

# NONPHARMACOLOGIC TREATMENTS FOR MENOPAUSE-ASSOCIATED VASOMOTOR SYMPTOMS

Karen M. Goldstein MD, MSPH

Remy R. Coeytaux MD, PhD

Megan Shepherd-Banigan PhD

John W. Williams Jr. MD, MHSc (Director)

ESP Center

Durham VA Healthcare System

Durham, NC

Full-length report available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

# Acknowledgements

## Co-authors/Collaborators

- Adam P. Goode, DPT, PhD
- Jennifer R. McDuffie, PhD
- Deanna Befus, BSN
- Soheir Adam, MD
- Varsha Masilamani, MBBS
- Megan Van Noord, MSIS

## Research Associates

- Avishek Nagi, MS
- Liz Wing, MA

## Technical Expert Panel/Reviewers

- Veronica Ades, MD MPH
- Nancy Avis, PhD
- Lori Bastian, MD, MPH
- Margery Gass, MD
- Tracey Gaudet, MD

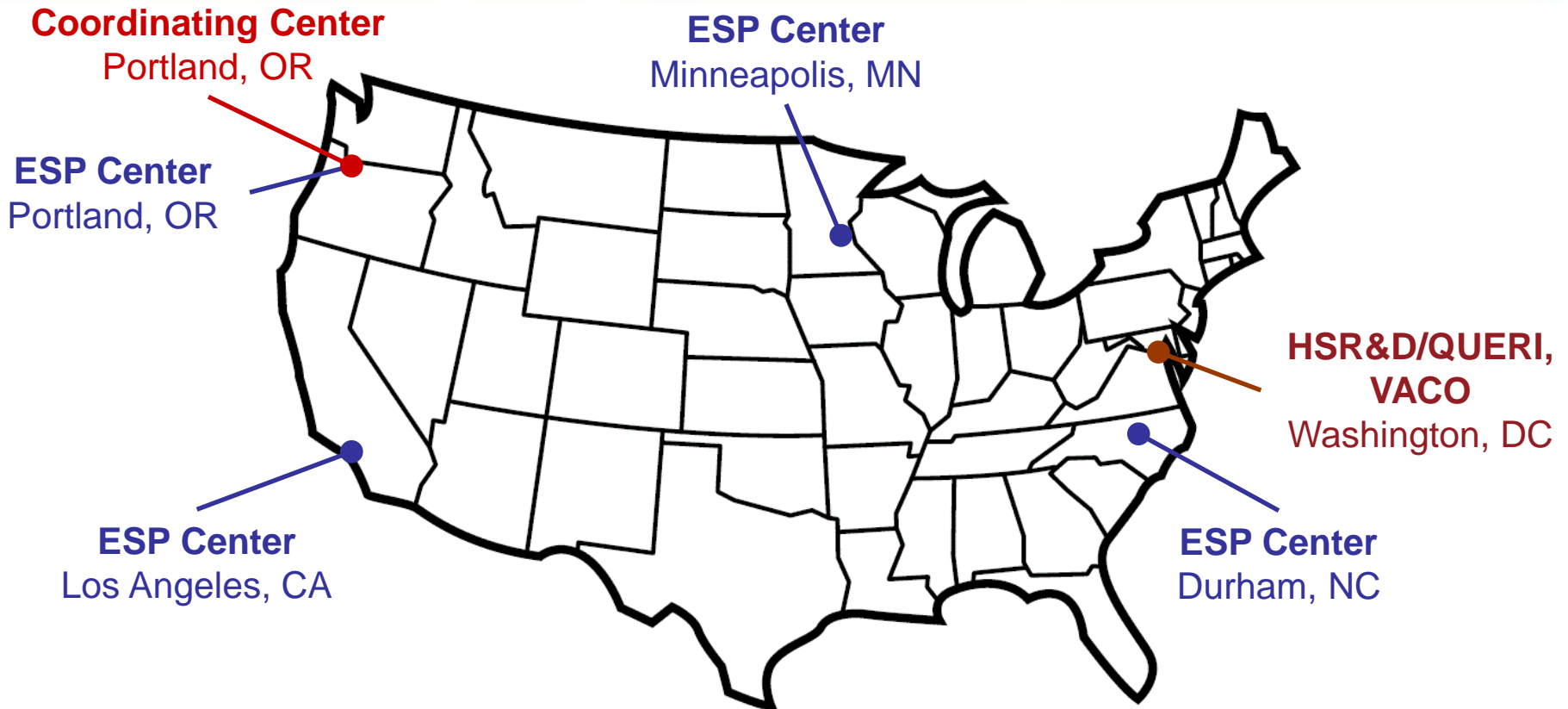
## Stakeholders

- Laurie Zephyrin, MD
- Jodie Katon, PhD

# Disclosure

This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the Durham Healthcare System Durham, NC funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

# Evidence-based Synthesis Program Centers





Please tell us how you spend the majority of your workweek?

- a) Primary care clinic/CBOC
- b) Women's Health Clinic
- c) Emergency room/in-patient setting
- d) Research
- e) Other

## **POLL QUESTION**

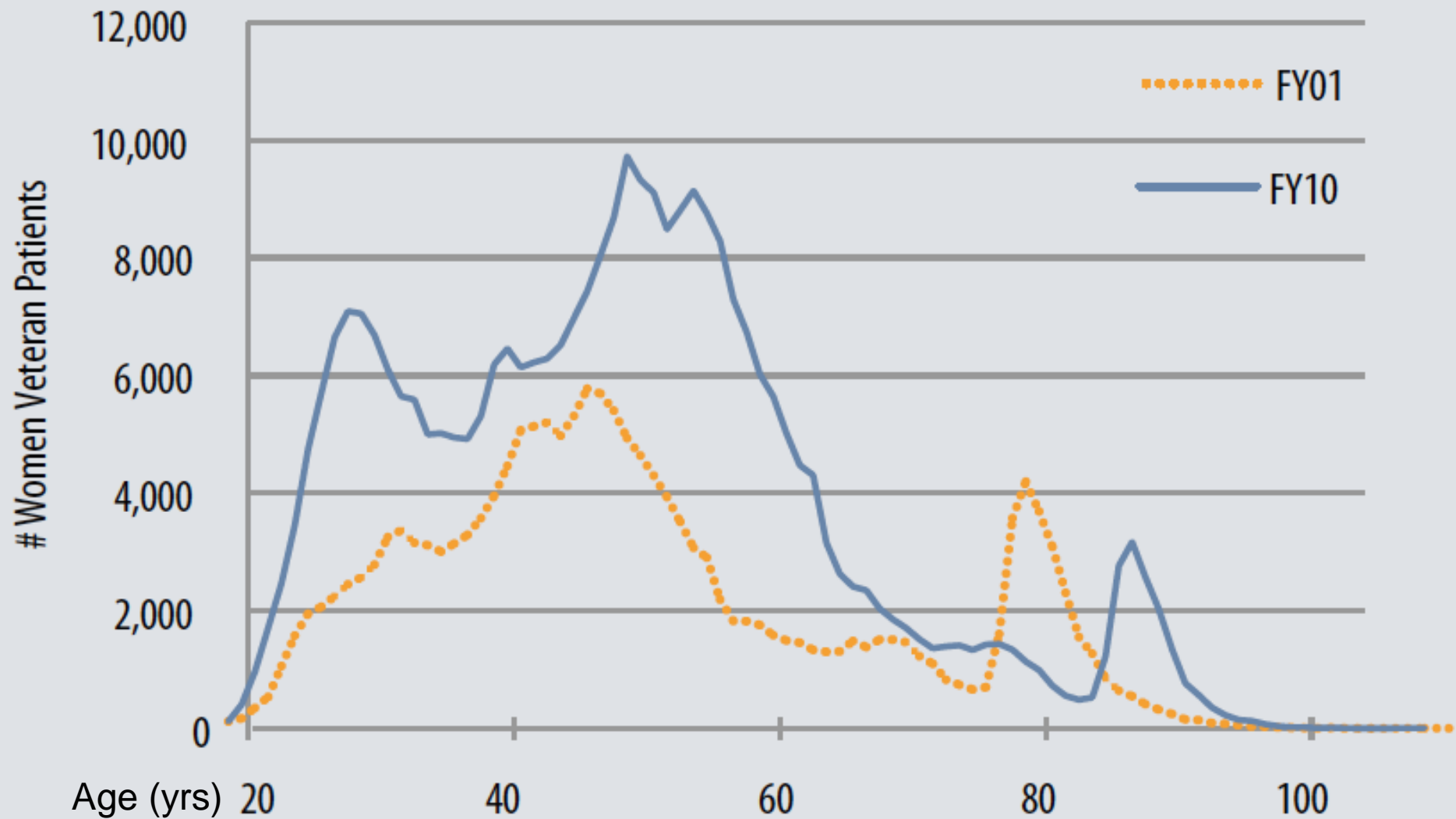
# Vasomotor Symptoms

- Hot flashes/Night sweats
- 80% women
- Median duration over 7 years
- Impact:
  - Physical
  - Psychological
  - Social
  - Healthcare utilization

Avis. 2015



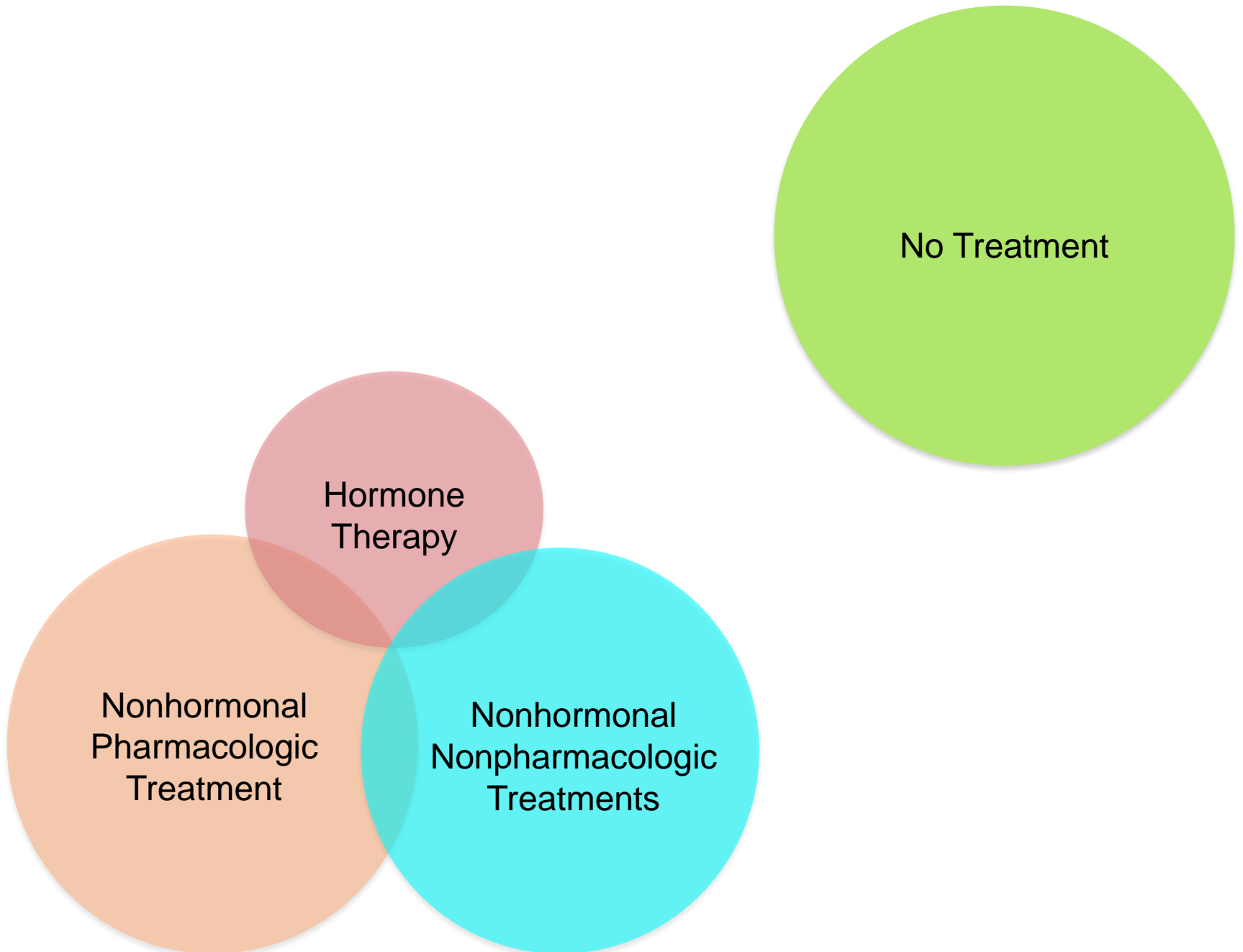
# Age distribution of women Veteran patients, FY01 and FY10



