:** Significant improvements at week 12 versus placebo were found in the total MENQOL score and in the vasomotor, psychosocial, and sexual functioning domain scores after E4 15 mg and E4 20 mg treatment, and in the physical domain score after E4 20 mg treatment (p<0.05). A significantly higher percentage of participants rated their condition as “much improved” or “very much improved” compared with baseline regarding the weekly frequency of moderate to severe VMS in the E4 15 mg (52.9% and 73.3%) and E4 20 mg (59.8% and 77.8%) groups versus placebo (27.9% and 47.0%) at weeks 4 and 12, respectively (p<0.0001). GSM symptoms numerically decreased in all treatment groups after 12 weeks of treatment. A significant treatment effect was observed with E4 15 mg compared to placebo at week 12 with a reduction in least square mean difference versus baseline in vaginal pain associated with sexual activity (-0.23 [95% confidence interval (CI): -0.41, -0.04]; p=0.0142) and vaginal dryness (-0.31 [95% CI: -0.53, -0.09]; p=0.0030). **Conclusion:** E4 demonstrated beneficial effects on QoL and GSM symptoms and provided clinically meaningful improvements in postmenopausal women with moderate to severe VMS.

**Sources of Funding:** Funded by Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Liège, Belgium

### P-106.

#### Female sexual desire in couples aged 50-70 years: Importance of male assessment

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**Objective:** To assess the prevalence of low female sexual desire among couples aged 50 to 70 years and the male and female factors associated with female sexual desire. **Design:** Cross-sectional study with 266 couples between 50 and 70 years old. The women were selected through the “snowball” technique, formed from the “ego” couples who answered the interview that included the Brazilian version of the SPEQ and the Brazilian Sexual Quotient-Male Version (QS-M). Interviews were conducted separately with the woman and her sexual partner. Univariate and multiple logistic regression analyses (with Stepwise variable selection criteria) studied the factors associated with the frequency of female sexual desire  $\geq 1$  time per week in the last month. **Results:** The mean age of women was 57.5 (5.08), and for men was 60 (6.28); 93% of women were postmenopausal, and 34% reported never having sexual desire. The male factors that were associated with female sexual desire  $\geq 1$  time a week were: self-perceived good/excellent male health (p=0.04; OR 1.76, 95% CI 1.02-3.03), frequency of sexual desire  $\geq 1$  time/week (p=0.001; OR 3.30, 95% CI 1.62-6.72) and most of the time/always the ability to seduce with confidence to launch into sexual conquest activities (p <0.001; OR 3.02, CI 95% 1.67-5.46), erection rigid enough to ensure satisfactory sexual intercourse (p=0.006; OR 3.69, CI 1.44-9.45), maintenance of the same quality of erection in the various sexual intercourses performed on different days (p=0.010; OR 2.50, CI 1.24-5.03), ejaculation control so that the sexual act lasts as long as desired (p =0.005; OR 2.25, CI 1.27-3.97). The female factors associated with sexual desire  $\geq 1$  time per week were: higher/graduate education (p=0.003; OR 5.43, CI 1.80-16.42); use of medication for depression (p=0.044; OR 0.46, CI 0.21-0.98) and for anxiety (p=0.026; OR 0.52, CI 0.29-0.93), absence/slight vaginal dryness (p<0.001; OR 3.90, CI 2.24-6.78), total MRS  $\geq 16$  (p=0.006; OR 0.39, CI 0.20-0.76), presence of GSM (p<0.001; OR 0.39, CI 0.23-0.67), penetration pain (p<0.001; OR 0.26, CI 0.12-0.53) and satisfaction with the partner as a lover (p =0.01; OR 2.53, CI 1.22-5.25). **Conclusion:** Over a third of the women in the sample said they never had a sexual desire in the last month. Sexual partner performance and menopausal symptoms influence female sexual desire. Taking a couple-oriented approach can help both members of the couple improve sexual function.

