

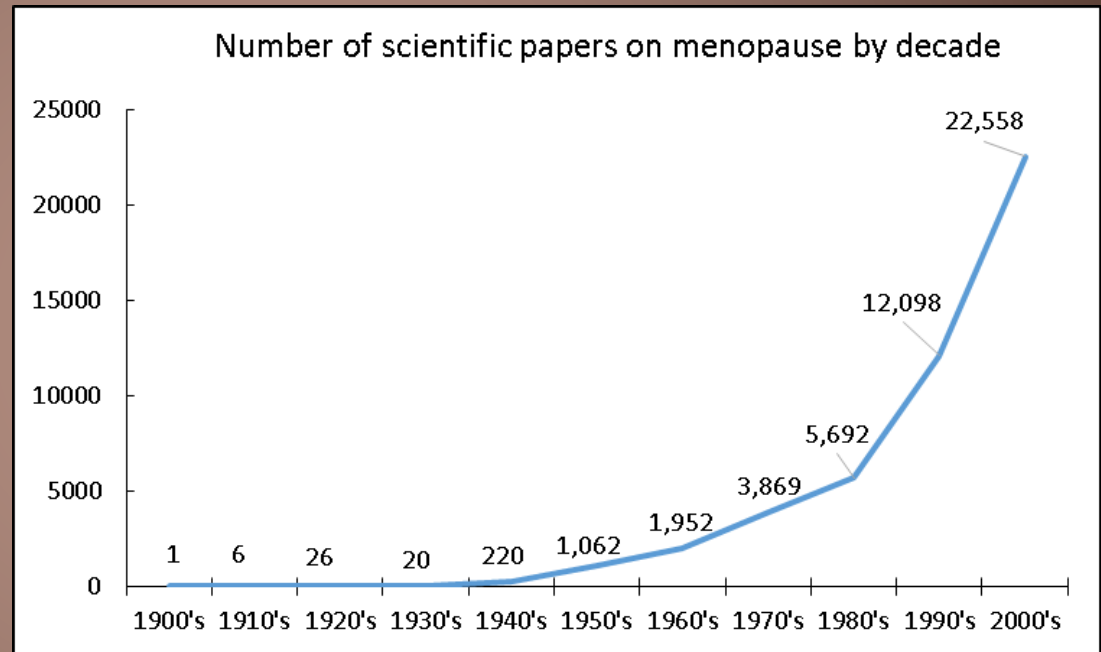


Symptom science: Clinical trials for alleviating menopausal hot flashes

**Janet S. Carpenter, PhD, RN, FAAN
IU School of Nursing**

Historical Context of Menopause Research

- Growth in research this century
- Greater emphasis on inclusion of women in research and on women's health
- Worldwide more women living post-menopause



1907, E. Pratt, "A case of sudden death at the climacteric"

Menopause Now

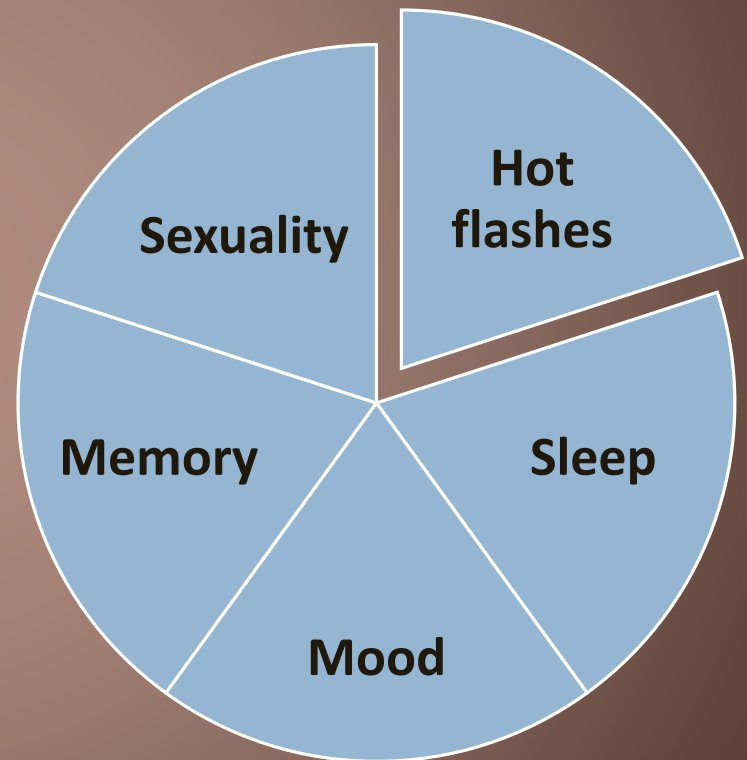
- **Postmenopausal women**

- 477 million in 1998 worldwide
- 1.1 billion in 2025 worldwide
- 6,000 women reach menopause *daily* in USA