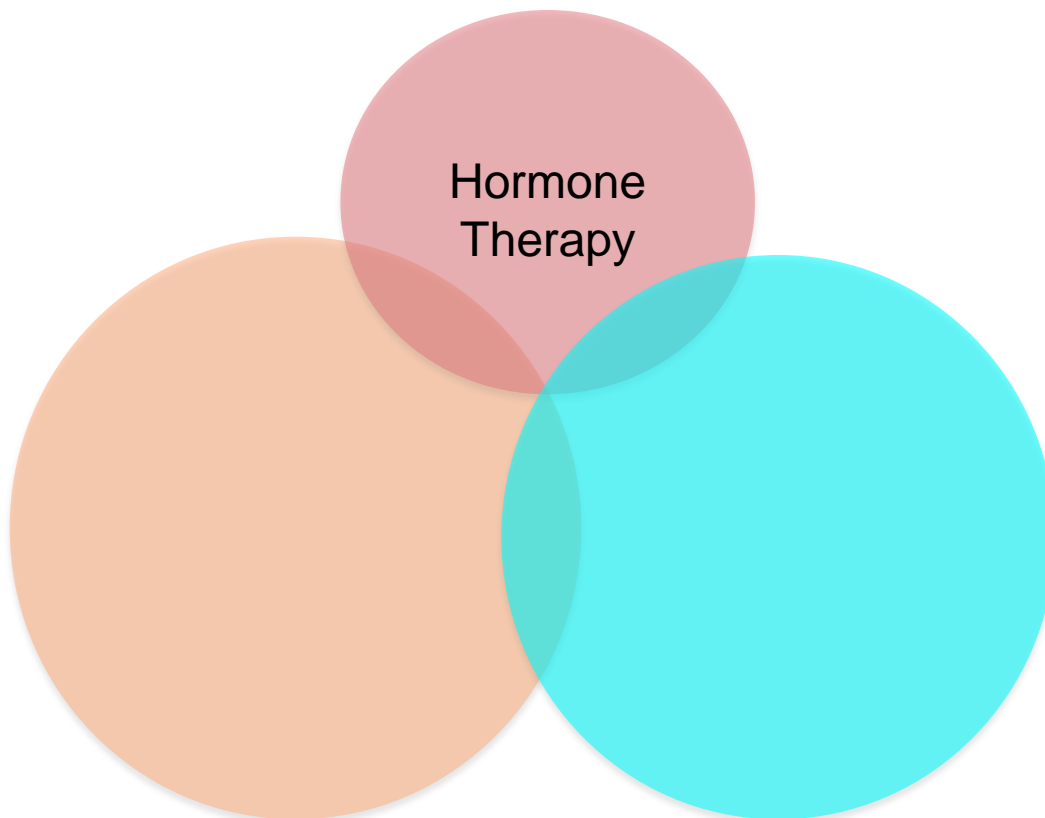


Women Veterans are twice as likely as civilian women to be prescribed hormone therapy

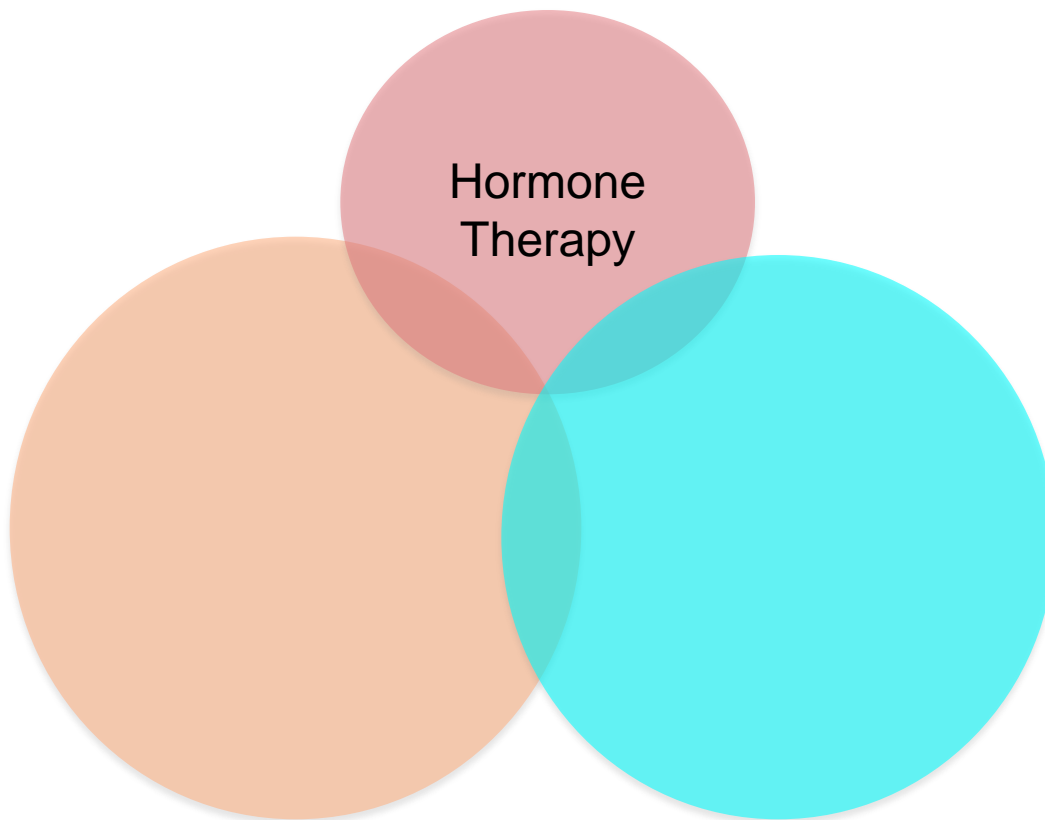
- 10.3% in FY 2009

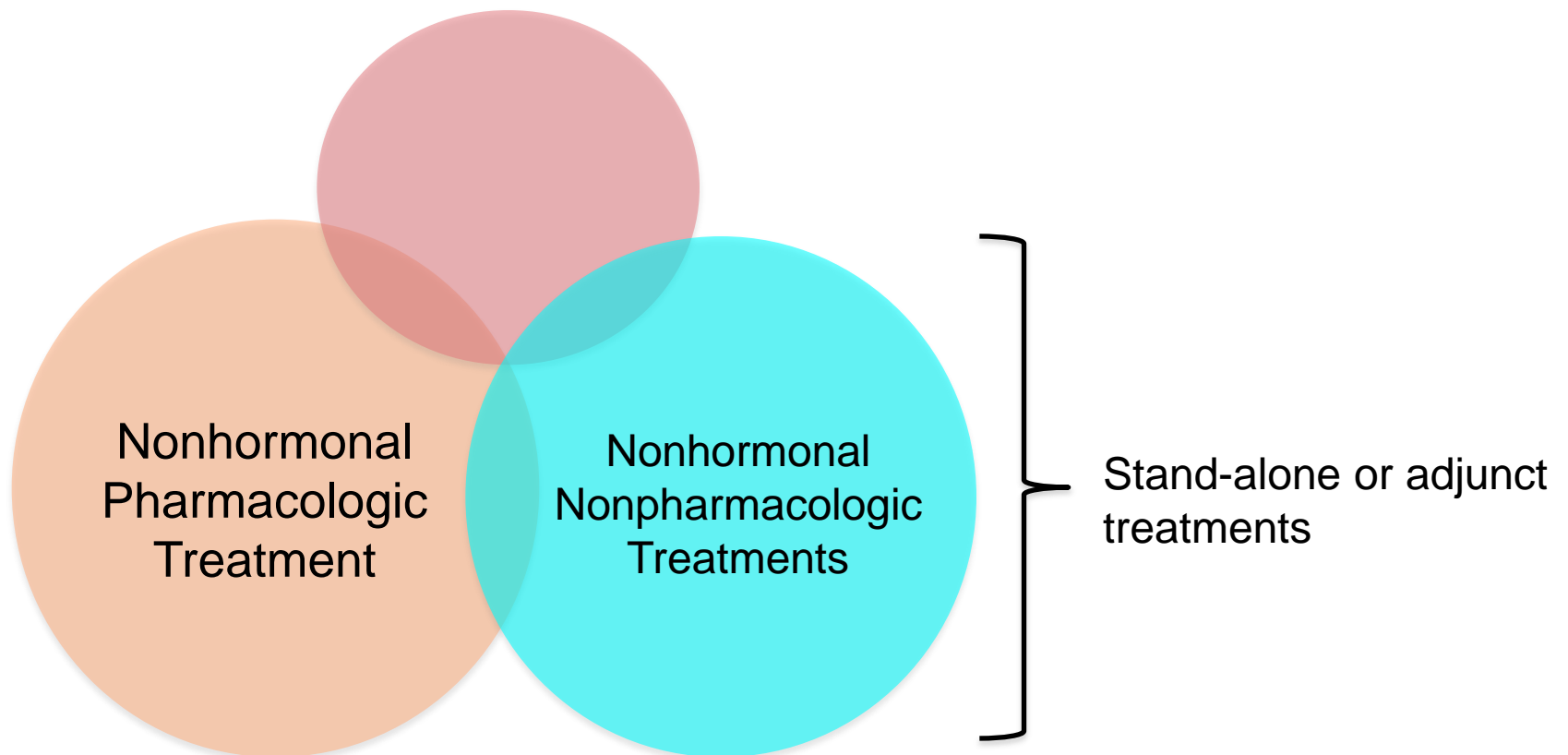


- Most effective treatment
- Women with bothersome VMS, aged <60 and <10 years since menopause
- Balance risks/benefits

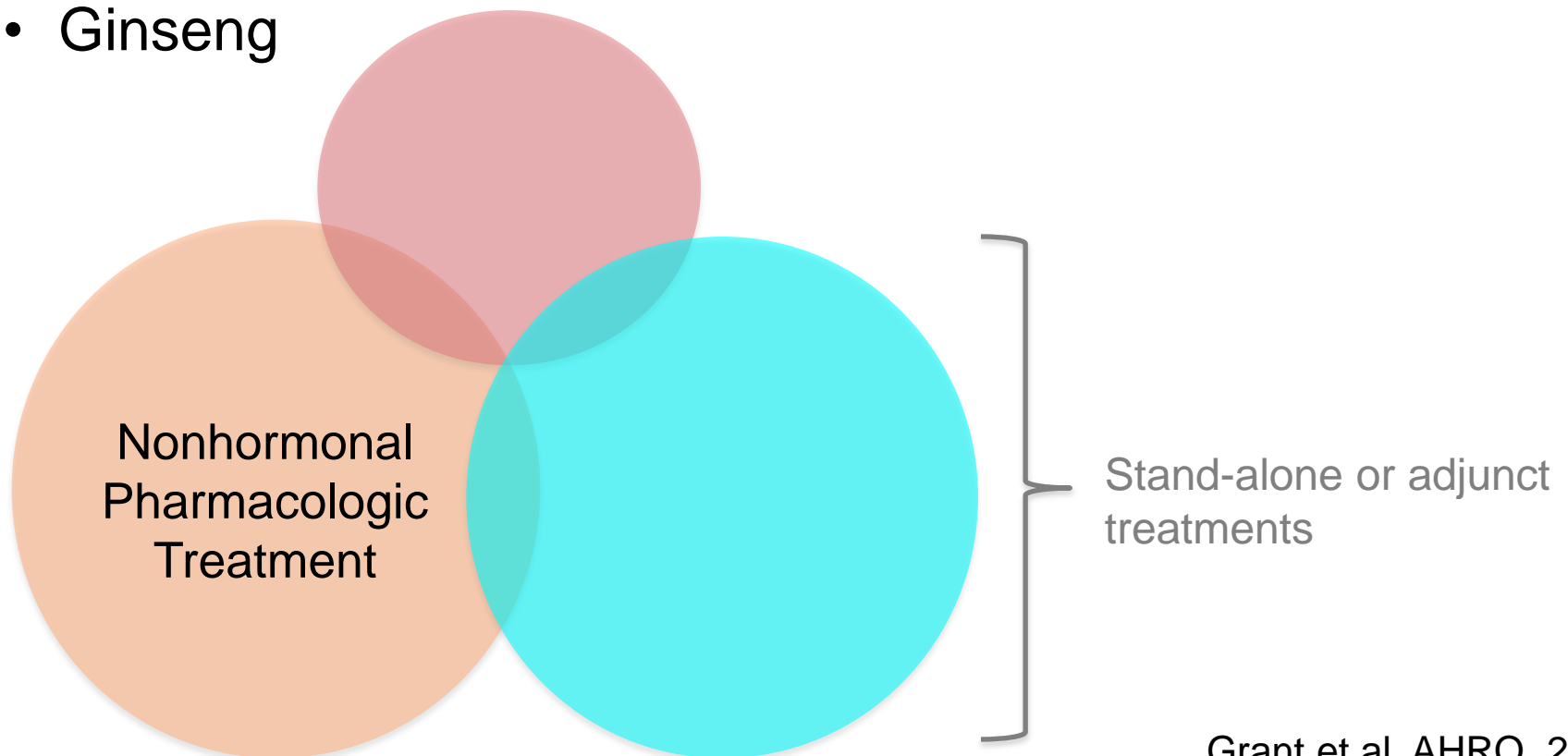


CURE ALL! → **Evil!!** → Maybe ok?