**Sources of Funding:** The São Paulo Research Foundation, FAPESP- Process number: 2020/04708-1

### P-107.

#### Efficacy of a Nonhormonal Neurokinin B Inhibiting Supplement for Reducing Vasomotor Symptoms

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**Objective:** The primary objective was to evaluate the effects of a nonhormonal, botanical blend (VMS-BH02; Thermella™), on hot flashes and night sweats in women who experience menopausal vasomotor symptoms (VMS). Preclinical studies showed that the combination of these ingredients synergistically inhibited the neurokinin B pathway and did not raise estrogen levels nor induce cell proliferation in MCF-7 cells. This was the first clinical study conducted to evaluate clinical benefits. **Design:** This is an ongoing open-label study in women 45-65 years of age. Thirty peri- and post-menopausal women were recruited if they reported a daily average of 5 or more VMS, regardless of severity. Participants were instructed to consume 2 capsules of the supplement daily. To date, participants have completed 8 weeks. The primary endpoint was the percent change in total VMS, collected using daily diaries. Secondary endpoints were assessed using various validated monthly questionnaires including the Menopause Specific Quality of Life (MENQOL), the Hot Flash Related Daily Interference Scale (HFRDIS), the Greene Climacteric Scale (GCS), and the Patient-Reported Outcomes Measurement Information System Sleep Disturbance Short Form 8b (PROMIS). Participants completed all questionnaires at Baseline, and weeks 2, 4, and 8, with the exception of the MENQOL, which was not administered at week 2. **Results:** Thirty women completed 8 weeks (55.5 ± 3.7 yrs) of supplementation. There was a significant decrease in self-reported total VMS occurrences (all severities) noted across the time points (Baseline: 10.7 ± 6.0; Week 4: 6.2 ± 4.2; Week 8: 5.1 ± 4.4; p < 0.01). Combined, moderate and severe hot flashes were significantly decreased at all weeks when compared to baseline (Baseline: 5.1 ± 2.6; Week 4: 2.9 ± 2.6; Week 8: 2.5 ± 2.9; p < 0.01). Night sweats significantly decreased from baseline at weeks 4 and 8 (Baseline: 2.9 ± 2.1; Week 4: 1.5 ± 1.2, p = 0.002; Week 8: 1.4 ± 1.3, p < 0.01). Significant improvements were also noted in the MENQOL total sum at weeks 4 and 8 compared to baseline (Baseline: 3.8 ± 1.2; Week 4: 3.0 ± 1.1; Week 8: 2.7 ± 1.4; p < 0.01), the HFRDIS total sum at all timepoints compared to baseline (Baseline: 42.7 ± 18.2; Week 2: 31.03 ± 18.3; Week 4: 26.1 ± 20.4; Week 8: 18.4 ± 18.4; p < 0.001), and the GCS total sum at weeks 2, 4, and 8 compared to baseline (Baseline: 20.3 ± 8.6; Week 2: 16.3 ± 8.3, p < 0.001; Week 4: 14.1 ± 8.5, p = 0.001; Week 8: 12.5 ± 10.3, p < 0.001). There were also significant improvements in PROMIS total score at weeks 2, 4, and 8 compared to baseline (Baseline: 30.3 ± 7.0; Week 2: 26.4 ± 8.3; Week 4: 25.5 ± 8.1; Week 8: 23.4 ± 8.3; p < 0.01). **Conclusion:** The eight-week daily supplementation with Thermella™, which has a high affinity for inhibition of the NK3 receptor, resulted in significant and consistent reductions in vasomotor symptoms,

including hot flashes and night sweats. These improvements were observed as early as two weeks into the study and continued throughout the investigation period. Notably, the frequency and severity of these symptoms decreased over time. Supplementation also showed positive effects on menopause-specific quality of life related outcomes and sleep disturbances. Overall, these findings underscore the promising clinical efficacy of this novel botanical blend in effectively managing vasomotor symptoms experienced by women throughout their menopausal transition.