- **85% have symptoms**

- **80% consult a health care provider**

- Health care expenditures 55% higher for midlife women than midlife men



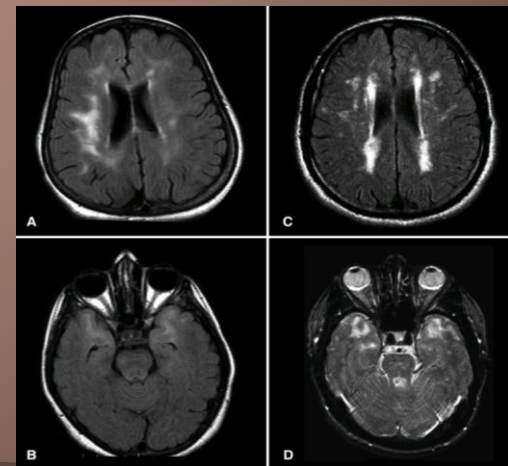
Etiology?

Serotonin
Norepinephrine
Estrogen
GABA
Orexin
Kisspeptin
Neurokinin B
Dynorphin
Electrolytes
Glucose

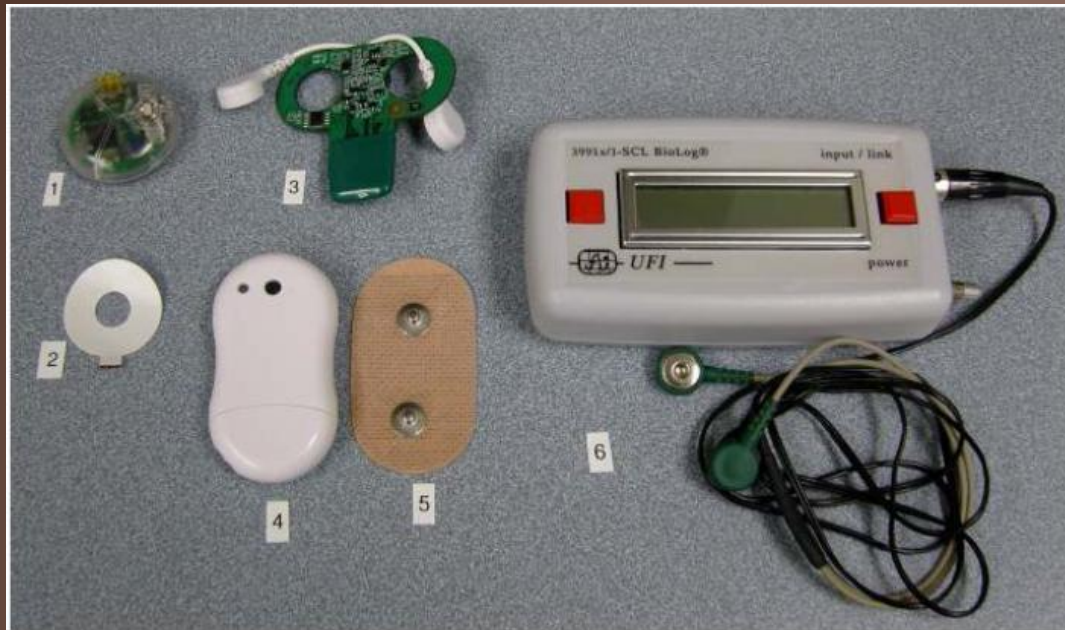
Central? Peripheral? Both?



White matter hyperintensities

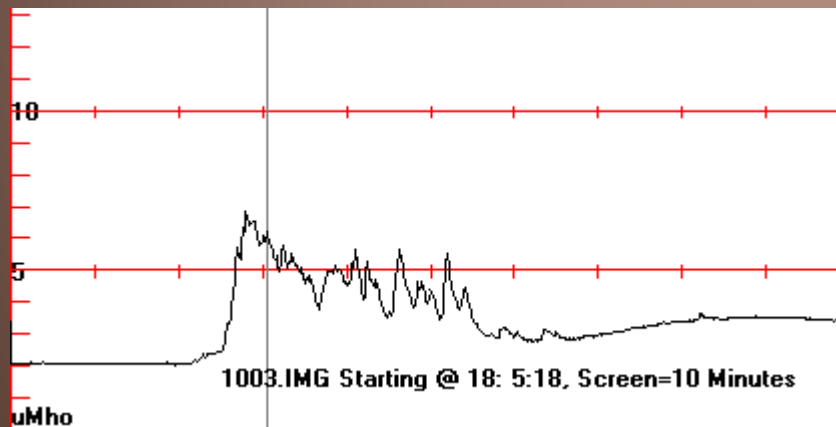


Menopausal Hot Flash Measurement



Repetitive,
multidimensional,
centrally-mediated,
physiological events

NIH measurement
workshop, NIH SBIR
funding, MsFLASH
measurement
recommendations



Total costs per system: \$1200 to \$4000

Original Article

The Hot Flash Related Daily Interference Scale: A Tool for Assessing the Impact of Hot Flashes on Quality of Life Following Breast Cancer