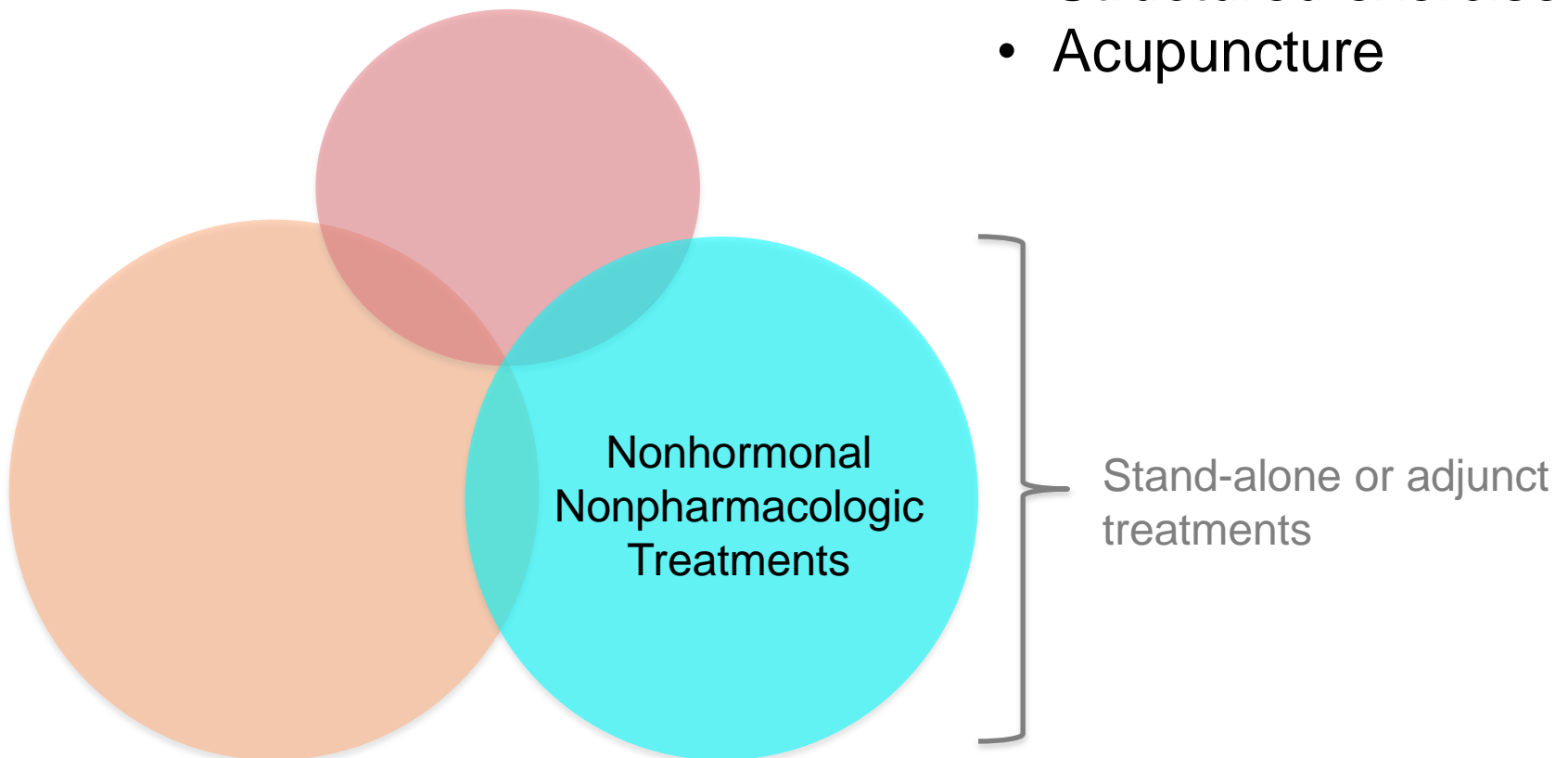




- SSRI/SNRI
- Gabapentin
- Isoflavones
- Black Cohosh
- Ginseng



- Mind/body practices
  - Yoga
  - Tai chi
- Meditation
- Structured exercise
- Acupuncture



## Treatment of Symptoms of the Menopause: An Endocrine Society Clinical Practice Guideline

Cynthia A. Stuenkel, Susan R. Davis, Anne Gompel, Mary Ann Lumsden, M. Hassan Murad, JoAnn V. Pinkerton, and Richard J. Santen

University of California, San Diego, Endocrine/Metabolism (C.A.S.), La Jolla, California 92093; Monash University, School of Public Health and Preventive Medicine (S.R.D.), Melbourne 03004, Australia; Université Paris Descartes, Hôpitaux Universitaires Port Royal-Cochin Unit de Gynécologie Endocrinienne (A.G.), Paris 75014, France; University of Glasgow School of Medicine (M.A.L.), Glasgow G12 8TA, Scotland; Mayo Clinic, Division of Preventive Medicine (J.V.P.), Charlottesville, Virginia 22902; University of Virginia, Obstetrics and Gynecology (J.V.P.), Charlottesville, Virginia 22902; Health System (R.J.S.), Charlottesville, Virginia 22902



The American College of  
Obstetricians and Gynecologists  
WOMEN'S HEALTH CARE PHYSICIANS

# PRACTICE BULLETIN

*CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS*

NUMBER 141, JANUARY 2014

(Replaces Practice Bulletin Number 28, June 2001)  
(See also Committee Opinion Number 565, Committee Opinion Number 556)

*Menopause: The Journal of The North American Menopause Society*  
Vol. 22, No. 11, pp. 000-000  
DOI: 10.1097/GME.0000000000000546  
© 2015 by The North American Menopause Society

## POSITION STATEMENT

Nonhormonal management of menopause-associated vasomotor symptoms: 2015 position statement of The North American Menopause Society

## Perceptions of Providers and Administrators in the Veterans Health Administration Regarding Complementary and Alternative Medicine

*Carol E. Fletcher, PhD, RN,\* Allison R. Mitchinson, MPH, NCTMB,\* Erika L. Trumble, MPH,\*  
Daniel B. Hinshaw, MD, FACS,\* and Jeffery A. Dusek, PhD†*

Med Care 2014; 52: S91-S96

## A Factor Analysis and Exploration of Attitudes and Beliefs Toward Complementary and Conventional Medicine in Veterans

*Lisa M. Betthausen, MA, MBA,\*† Lisa A. Brenner, PhD,\*‡ Jeri E. Forster, PhD,\*§  
Trisha A. Hostetter, MPH,\* Alexandra L. Schneider, BA,\* and Theresa D. Hernández, PhD\*||*

Med Care 2014; 52: S50-S56.

## Key Question


In women with vasomotor symptoms (VMS) that are associated with perimenopause or postmenopause, what are the effects on VMS, health-related quality of life, and adverse events of the following nonpharmacologic, nonhormonal interventions:

**Yoga, tai chi, and qigong**

**Acupuncture**

**Relaxation, hypnosis, meditation, and  
mindfulness**

**Structured exercise**



Nonhormonal  
Nonpharmacologic  
Treatments

## Poll Question

- Which of the following treatments are available to Veterans at your local facility (choose all that apply)?
  - Acupuncture
  - Relaxation or meditation training
  - Yoga
  - Structured exercise
  - I don't know



# METHODS

Review of reviews



Recent Randomized Controlled Trials



Qualitative &  
Quantitative Summaries  
as appropriate

Grouped systematic reviews (SRs) and new  
Randomized Controlled Trials (RCTs)  
by intervention type



Prioritized highest-quality SRs



Graded quality of SRs/RCTs



Rated strength of evidence

**Primary Outcomes:**

- 1) Vasomotor symptoms
- 2) Quality of life (QoL)

Study characteristic	Eligibility Criteria
Population	Peri/postmenopausal women with bothersome VMS
Interventions	Acupuncture Yoga, tai chi, qigong Structured exercise Relaxation, hypnosis and meditation
Comparators	Any inactive or active control
Outcomes	Frequency/severity of VMS Overall Quality of Life (QOL), or Menopause-specific QOL
Timing	SRs: as specified by authors RCTs: outcomes assessed >60 days after treatment assignment
Setting	Outpatient or community setting

PROTOCOL

Open Access



# Nonpharmacologic, nonherbal management of menopause-associated vasomotor symptoms: an umbrella systematic review (protocol)

Karen M. Goldstein<sup>1,2\*</sup>, Jennifer R. McDuffie<sup>1,2</sup>, Megan Shepherd-Banigan<sup>1</sup>, Deanna Befus<sup>3</sup>, Remy R. Coeytaux<sup>4</sup>, Megan G. Van Noord<sup>5</sup>, Adam P. Goode<sup>4,6</sup>, Varsha Masilamani<sup>1</sup>, Soheir Adam<sup>7</sup>, Avishek Nagi<sup>1</sup> and John W. Williams Jr<sup>1,2</sup>



# RESULTS

## Yoga, tai chi, qigong

**Yoga**—a spiritual and ascetic Hindu discipline, including breath control, simple meditation, and specific bodily postures, that is practiced for health and relaxation

**Tai chi**—a Chinese martial art and form of stylized, meditative exercise characterized by slow circular and stretching movements and positions of bodily balance

**Qigong**—an ancient Chinese health care system that integrates physical postures, breathing techniques and focused intention

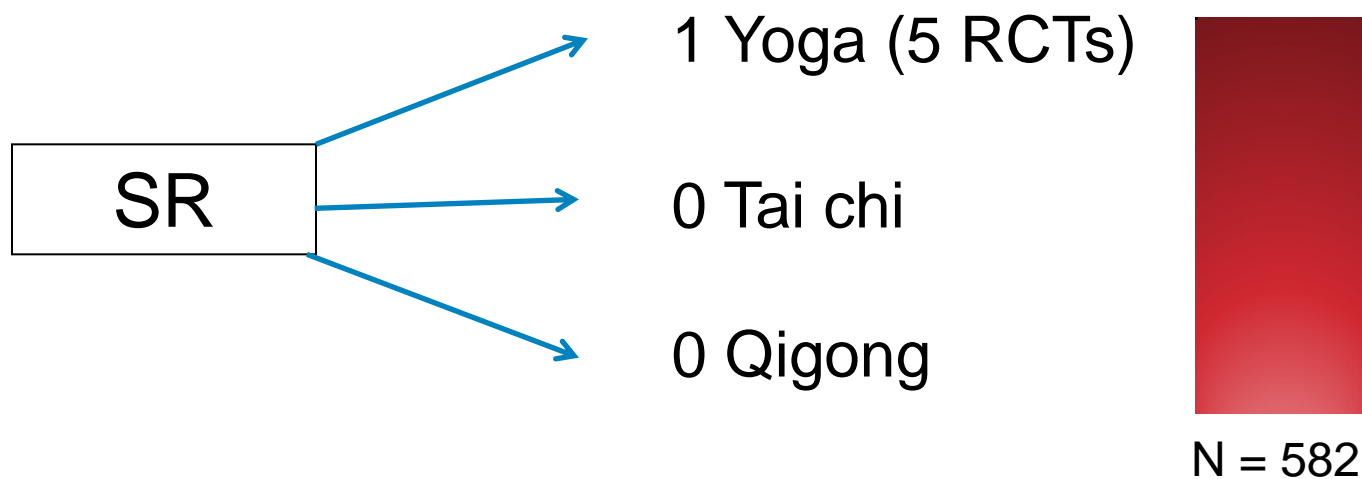
## Yoga, tai chi, qigong

**Yoga**—a spiritual and ascetic Hindu discipline, including breath control, simple meditation, and specific bodily postures, that is practiced for health and relaxation