**Sources of Funding:** Bonafide Health, LLC

#### P-108.

##### Assessing Knowledge Gaps in Primary Care: Patients at High Risk for Breast Cancer

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**Objective:** The objective of this study is to 1) survey knowledge around breast cancer risk and 2) to identify potential knowledge gaps amongst PCPs. This information will subsequently be used to help develop an educational program tailored to PCPs to improve standardized knowledge base regarding breast cancer risk to identify and offer enhanced surveillance and/or risk reducing medications to women who are at high risk for breast cancer. **Design:** A short questionnaire was distributed to PCPs within the Mayo Clinic enterprise that assessed knowledge and awareness about breast cancer risk factors, risk assessment, and management of patients at high risk for breast cancer. Targeted respondents included physicians at or above the level of residency, and advanced practice providers (nurse practitioners (NPs) or physician assistants (PAs)). Knowledge assessment questions focused on clinical scenarios to assess various domains of patient risk and guideline-based management recommendations. Data regarding respondent demographics including age, gender, medical speciality, time in practice, and practitioner experience in caring for high-risk patients was collected. Results were modeled as univariate and multivariable linear regression with percent score as the outcome, as well as descriptive analysis. **Results:** 145 survey responses were received, the majority practicing family medicine (66.4%) or internal medicine (31.4%). 61.5% of respondents had been practicing at least 5 years. The average final score was 55.9% correct, with 55.2% (80/145) respondents receiving a final score of 60% correct or above and 44.8% (65/145) respondents receiving a final score at or below 50% correct. 46.2% of respondents correctly answered both breast cancer screening questions and 42.1% of respondents correctly answered the single question on utilization of risk reducing medications. 46.9% of respondents correctly identified the overall risk associated with mammographic breast density. **Conclusion:** PCPs demonstrated a knowledge gap in appropriate use of breast cancer screening modalities as well as risk-reducing medications for patients at high risk of developing breast cancer. As a one of the first points of contact in the health care system, further education-based programs should be developed to improve PCP knowledge of early breast cancer risk factors, detection, screening, and prevention options, in order to improve shared patient discussions surrounding breast cancer screening and ultimately improve overall patient outcomes.

**Sources of Funding:** Mayo department of medicine, AZCFR

#### P-109.

##### Assessing Point of Care Diagnostic Methods for Vulvovaginal Candidiasis in Pre- and Postmenopausal Patients

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**Objective:** The primary objective of this review is to assess the accuracy of point of care methods of diagnosing vulvovaginal candidiasis in comparison to standardized methods of diagnosis (culture and NuSwab/SureSwab) in pre- and postmenopausal patients. **Design:** This is a retrospective chart review of patients who were seen in the Rutgers Robert Wood Johnson Center for Vulvovaginal Health and diagnosed with vulvovaginal candidiasis between 1/1/2021 to 6/30/2021. Wet preparation findings, culture or NuSwab/SureSwab results, presenting symptoms, and patient characteristics including age, race, menopausal status and use of hormone therapy (HT) at time of visit were abstracted from medical records. Patients ages 18 to 89 years old were included. Exclusion criteria was absence of yeast culture and/or Nuswab/SureSwab result despite wet preparation completion. Statistical analysis was performed using a P-value calculator to determine statistical difference in accuracy of wet prep diagnosis versus laboratory diagnosis between groups. **Results:** A total of 157 premenopausal and 112 postmenopausal patients (64 on HT and 48 not on HT) were included in the final analyses. We found that the concordance rate of wet prep and laboratory testing was significantly different between pre- and post-menopausal women (74.9% vs 54.5% p=.005). However, this difference was present only in postmenopausal women not on HT (74.9% vs 25% p=.0003) and not present in those on HT. (74.9% vs 76.6% p=0.81). Of the women on HT, 55 were on vaginal estradiol alone, 4 on systemic and 5 on both. **Conclusion:** The diagnosis of vulvovaginal candidiasis is postmenopausal women not on HT is significantly less accurate on wet prep point of care testing than in women who are either pre-menopausal or post-menopausal on HT. Although VVC is less prevalent in the postmenopausal population not on HT, when this diagnosis is suspected to be present, laboratory testing should be collected in addition to wet prep diagnosis for most accurate results.

**Sources of Funding:** none

#### Concordance/Discordance in All groups

Group	Concordance n (%)	Disscordance n (%)
Premenopausal	125 (74.9)	42 (25.1)
Postmenopausal - all	61 (54.5)	51 (45.5)
Postmenopausal - no HT	12 (25)	36 (75)
Postmenopausal - on HT	49 (76.6)	15. (23.4)