Janet S. Carpenter, PhD, RN

Vasomotor symptoms = hot flashes/flushes + night sweats

Hot Flash Phrases	Country
les bouffées de chaleur	France
hitzewallengun	Germany
vampate di calore	Italy
los sofocos	Spain, Mexico
návaly horka	Czech Republic
goroom vap laga	Bangladesh
sicak basmasi	Turkey

Menopausal Hot Flash Measurement

Cited in 171 scientific papers

Translated in 12 languages:
Afrikaans, Danish, Farsi, Flemish, French, Italian, Mandarin, Norwegian, Portugese, Spanish, Swedish, Taiwanese

MsFLASH and Other PI/Col Treatment Trials

Preventing BrCA Through Non-hormonal Menopause Management



Integrative/ Alternative

- Breathing
- Exercise
- Yoga
- Hypnosis

Supplements

- ~~Omega-3~~ fatty acids



Medications

- Venlafaxine
- Escitalopram
- Estrogen



MsFLASH 01: Escitalopram vs. Placebo

SCREENING			TREATMENT							POST-TREATMENT			
			Escitalopram 10 mg po qd				Continue 10 mg po qd			Stop	→	Follow-up	
							Increase to 20 mg po qd			Taper off		Follow-up	
2 week screening → Baseline →													
			Placebo 1 po qd				Continue 1 po qd			Stop	→	Follow-up	
							Increase to 2 po qd			Taper off		Follow-up	
	V	V	Ph			V				V			Ph
Week	-1	0*	1	2	3	4	5	6	7	8	9	10	11
V = visit, Ph = phone													
*Stratified randomization by race & clinical Site													

MsFLASH02: 3x2 Factorial Trial of Omega-3, Yoga, Exercise vs. Placebo

SCREENING			TREATMENT											
2 week screening	→	Baseline	→											
			Omega-3 fatty acids (EPA [1275mg] + DHA [300mg])											
			Placebo											
			Omega -3 Plus Exercise (3 times/week)											
			Placebo + Exercise											
			O3 Plus Yoga											
Placebo + Yoga														
	V	V	Ph					M		V				v
Week	-1	0*	1	2	3	4	5	6	7	8	9	10	11	12
V = visit, Ph = phone														
*Stratified randomization by race & clinical Site														

Paced Respiration for Vasomotor and Other Menopausal Symptoms: A Randomized, Controlled Trial

Janet S. Carpenter, Debra S. Burns, Jingwei Wu, Julie L. Otte, Bryan Schneider, Kristin Ryker, Eileen Tallman & Menggang Yu

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Methods for the design of vasomotor symptom trials: the Menopausal Strategies: Finding Lasting Answers to Symptoms and Health network

Katherine M. Newton, PhD,¹ Janet S. Carpenter, PhD, RN, FAAN,² Katherine A. Guthrie, PhD,³ Garnet L. Anderson, PhD,³ Bette Caan, DrPH,⁴ Lee S. Cohen, MD,⁵ Kristine E. Ensrud, MD, MPH,⁶ Ellen W. Freeman, PhD,⁷ Hadine Joffe, MD,⁵ Barbara Sternfeld, PhD,⁴ Susan D. Reed, MD, MPH,⁸ Sheryl Sherman, PhD,⁹ Mary D. Sammel, ScD,¹⁰ Kurt Kroenke, PhD,¹¹ Joseph C. Larson, MS,³ and Andrea Z. LaCroix, PhD³

ORIGINAL ARTICLE: GYNECOLOGY AND MENOPAUSE

Effect of escitalopram on hot flash interference: a randomized, controlled trial

Janet S. Carpenter, Ph.D., R.N.,^a Katherine A. Guthrie, Ph.D.,^b Joseph C. Larson, M.S.,^b Ellen W. Freeman, Ph.D.,^c Hadine Joffe, M.D., M.Sc.,^d Susan D. Reed, M.D.,^e Kristine E. Ensrud, M.D., M.P.H., F.A.C.P.,^f and Andrea Z. LaCroix, Ph.D.^b



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Clinical hypnosis in the treatment of postmenopausal hot flashes: a randomized controlled trial

Gary R. Elkins, PhD,¹ William I. Fisher, MA,¹ Aimee K. Johnson, MA,¹ Janet S. Carpenter, PhD, RN, FAAN,² and Timothy Z. Keith, PhD³