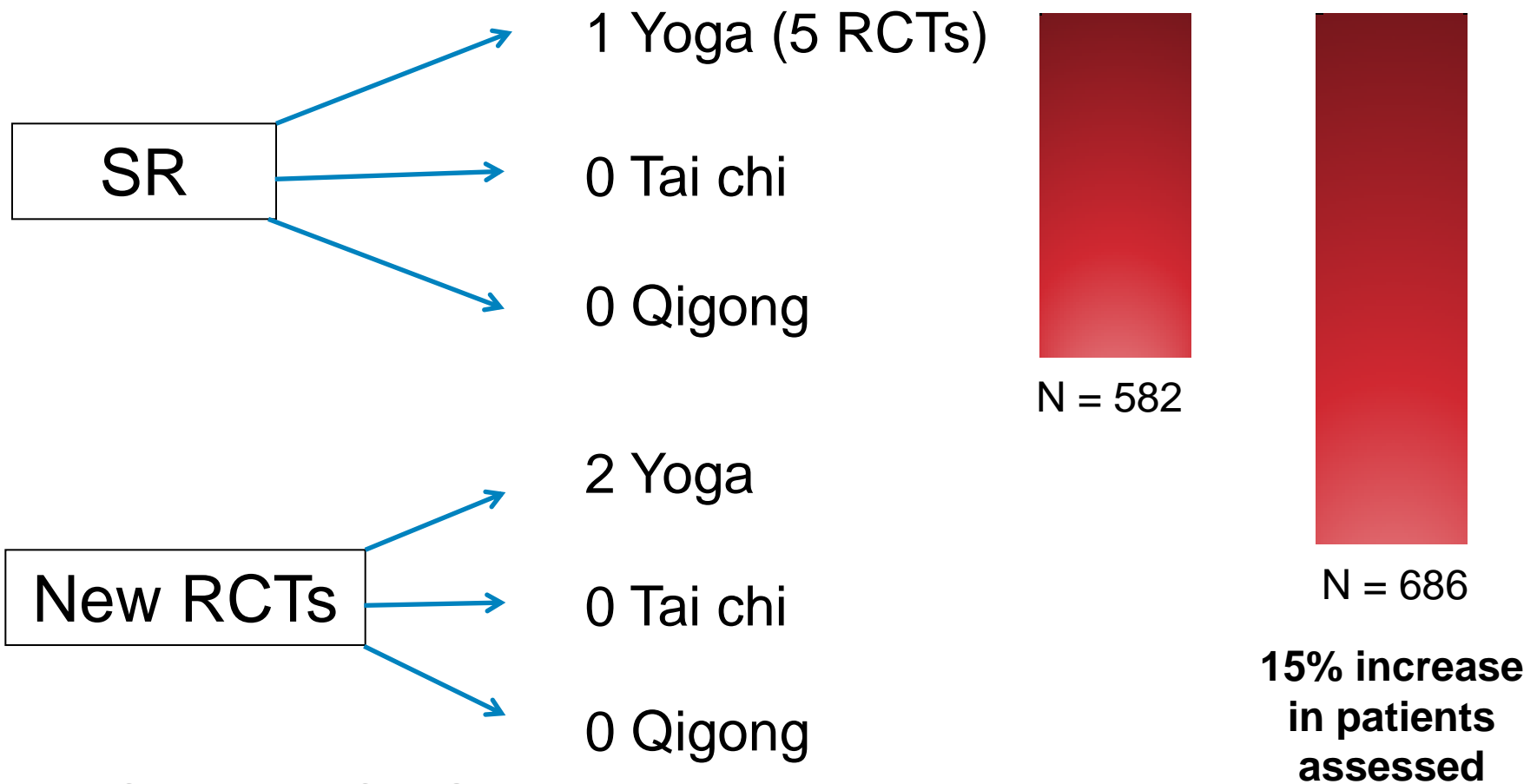
- Relieves conditions that may affect women in menopausal transition: QoL, anxiety, sleep disturbances
- More commonly used by women than men
- Used by older adults



## Yoga, tai chi, qigong




# Yoga, tai chi, qigong

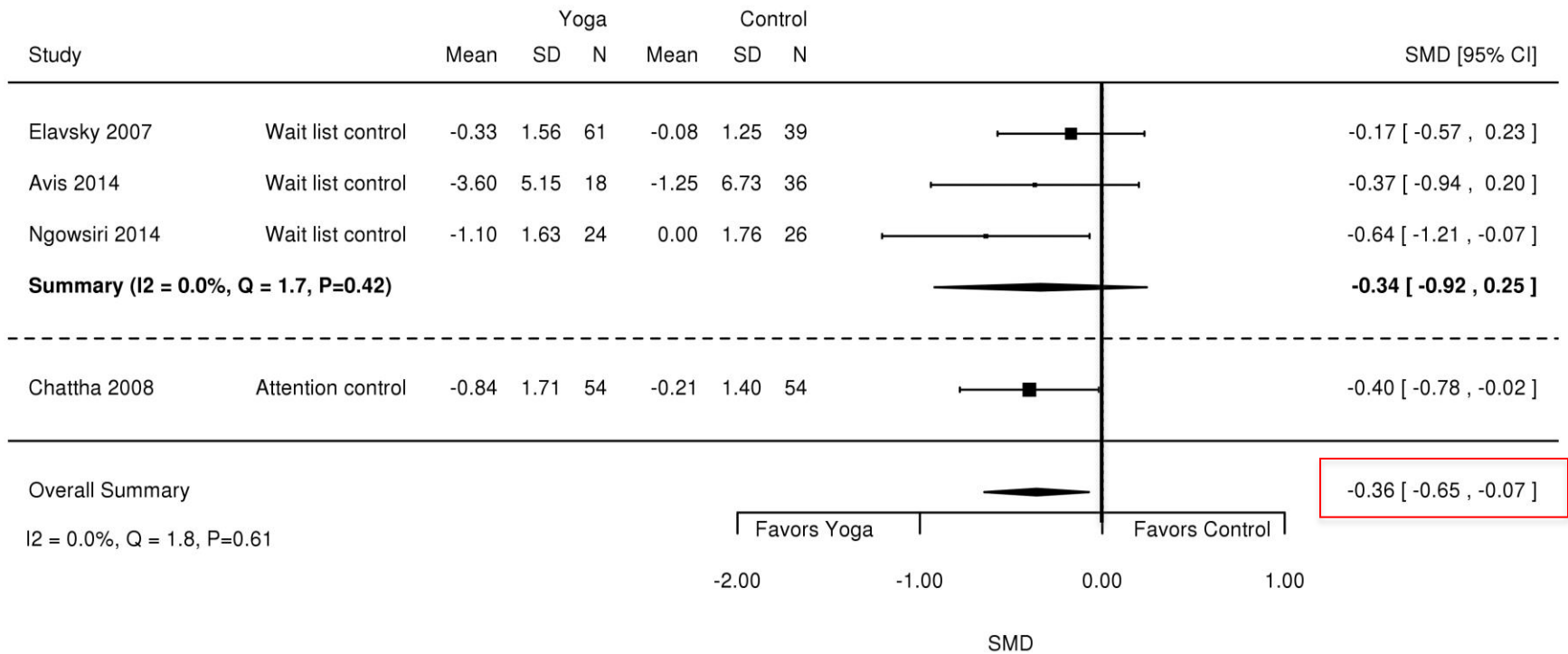


# Yoga

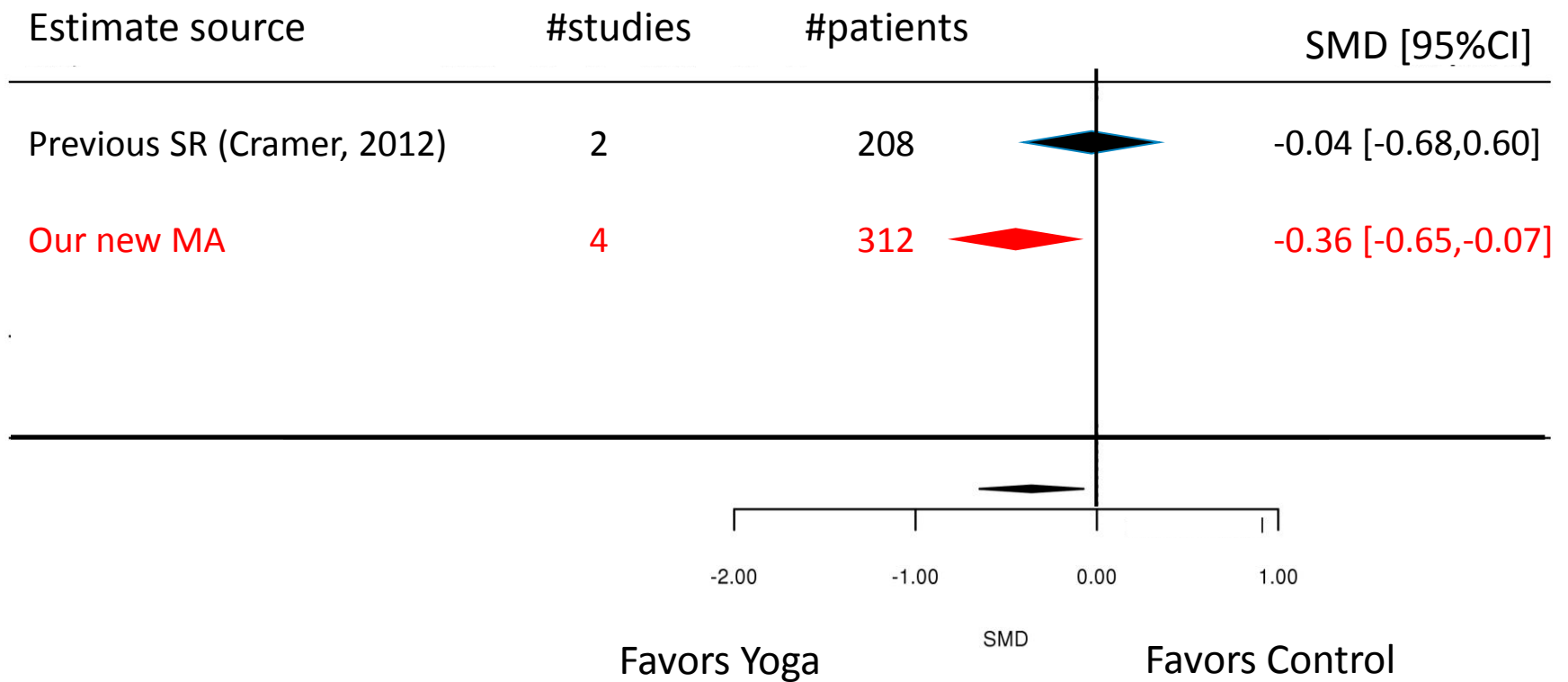
	Method	Comparator	Finding
<b>Prior Systematic Review</b>  Cramer 2012	Meta-analysis 2 RCTs; n = 208	Active/inactive control	No difference
	Meta-analysis 2 RCTs; n = 232	Active control (subgroup)	No difference

	Study	Comparator	Finding
<b>New RCTs</b>	Avis, 2014 n = 54	Active/Inactive control	No effect
	Ngowsiri 2014 n = 50	Wait list control	 VMS Severity

# Yoga versus Control on change in hot flash *severity* at end of treatment



# Yoga versus Control on change in hot flash *severity* at end of treatment



## Yoga - conclusions

- Yoga associated with reduction in hot flash severity
  - Results contradict those from past SRs
- Yoga might be an acceptable therapy for women in the menopausal transition
- Updated results should be taken into consideration when revising clinical or policy recommendations

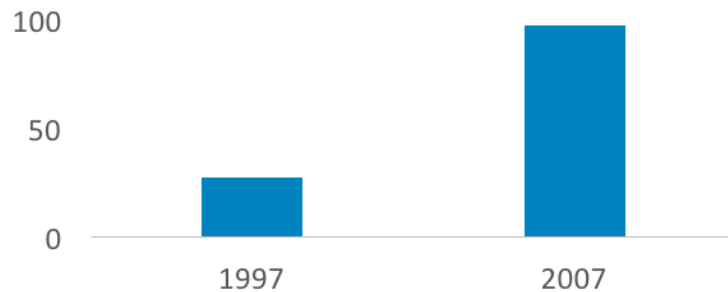
# Acupuncture

- Acupuncture is a therapeutic modality that involves inserting small, metal needle into the skin
- Acupuncture has been an integral part of clinical medicine in Asia for several thousand years
- Acupuncture has increased in popularity and use in the U.S. in the past 40 years
- Vasomotor symptoms are a common indication for acupuncture

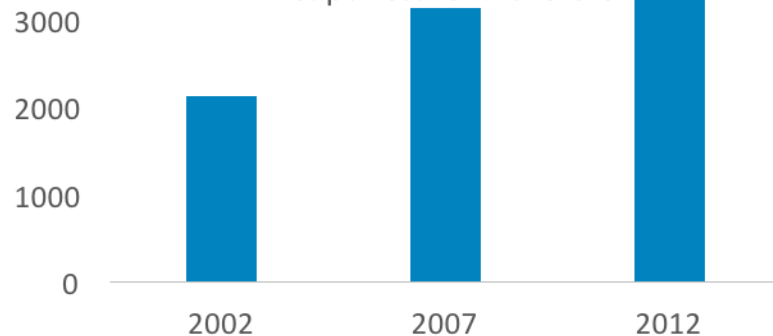


# Acupuncture

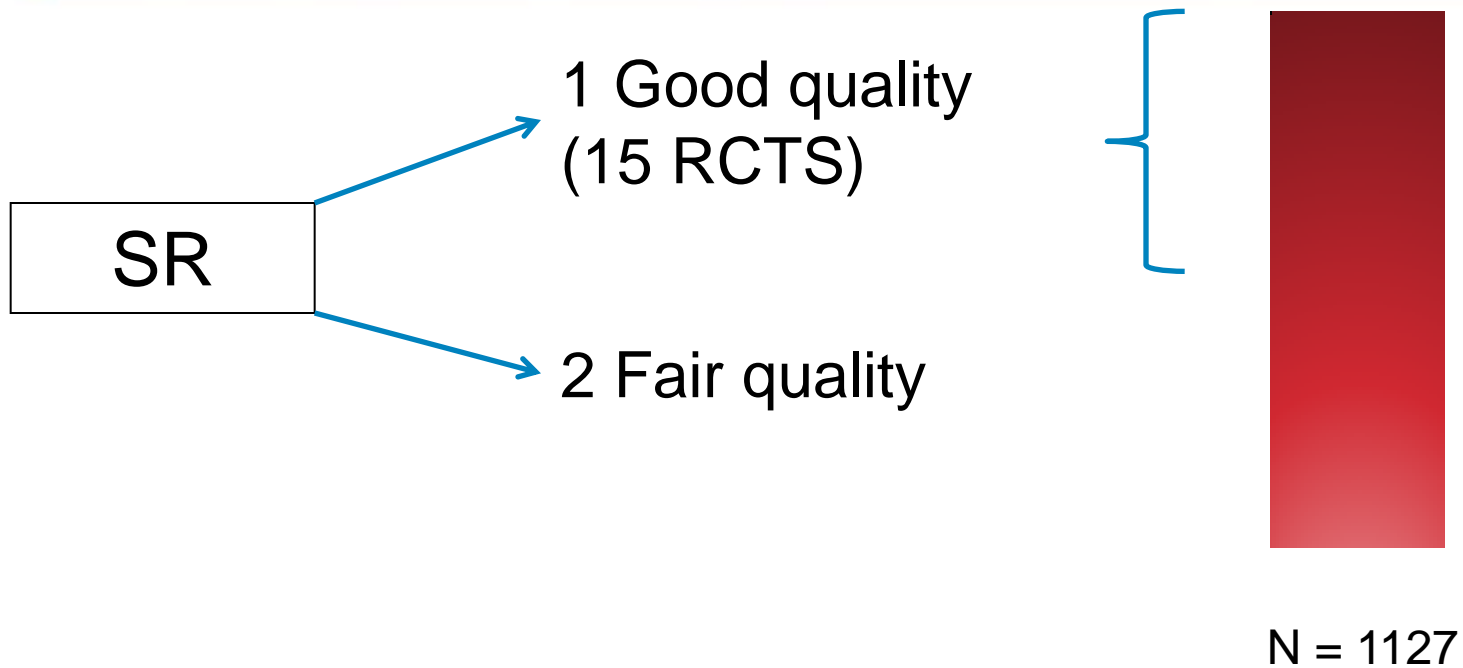
Acupuncture Visits per 1000 People in the U.S.