HT = hormone therapy

#### P-110.

##### Sleep Disturbances Among Menopausal Hispanic Subgroups

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**Objective:** The menopausal transition is associated with range of somatic, psychological, and urogenital symptoms. Sleep disturbances, including insomnia, fragmented sleep, decreased sleep quality, and early-morning awakening, are a common somatic symptom experienced by women during menopause. Prior studies suggest the severity of these symptoms varies across different racial and ethnic groups. One such group is Hispanic women, who represent a diverse population encompassing women from various countries, continents, and subcultures. This review assessed sleep disturbances during menopause among several subgroups within Hispanic women. **Design:** A literature review was conducted using Rutgers Libraries PubMed Database. Keywords included "menopause", "sleep" and "Hispanic". **Results:** Among cohorts of Caucasian, African-American, Chinese, and Japanese women, Hispanic women reported the highest rates of sleeping difficulty [1]. Further, differences in sleep disturbances also exist within Hispanic subgroups [2]. Based on findings from Green et al., the proportion of Puerto Rican, Dominican, Cuban, Central American, and South American women reporting trouble sleeping was 66.1%, 64.3%, 36.4%, 51.7%, and 45.3% respectively. Overall, more Puerto Rican and Dominican women reported difficulty sleeping compared to Cuban, Central American, and South American women. Within the "sleeping problems" subcategory of the Menopausal Rating Scale, indigenous women from Quechua (Peru) experienced more sleeping difficulties compared to women from Zenu (Colombia) [3]. Conversely, sleeping difficulties among non-Afro and Afro-Colombian were not significantly different [4]. **Conclusion:** These data suggest that sleeping difficulties in Hispanic women vary depending on their country of origin. Furthermore, sleeping difficulties experienced by Latin American women may be influenced by their indigenous ethnic background. These results highlight the importance of recognizing the heterogeneity within the Hispanic population. Additional studies are suggested to investigate the factors contributing to these subgroup differences to inform targeted guidance and management for improved health outcomes.

**Sources of Funding:** None

#### P-111.

##### Growing Acceptance of the Life-long Beauty of Women in the Media

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**Objective:** Throughout modern Western history, stringent beauty standards have typically excluded aging women. Such beauty standards, which promote an eternal youthful appearance, have a significant negative impact on the self-image and mental health of aging women, who may feel helpless about natural signs of healthy aging. Fortunately, in recent years, the anti-ageism movement has challenged this concept and increased visibility of authentic aging experiences. This review explores the popular media discourse on aging and beauty in women to assess whether the Western media is becoming more accepting of aging changes in women. **Design:** A Google search with the term "online beauty magazine" was conducted to determine the first five most popular online beauty magazines. The top 50 results from a search using the terms "aging," "beauty," and "women" were obtained from each online magazine. Articles not discussing aging women and self-care or beauty theory were eliminated. Remaining articles were analyzed based on content that included views of beauty and aging. **Results:** The analyzed articles did support greater acceptance of beauty with aging. Anti-ageism articles critiquing anti-aging beauty standards and discussing celebrities, health experts, and older women embracing the aging process encompassed two out of five (40%) articles obtained from Elle, 20 out of 41 (48.78%) articles obtained from Allure, 18 out of 41 (43.9%) from Vogue, and three out of four (75%) articles from InStyle. Relatively neutral, informational articles on skin care during aging or the aging process accounted for one (20%) article from Elle, 18 (43.9%) articles from Allure, 21 (51.22%) articles from Vogue, four (100%) articles from Beauty News NYC, and one (25%) article from InStyle. However, articles perpetuating anti-aging beauty standards were also present. Two (40%) articles from Elle, one (2.44%) article from Allure, and two (4.88%) articles from Vogue expressed anti-aging products as "treatments" for aging, likening aging to a disease that must be fixed. Two (4.88%) articles from Allure also included celebrities supporting anti-aging beauty standards. Overall, out of the 95 total articles analyzed, seven (7.37%) perpetuated anti-aging beauty standards. **Conclusion:** Recent years have shown great progress in accepting life-long beauty in women. However, anti-aging beauty standards still persist. To further assess prevalent beauty standards for aging women, research into standards prevailing in other forms of media/wider range of magazines should be done. Surveying aging women's perceptions of their experiences may be useful to demonstrate whether improving acceptance of beauty with aging has a positive impact on women's mental health. Research comparing the beauty standards of aging men and women should also be done to distinguish whether more stringent beauty standards apply to aging women.

**Sources of Funding:** None

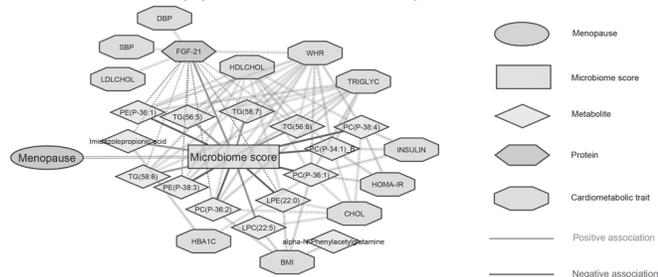
P-112.