Insight



Coping With Menopausal Symptoms After Breast Cancer Treatment

BY ANGELA KNIGHT, FOR LBBC



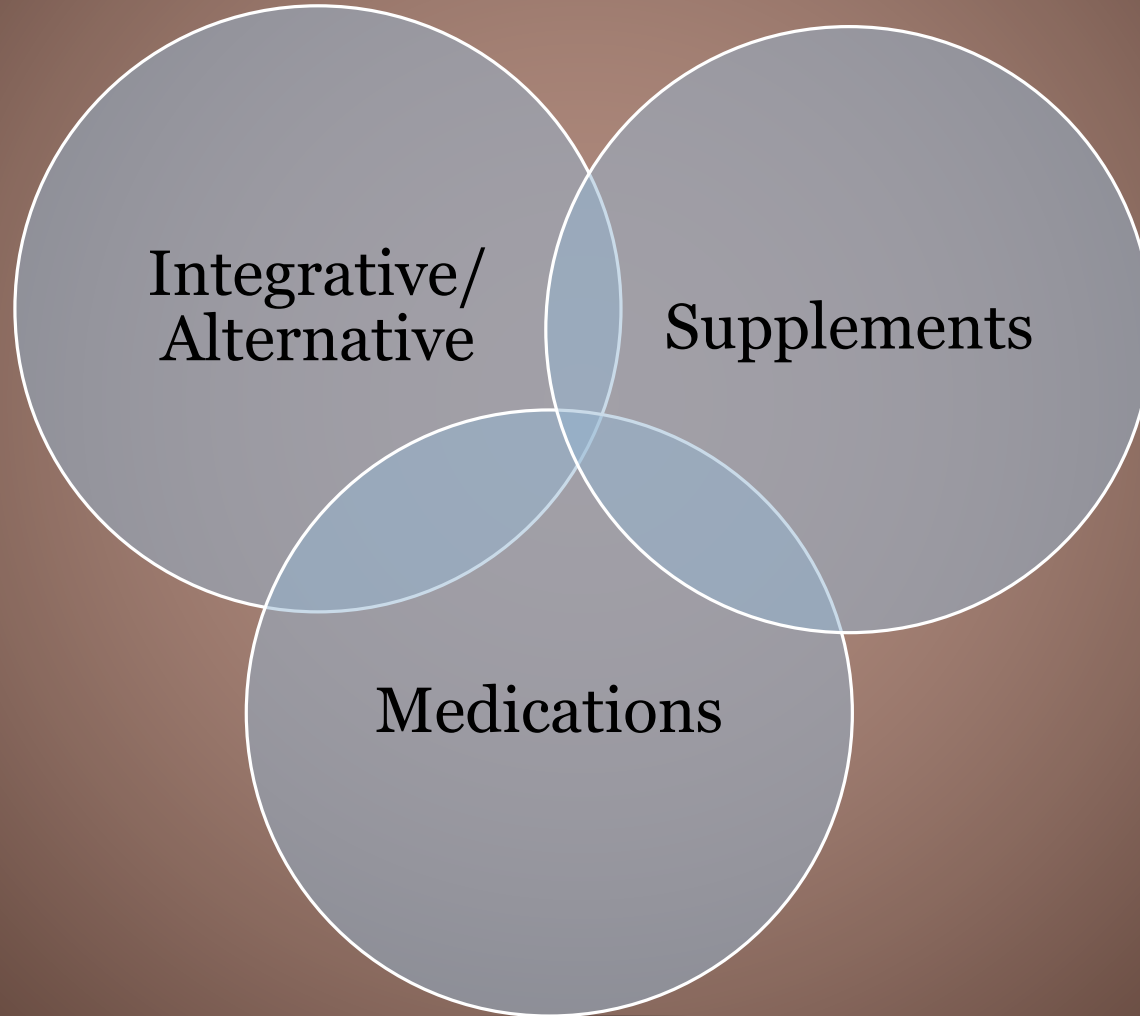
2015 NAMS Position Paper

- North American Menopause Society
- Non-hormonal management of menopausal symptoms
- Expert panel reviewed 340 original research articles and 105 systematic reviews
- Treatments classified according to level of evidence and implications for practice

NAMS Recommendations

Recommended	<ul style="list-style-type: none">• Cognitive behavioral therapy• Clinical hypnosis• Paroxetine (FDA approved) and other SSRI / SSNRI• Gabapentin• Clonidine
Recommend with Caution	<ul style="list-style-type: none">• Weight loss• Mindfulness-based stress reduction• Soy extracts• Stellate ganglion block
Do Not Recommend at this Time	<ul style="list-style-type: none">• Paced respiration, relaxation training• Exercise, yoga• Acupuncture• Avoiding triggers• Cooling techniques

Novel Treatment Trials





Questions?