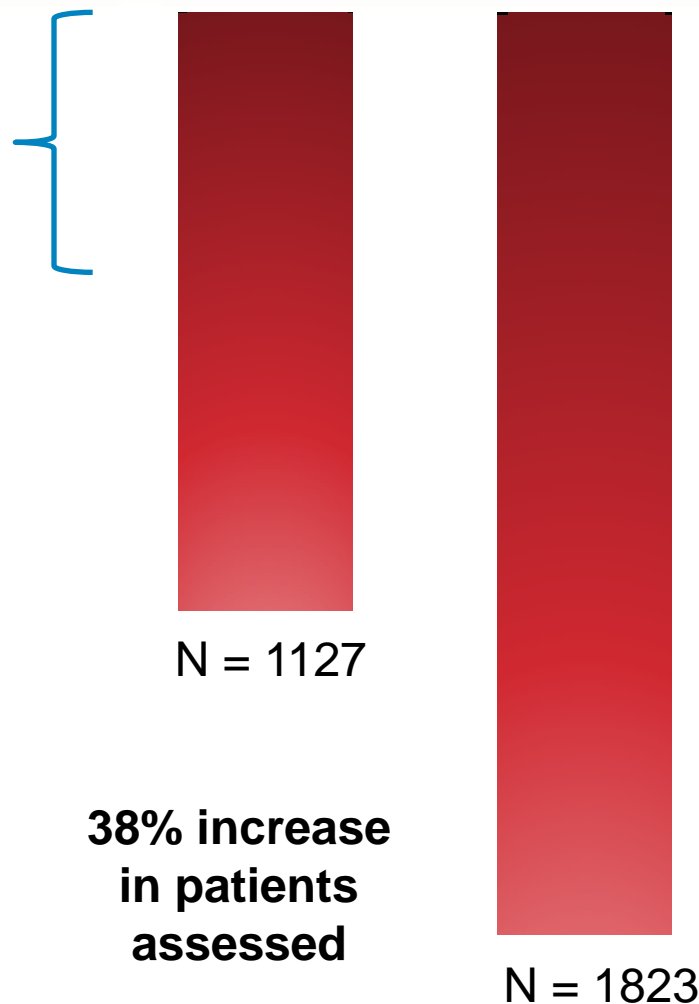
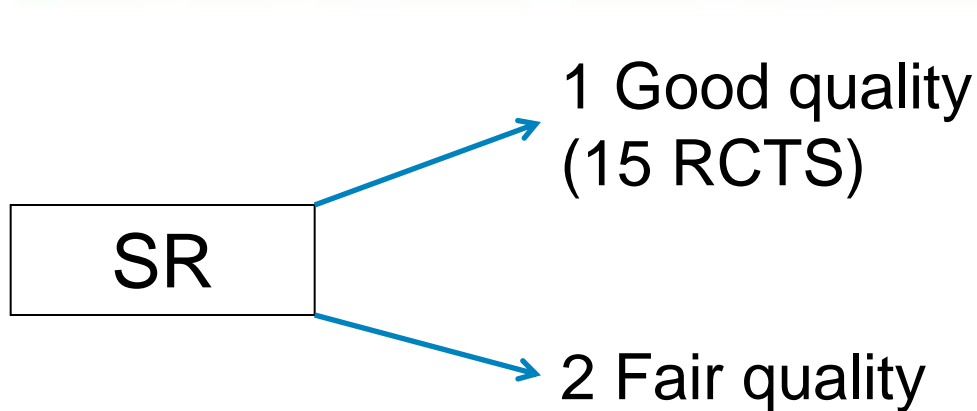
Patients (in Thousands) Who Received Acupuncture in the U.S.





# Acupuncture







# Acupuncture

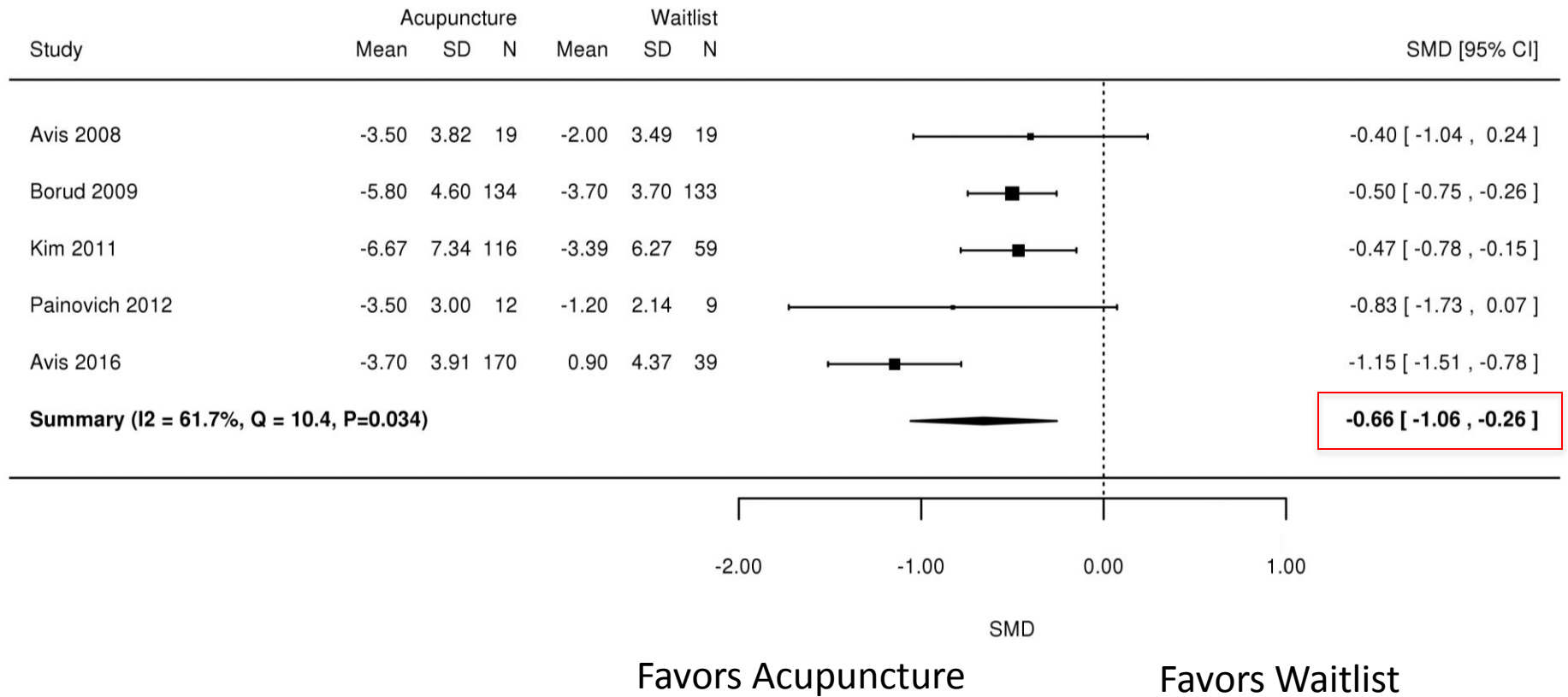


# Acupuncture

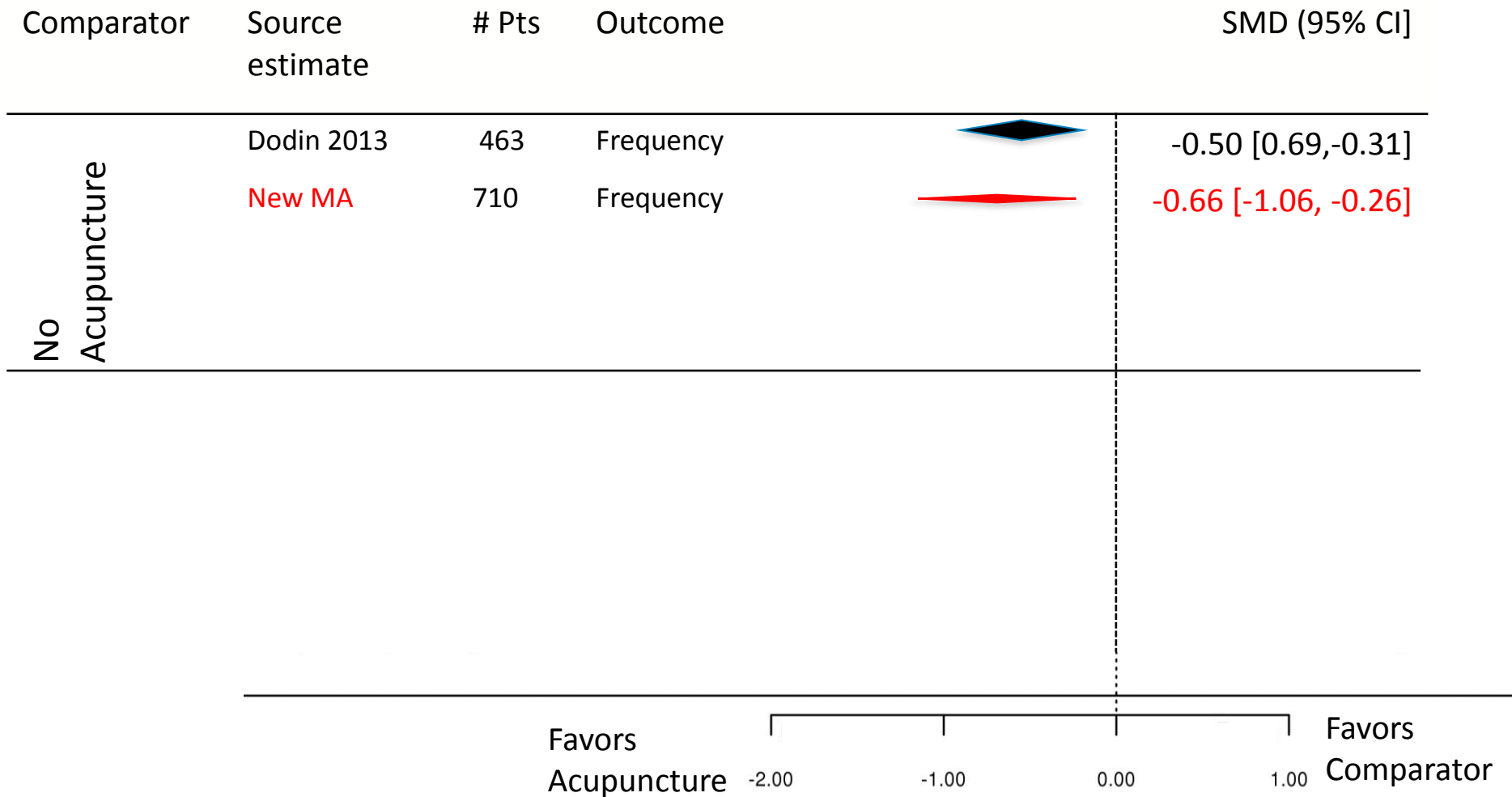
	Method	Comparator	Finding
<b>Prior Systematic Review</b>  Dodin 2013	Meta-analysis 3 RCTs; n = 463	No Acupuncture	 VMS frequency/severity
	Meta-analysis 8 RCTs; n = 414	Sham Acupuncture	 VMS severity only