**The Menopause-related Gut Microbiome: Associations with Metabolomics, Inflammatory Protein Markers, and Cardiometabolic Health in Women With and Without HIV**

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**Objective:** Menopause may alter the gut microbiome, but little is known regarding mechanisms linking menopause-related gut microbiome alterations and cardiometabolic risk. We sought to identify menopause-related gut microbial species, as well as their related metabolites and inflammatory protein markers, and link with cardiometabolic risk factors in women with and without HIV (WWH and WWOH). **Design:** In a Women's Interagency HIV Study (WIHS) sub-study, we performed shotgun metagenomic sequencing on 696 stool samples from 446 participants (67% WWH), and quantified plasma metabolomics and serum proteomics in a subset (~86%). We examined associations of menopause (post- vs. pre-menopausal) with gut microbial features in a repeated measure design, and further evaluated those features in relation to metabolites, proteins, and cardiometabolic risk factors. **Results:** Mean age was 53.0±8.7 years and 69% were post-menopausal at the time of their first stool sample. Menopause was associated with altered overall gut microbial composition in WWH only. We identified a range of gut microbial features that differed between post- vs. pre-menopausal WWH (but none in WWOH), including 32 species and lower β-glucuronidase bacterial gene abundance. Specifically, highly abundant species *Faecalibacterium prausnitzii*, *Bacteroides sp. CAG:98* and *Bifidobacterium adolescentis* were depleted in post-menopausal WWH. Menopause-depleted species (mainly class Clostridia) in WWH were positively associated with several glycerophospholipids, while negatively associated with imidazolepropionic acid and FGF-21. Furthermore, cardiometabolic traits, especially waist-to-hip ratio, were associated with menopause-related microbes, metabolites and FGF-21 in WWH (Figure 1). **Conclusion:** Menopause may shift the gut microbiome in WWH, leading to altered metabolite and protein profiles that potentially contribute to elevated cardiometabolic risk.

**Sources of Funding:** B.A.P., Q.Q., and R.C.K. were supported by the National Heart, Lung, and Blood Institute (B.A.P. K01HL160146; R.C.K. R01HL148094 and U01HL146204-04S1; Q.Q. and R.C.K. R01HL140976).



**Figure 1. Network plot visualizing relationships of the menopause-related microbiome score with metabolites, inflammatory protein markers, and cardiometabolic traits in women with HIV.**

P-113.

**Bridging Menopausal History and Alzheimer Disease: A Pilot Study Targeting Sex-Based Disparities in Alzheimer's Risk**

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**Objective:** Two-thirds of Alzheimer's disease (AD) patients are women. Compelling evidence suggests female-specific cardiometabolic and endocrinological changes emerge in midlife contributing to increased AD risk. These processes can be exacerbated by the menopausal transition experienced by 1.5 million American women annually. Clear evidence suggests brain changes precede onset of clinical AD symptoms by 15-20 years. Thus, midlife is the optimal window to target preventive efforts for AD risk reduction. Despite this, most AD research relies on samples aged 65+. Our objective was to expand the capacity of our NIH-designated Alzheimer's Disease Research Center by building a midlife cohort to investigate sex-specific AD risk. Evidence supports 5 key mechanisms to explain sex-based disparities in AD risk including sociodemographics, menstrual and reproductive history, cardiometabolic risk, psychological factors, and lifestyle factors. Results will support funding applications for longitudinal follow up

and inform the design of AD risk reduction interventions in peri- and post-menopausal women. **Design:** We recruited adults ages 40-60, from the Kansas City and Wichita, KS metro areas. Via online surveys, we collected 1) sociodemographic data (age, education, race/ethnicity, disability, SES), 2) reproductive history (menstrual status & history, gynecological surgery history, menopausal symptom presence & severity, pregnancy history, medication history), 3) cardiometabolic risk (ACSM checklist, personal & family health & dementia history, BMI, waist circumference), 4) psychological factors (PROMIS depression & anxiety scales, Adverse Childhood Experiences (ACE) questionnaire), and 5) lifestyle (International Physical Activity Questionnaire, Rapid Eating Assessment for Patients, Soy Foods Screener, Pittsburgh Sleep Quality Index, caffeine, alcohol, & tobacco). **Results:** To date, 114 participants have completed measures (Mean Age 49.9; 67% women). The sample is 17.5% African American, 4.4% multi-racial, 2.6% Asian, 12.3% Hispanic/Latino/a/x, 68.4% White, and 1.8% other race. Among women, 13.4% were pre-menopausal, 25.3% were peri-menopausal, 20.9% were post-menopausal (spontaneous), 22.4% had surgical menopause, and 16.5% did not have periods for other reasons. Over two-thirds of women reported being treated for women's health issues (i.e., reproductive cancers, thyroid dysfunction, bone loss, uterine fibroids, endometriosis, PCOS, or infertility). Preliminary analyses revealed women in our sample had higher AD risk in several domains. Sociodemographically, women had lower income ( $t(df)=2.40(101)$ ,  $p=.009$ ). Women reported more family history of dementia ( $\chi^2(df)=11.19(1)$ ,  $p=.001$ ), hypertension ( $\chi^2(df)=8.42(1)$   $p=.005$ ), and hypercholesterolemia ( $\chi^2(df)=6.18$ ,  $p=.022$ ). Women were more likely to report heart palpitations ( $t=6.81$ ,  $p=.009$ ). Psychologically, women had higher ACE scores ( $t(df)=-2.76(100.5)$ ,  $p=.003$ ), more depression ( $t(df)=-2.81(104)$ ,  $p=.003$ ) and anxiety ( $t(df)=-1.70(101)$ ,  $p=.046$ ). Women spent less time in vigorous physical activity ( $t(df)=-2.91(108)$ ,  $p=.004$ ). Women who underwent ovariectomy had several elevated AD risks compared to women without this surgery, including lower educational attainment ( $t(df)=-2.92(67)$ ,  $p=.005$ ) and greater rates of disability ( $\chi^2(df)=5.96(1)$ ,  $p=.044$ ). They reported higher ACE scores ( $t(df)=-2.30(64)$ ,  $p=.025$ ), and more anxiety ( $t(df)=-2.61$ ,  $p=.011$ ). They ate more fried foods and sweets ( $t(df)=-2.845(67)$ ,  $p=.006$ ), and reported poorer sleep ( $t(df)=-2.39(67)$ ,  $p=.020$ ). Post-menopausal women reported more dizziness ( $\chi^2(df)=4.87(1)$ ,  $p=.034$ ) and eating more sweets ( $t(df)=-2.18(65)$ ,  $p=.029$ ). **Conclusion:** We have successfully begun building a midlife cohort with diverse participants to support development of interventions targeting sex-based disparities in AD risk that may originate in or be exacerbated by the menopausal transition. Preliminary results support the existence of differences in AD risk based on sex and menopausal history that warrant further investigation. Although the present study was conducted by online self-report, participants indicated willingness to participate in future research including health interventions, neuroimaging, and biomarker collection.

**Sources of Funding:** P30AG035982

P-114.