	Study	Comparator	Finding
<b>New RCTs</b>	Ee 2016 n = 327	Sham acupuncture	 VMS composite score
	Avis 2016 n = 209	Waitlist control	 VMS frequency/severity
	Mao 2015 n = 120	Placebo, Gabapentin, Sham acupuncture	 VMS composite score
	Nedeljkovic n = 40	Sham acupuncture, Placebo	 VMS frequency/severity

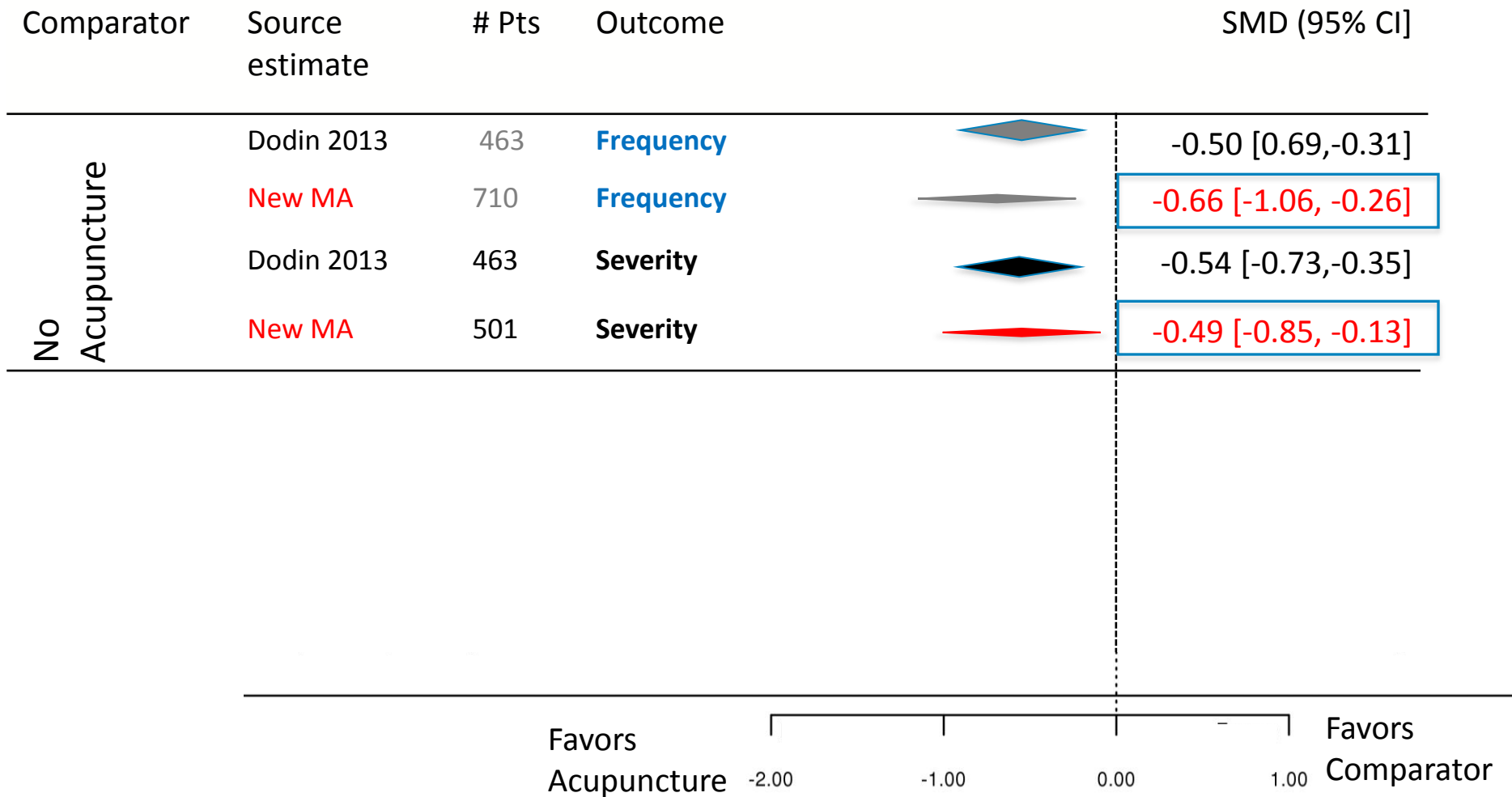
# Acupuncture vs. No Acupuncture: Change in VMS Frequency



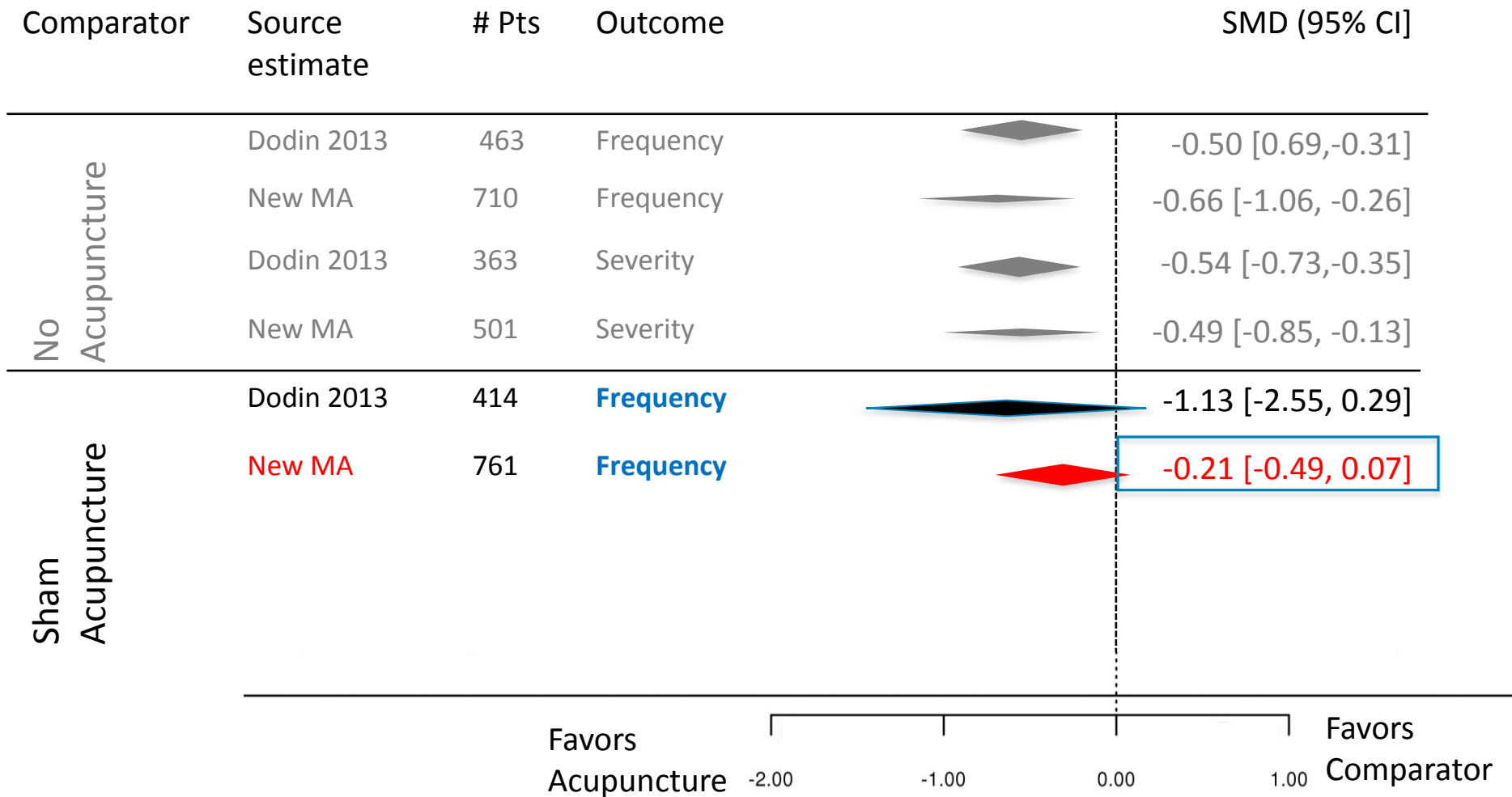
# Acupuncture vs. No Acupuncture: Change in VMS frequency



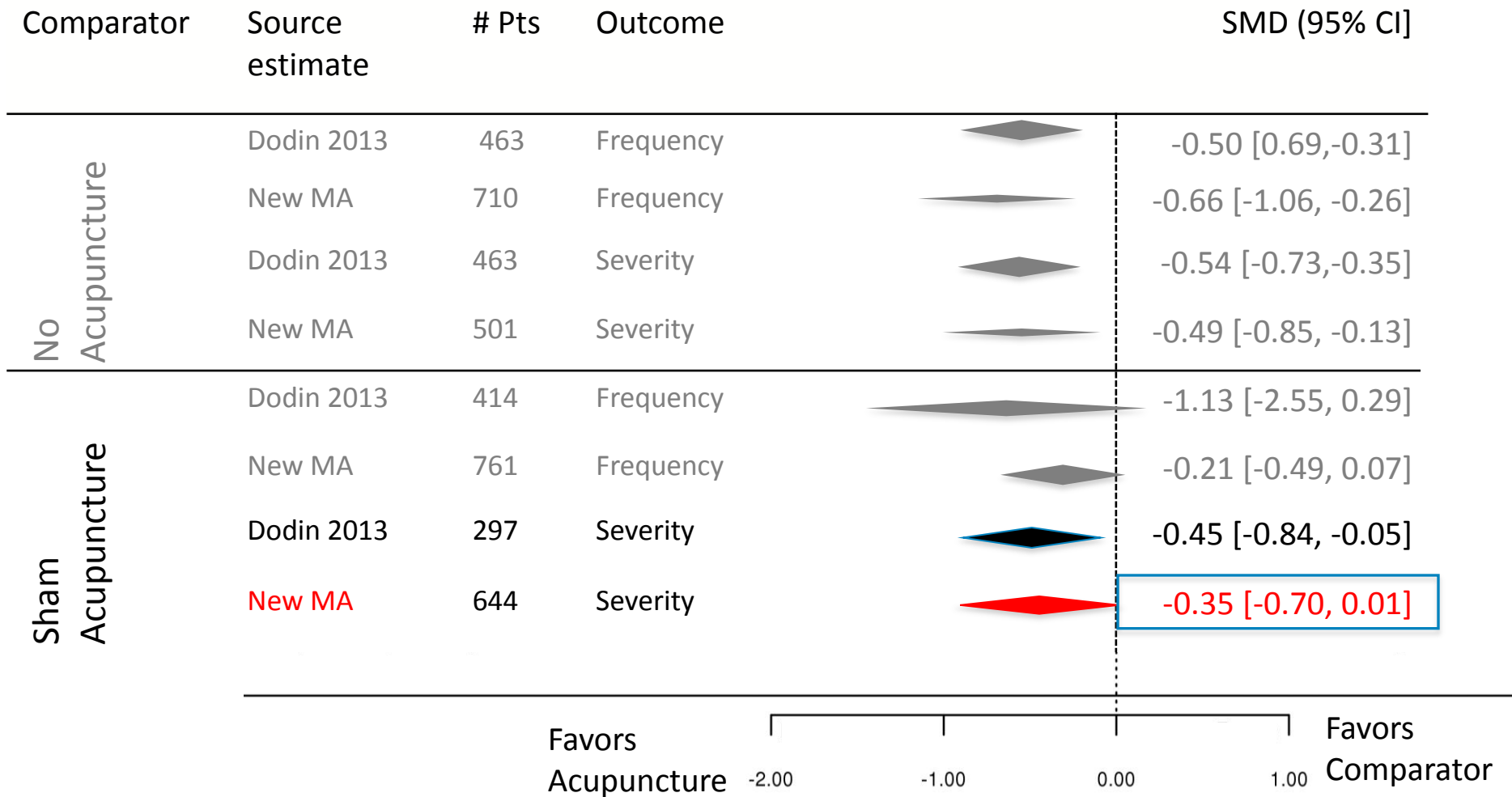
# Acupuncture vs. No Acupuncture: Change in VMS severity