**Obstructive sleep apnea and type 2 diabetes mellitus in middle-aged and older women**

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**Objective:** Sleep problems are known to affect insulin sensitivity and glucose metabolism. However, limited evidence is available on the association between obstructive sleep apnea (OSA) and type 2 diabetes mellitus (T2DM) in middle-aged and older women in menopausal transition. Hormone changes may alter the risk of OSA and T2DM. The aim of this study was to explore the association between OSA and T2DM among middle-aged and older women living in South Korea. **Design:** This was a cross-sectional study using nationwide data extracted from the 2019-2021 Korea National Health and Nutrition Examination Survey. Among 22,559 participants in the database, 6,003 women aged ≥40 years were included in the study. Participants were classified into diabetes, pre-diabetes, and non-diabetes groups according to the criteria of the Korean Diabetes Association, using fasting blood glucose and HbA1c concentrations. According to the STOP-Bang score, participants were classified into low-, moderate-, and high-risk groups for OSA. For data analysis, the Rao-Scott  $\chi^2$  test for categorical variable, t-test or F-test for continuous variable, and multiple logistic regression were conducted using the SAS software program. **Results:** Of the 6,003 participants, 14.0% had T2DM and 0.8% had a high risk of OSA. The prevalence of T2DM significantly differed among women in low- (11.8%), moderate- (22.8%), and high-risk (32.7%) groups for OSA ( $\chi^2=106.70$ ,  $p<.001$ ). Women with a high risk of OSA (mean=6.4) and those with a moderate risk of OSA (mean=6.0) had a higher HbA1c concentration than those with a low risk of OSA (mean=5.8) in age-adjusted F-test ( $p<.001$ ). There was significant difference between pre- and post- menopause group on the risk of OSA ( $p<.001$ ). Upon multiple logistic regression, women with a moderate- (Odds Ratio [OR]: 1.48, 95% Confidence Interval [CI]: 1.18-1.84) or high- (OR: 3.65, 95% CI: 1.55-8.58) risk of OSA had a higher risk of T2DM than low risk of OSA. Thus, post-menopause women had higher risk of T2DM than pre-menopause women (OR: 1.51, 95% CI: 1.02-2.03) after adjusting covariates. **Conclusion:** The study results support the necessity of screening and managing middle-aged and older women for OSA and T2DM, and for such women to enhance their glucose control. Because of the methodological limitation in the cross-sectional study, we suggest that further studies should be conducted to fully understand the interrelationships between OSA and T2DM.

**Sources of Funding:** This study was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (Ministry of Science and ICT) (No. NRF-2020R1C1C1006343).

#### P-115.

##### **Relationship Between Menopausal Hormone Therapy and Breast Cancer: A Cohort Study Utilizing the Health Insurance Database in South Korea (HISK)-II**

Tae-ran Kim, MD, Jin-Sung Yuk, M.D., Ph.D.. Department of Obstetrics and Gynecology, Inje University Sanggye Paik Hospital, Nowon-gu, Korea (the Republic of Korea). **Objective:** The purpose of this retrospective cohort study was to evaluate the breast cancer risk related to menopausal hormone therapy (MHT). **Design:** Postmenopausal patients over the age of 40 who were selected using the National Health Insurance Database in South Korea (2011-2014) were included in this study. Women who had used MHT for more than six months during this period were selected as the MHT group, while women who had never used MHT were selected as the non-MHT group. The two groups were matched 1:1 based on several variables using propensity score matching. Both groups were followed until 2020. **Results:** The non-MHT and MHT groups comprised 153,736 women each. In an extended Cox proportional hazard analysis with time-dependent covariates, MHT was associated with an increased risk of breast cancer (hazard ratio [HR] 1.224, 95% confidence interval [CI] 1.152–1.302). Tibolone (HR 0.973, 95% CI 0.896–1.057), estradiol valerate (EV)/medroxyprogesterone acetate (MPA) (HR 1.525, 95% CI 0.946–2.459), EV/norethisterone acetate (NETA) (HR 1.772, 95% CI 0.571–5.498), conjugated equine estrogen (CEE) (HR 0.834, 95% CI 0.517–1.344), EV (HR 1.049, 95% CI 0.892–1.234), estradiol hemihydrate (EH) (HR 1.137, 95% CI 0.366–3.529), CEE/micronized progesterone (MP) (HR 0.223, 95% CI 0.031–1.583), CEE/MPA (HR 2.005, 95% CI 0.501–8.024), EV/MP (HR 0.791, 95% CI 0.297–2.110), EV/MPA (HR 2.066, 95% CI 0.984–4.340), and EH/MP (HR 0.763, 95% CI 0.191–3.052) did not increase the risk of breast cancer compared to the non-MHT group. However, EH/drospirenone (DRSP) (HR 1.511, 95% CI 1.38–1.655), EH/NETA (HR 1.664, 95% CI 1.343–2.063), EH/dydrogesterone (DYD) (HR 1.367, 95% CI 1.115–1.676), and EV/cyproterone acetate (CPA) (HR 1.741, 95% CI 1.544–1.964) increased the risk of breast cancer compared to the non-MHT group. Subgroup analyses by duration of MHT use showed that MHT was associated with an increased risk of breast cancer at all durations of use. **Conclusion:** MHT is associated with an increased risk of breast cancer. Most combined estrogen plus progestin, including EH/DRSP, EH/NETA, EH/DYD, and EV/CPA, were also associated with a higher risk of breast cancer. **Sources of Funding:** None

#### P-116.

##### **Prevalence and impact of vasomotor symptoms due to menopause: Canadian subgroup of the Women with Vasomotor Symptoms Associated With Menopause (WARM) study**

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**Objective:** The primary objective of this analysis was to determine the prevalence of moderate/severe vasomotor symptoms (VMS) among Canadian women in postmenopause in the multinational WARM study. Secondary objectives were to assess the impact of moderate/severe VMS on quality of life (QoL), work productivity, daily activities, and sleep and to describe VMS treatment patterns and experiences among Canadian women in perimenopause and postmenopause. **Design:** This cross-sectional, online survey included Canadian women in perimenopause and postmenopause aged 40–65 years who had moderate/severe VMS in the prior month. Women in the primary analysis were postmenopausal, and women in the secondary analysis were perimenopausal or postmenopausal with moderate/severe VMS. The primary outcome was the prevalence of moderate/severe VMS ( $\geq 1$ /day in prior month) postmenopause. Secondary outcomes included the impact of VMS on QoL (Menopause-Specific QoL [MENQoL] questionnaire; 0–6 scale for 4 domains, with higher scores indicating greater bother), work productivity and daily activity impairment (Work Productivity and Impairment-VMS [WPAI-VMS] questionnaire; percentage, with higher scores indicating greater impairment), and sleep (Patient-Reported Sleep Disturbances [PROMIS] questionnaire–Short Form 8b; 5-point scale per item [range, 8–40], with higher scores indicating more severe disturbance). Secondary outcomes also included VMS treatment patterns and attitudes toward menopause (1–7 scale; higher scores indicated greater agreement with specific statements). **Results:** In the primary analysis, 360 of 2456 (14.7%) Canadian women in postmenopause reported moderate/severe VMS. The secondary analysis included 400 women in perimenopause or postmenopause with moderate/severe VMS; results from this population are presented here. The largest age group was 56–60 years (136 [34.0%]), and most were White (359 [89.8%]). The mean (SD) number of daily hot flashes was 4.6 (5.4), with a mean duration of 22.3 (56.9) minutes. Mean MENQoL scores showed some level of bother (scores  $>3$ ) in all domains: vasomotor, 3.3 (1.3); sexual, 3.3 (1.6); psychosocial, 3.4 (1.4); and physical, 3.7 (1.3). Based on MENQoL responses, the most frequent symptoms were hot flashes (92.8%), sweating (80.2%), feeling tired/worn out (79.3%), and night sweats (72.9%). Among 205 employed women completing the WPAI-VMS questionnaire, 184 (89.8%) did not miss any work because of VMS, although mean work impairment was high (30.2%) due to the impact of VMS on presenteeism (29.3%; absenteeism, 3.2%). Daily activities were impaired to a greater extent (mean, 35.7%; assessed in all 400 women). Mean total PROMIS scores showed substantial impact of VMS on sleep (28.5 [6.9]), with greatest impact on restless sleep (3.6 [1.2]), trouble staying asleep (3.6 [1.1]), and trouble sleeping (3.4 [1.1]). Overall, 41.0% of women sought medical advice but did not receive pharmacologic treatment. Most (66.5%) were not taking any treatments for VMS. Among 134 women (33.5%) on treatment, supplements (21.5%), hormone therapy (10.0%), and nonhormonal prescription medications (7.0%) were most common. Attitudes toward menopause were

generally neutral or positive; 23.0%–81.0% and 20.0%–71.8% strongly agreed with neutral and positive statements about VMS, respectively. Mean scores showed that women most strongly agreed with “Menopause is a natural and inevitable part of the aging process,” 6.2 (1.1); “Thanks to menopause, I do not worry about my menstruation anymore,” 5.8 (1.6); and “Menopause is an undesired time, since it implies facing bothersome symptoms,” 4.7 (1.8). **Conclusion:** In the WARM study, 14.7% of Canadian women in postmenopause reported moderate/severe VMS. VMS had a considerable effect on QoL, work, daily activities, and sleep, highlighting an unmet need for access to menopause management and effective therapies to relieve symptoms and help alleviate the impact of moderate/severe VMS due to menopause.

**Sources of Funding:** The study was sponsored by Astellas Pharma, Inc. (Northbrook, IL). Writing support provided by Hannah L. Mayberry, PhD, and Jessica D. Herr, PharmD, of Echelon Brand Communications, LLC, an OPEN Health company, was funded by Astellas.