# Acupuncture vs. Sham Acupuncture: Change in VMS frequency



# Acupuncture vs. Sham Acupuncture: Change in VMS severity



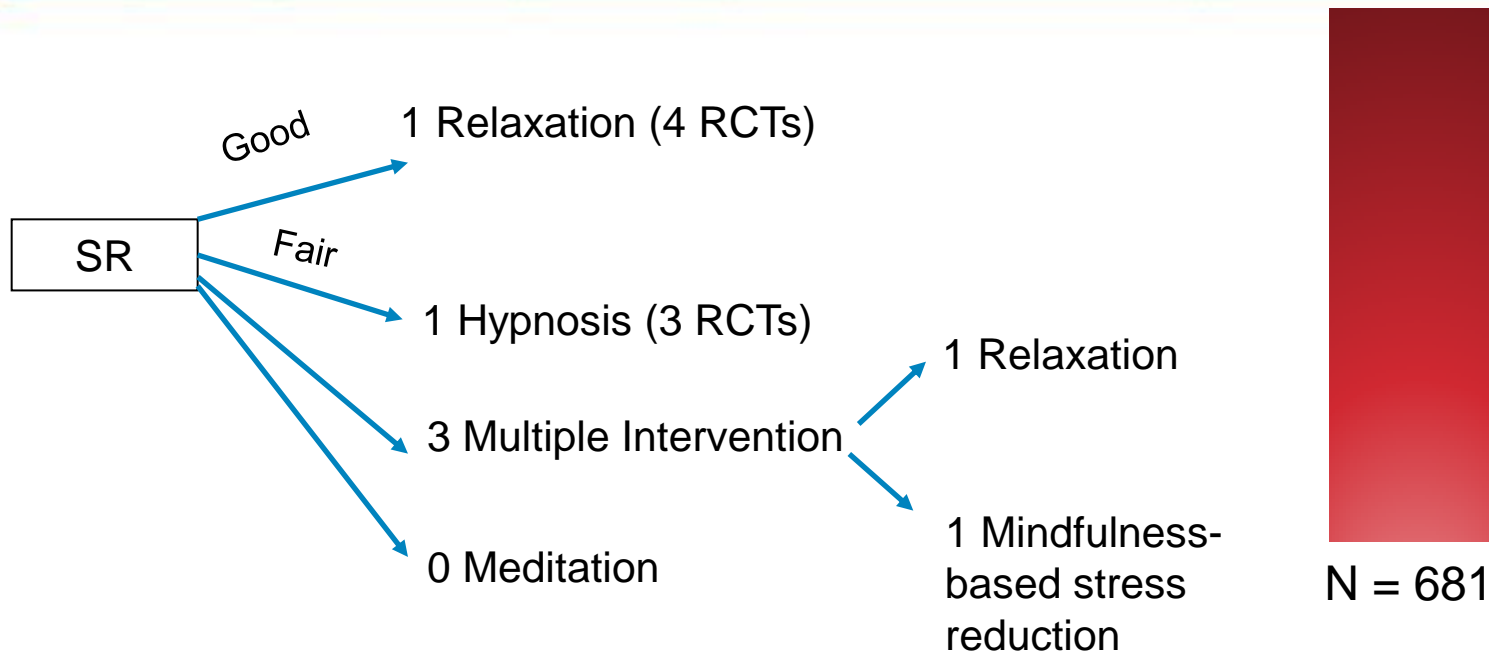
## Acupuncture conclusions

- Acupuncture is associated with significant improvement in VMS frequency and severity as well as quality of life measures compared with no acupuncture
- There are mixed findings regarding acupuncture's effectiveness compared with sham acupuncture
- These findings suggest that acupuncture may be effective as an adjunctive treatment for VMS
- The extent to which nonspecific or placebo effects contribute acupuncture's effectiveness is unclear

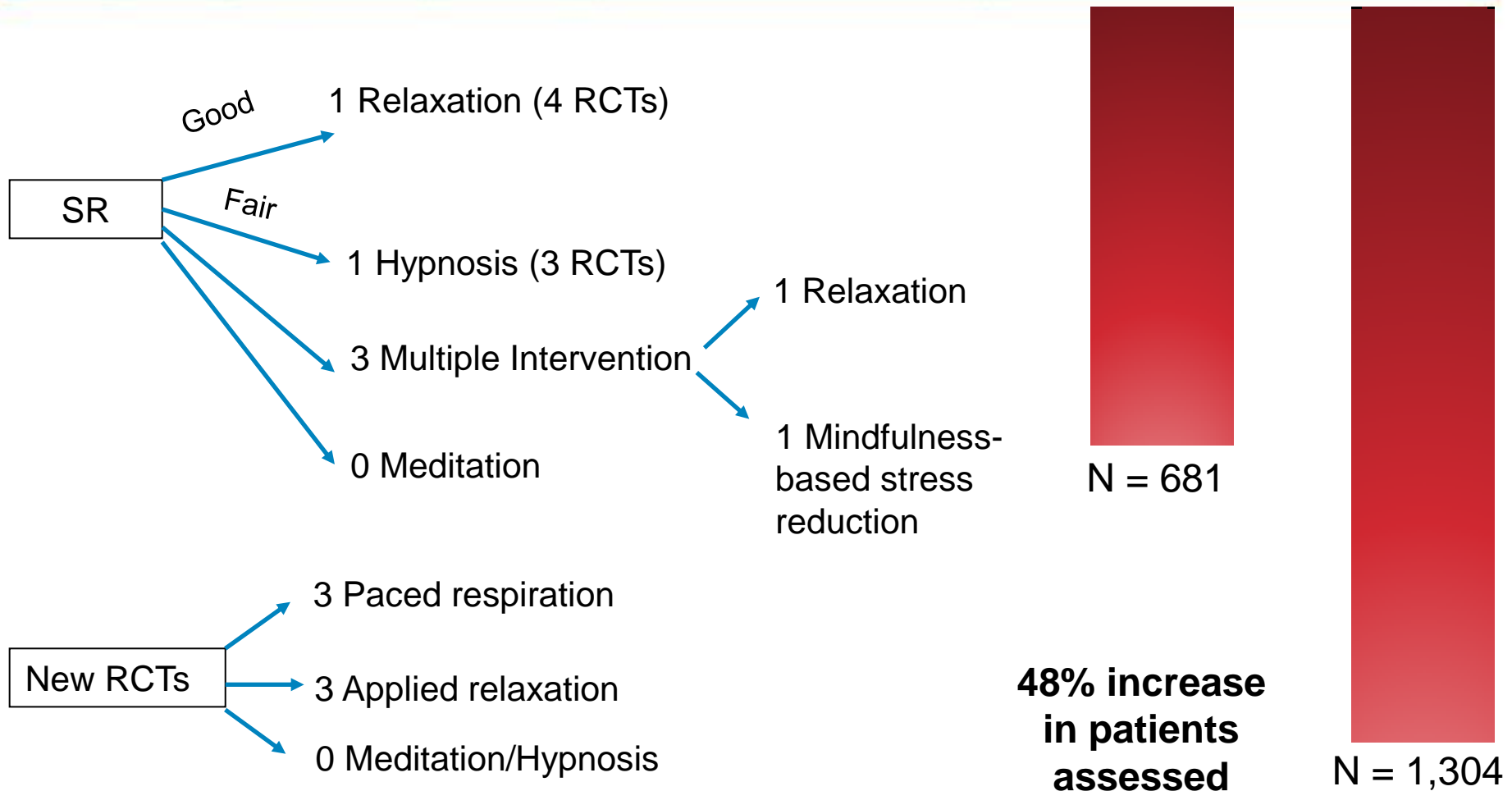
## Relaxation, hypnosis, meditation, and mindfulness

- **Relaxation** – collection of behavioral techniques related to somatic and/or cognitive relaxation
  - Example: paced respiration, progressive muscle relaxation
- **Hypnosis** – use of suggestions to change perception, sensation, emotion, thought or behavior
- **Meditation** – action or practice of meditating
- **Mindfulness**– self-regulation on attention and an orientation to the present
  - Example: Mindfulness Based Stress Reduction

# Relaxation, hypnosis, meditation and mindfulness




# Relaxation, hypnosis, meditation and mindfulness



# Hypnosis

## Prior Systematic Review


Cramer 2015

Method	Comparator	Finding
2 RCTs (n = 247)	Active/inactive control	 VMS frequency/severity
1 RCT (n = 27)	Gabapentin	No difference

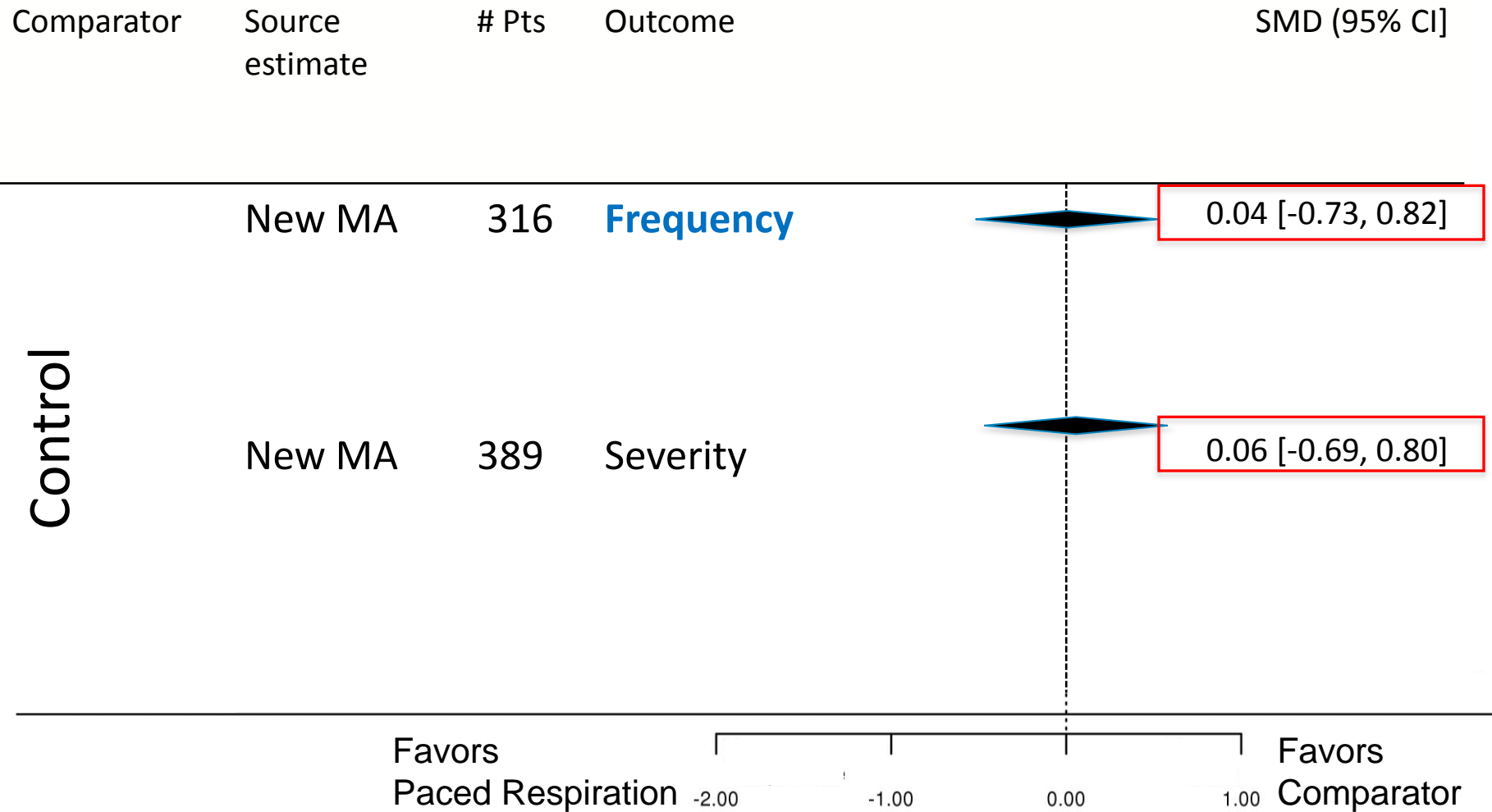
No new RCTS

# Applied Relaxation

	Method	Comparator	Finding
<b>Prior Systematic Review</b>  Saensak 2014	Meta-analysis 2 RCTs; n = 72	Acupuncture	No difference
	2 RCTs; n = 183	Inactive/active control	No effect

	Study	Comparator	Finding
<b>New RCTs</b>	Lindh-Astrad 2013 n = 327	Inactive control	 VMS at 12 weeks
	Saensak 2013 n = 71	Modified-training	No difference
	Lindh-Astrad 2015 n = 46	Inactive control	Stopped early

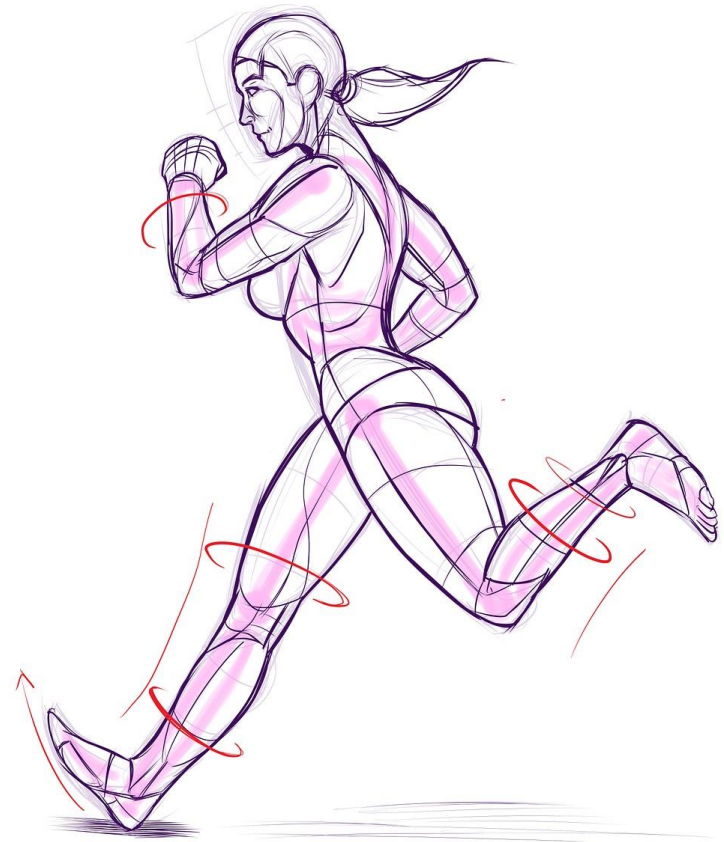
# Paced Respiration on change in VMS at end-of-treatment



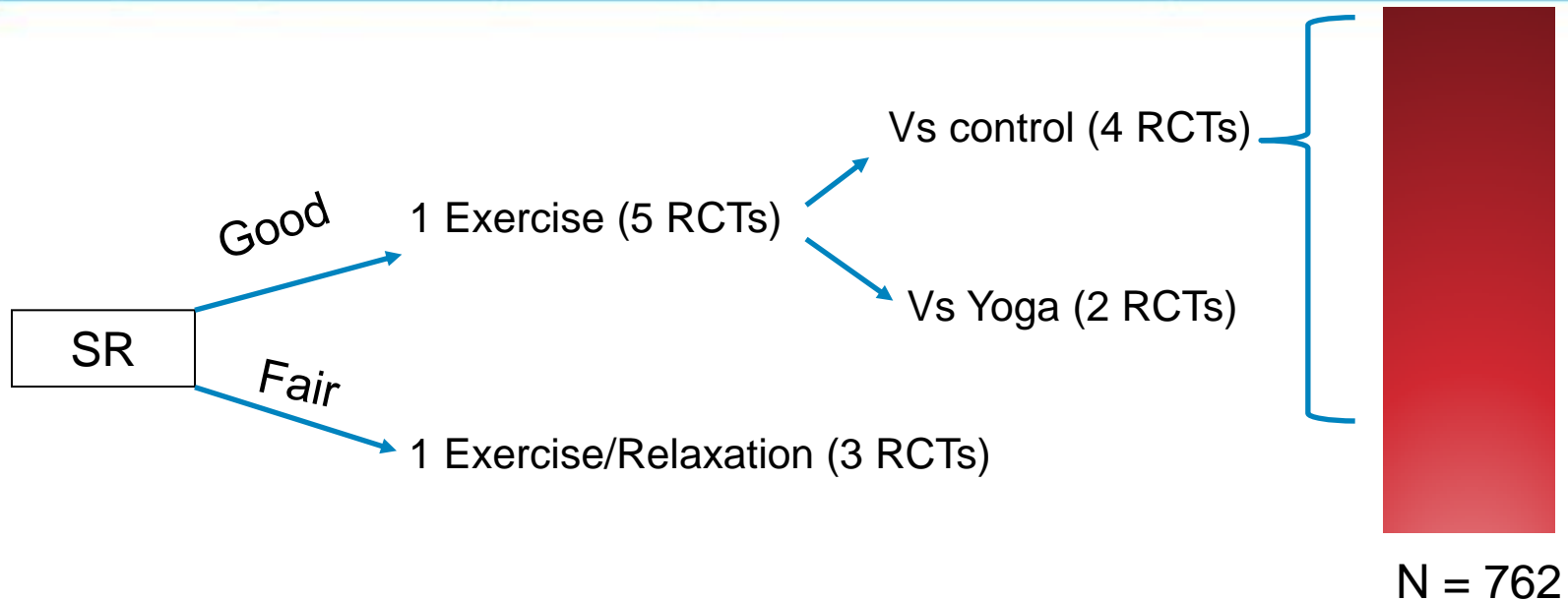
# Structured exercise

## Regular physical activity:

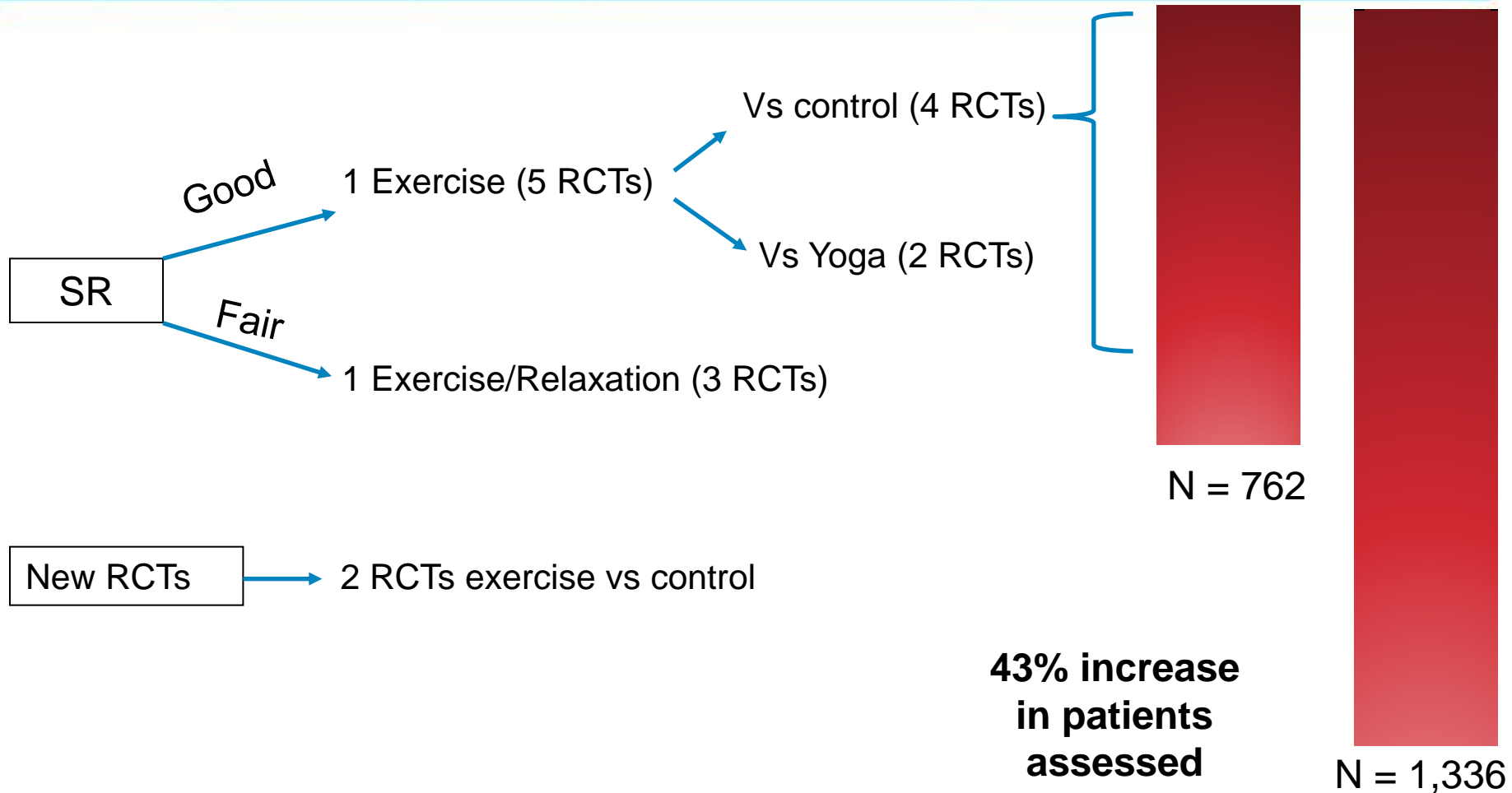
- Done with the intention of improving or maintaining physical fitness or health
- Or, performed as a part of a class
- Or, with support from a health professional



## Structured exercise



## Structured exercise



## Structured exercise

### Prior Systematic Review

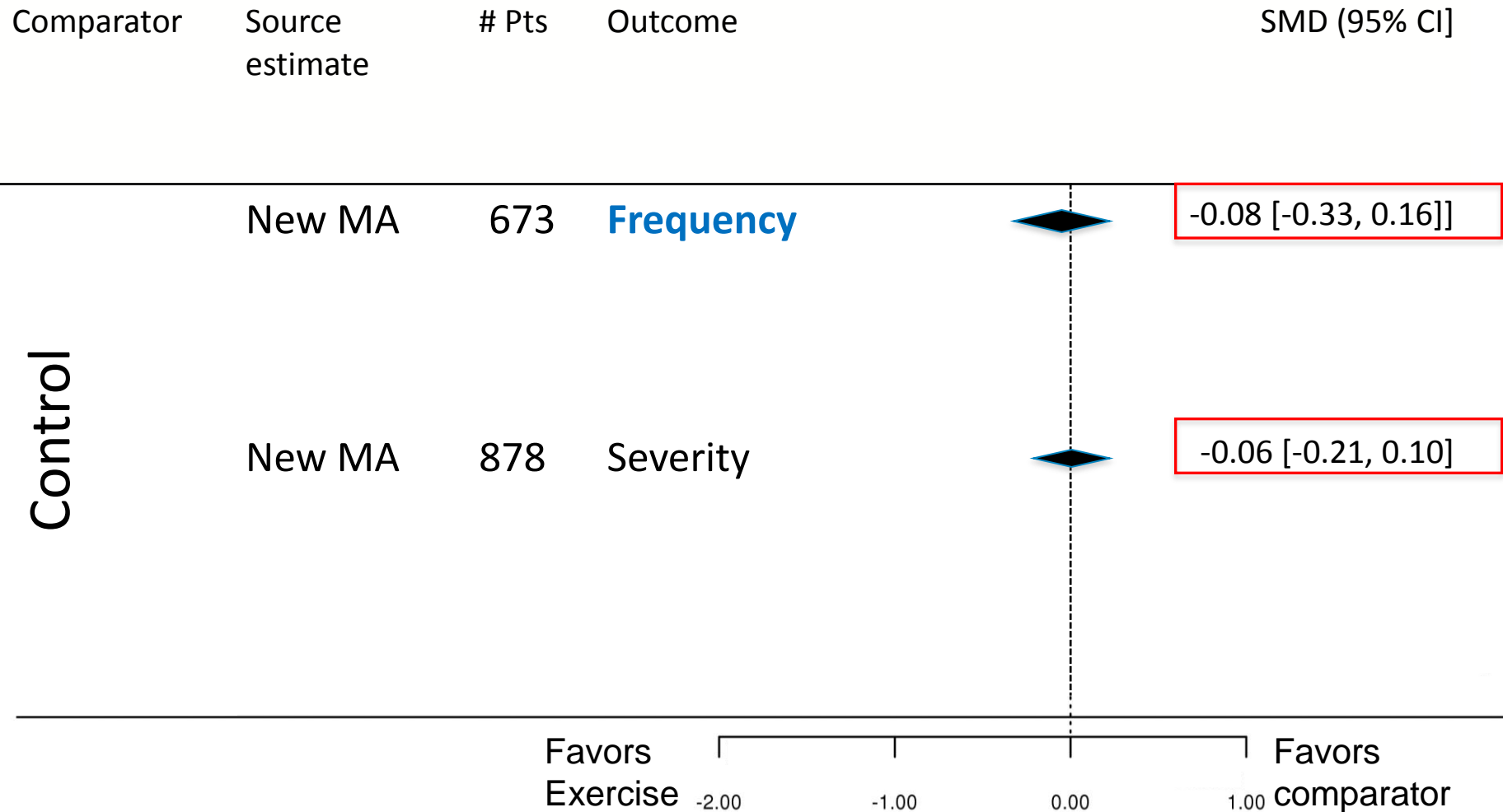
Daley 2014

Method	Comparator	Finding
Meta-analysis 3 RCTs	Inactive Control	No effect
Meta-analysis 2 RCTs	Yoga	No difference

### New RCTs

Study	Comparator	Finding
Dujits 2012 n = 313	Inactive control	No effect
Daley 2015 n = 261	Inactive control	No effect

## Structured exercise on change in VMS at end-of-treatment



Intervention Type	Adverse events
Acupuncture	Mild reactions when reported
Yoga	None
Structured Exercise	No serious adverse reactions Similar to placebo
Relaxation, Hypnosis & Meditation	Mild

## Quality of Life

- **Acupuncture**
  - Insufficient data for acupuncture vs. no acupuncture
  - No improvement in quality of life vs. sham acupuncture:  
**New MA: SMD -0.23, 95% CI -1.40, 0.95, 5 trials**
- **Yoga**
  - Insufficient data for new MA
  - One small trial found non-statistically significant improvement
- **Structured exercise**
  - Insufficient data
- **Relaxation, hypnosis, and meditation**
  - Insufficient data

## Limitations

- **Of the Review of Reviews**
  - Reliance on authors assessment of risk of bias, search strategy and synthesis
- **Of the studies**
  - Most were small, short-term trials
  - Mostly unmasked, self-report assessments
  - Varying outcome measures
  - Unexplained heterogeneity
- None of trials specifically involved Veterans

# Nonpharmacologic, nonhormonal treatments for VMS



Acupuncture vs control  
Yoga vs control  
+/- Hypnosis



Acupuncture vs Sham Acupuncture  
Paced respiration  
Structured exercise



Mindfulness  
Applied Relaxation  
Qigong  
Tai Chi  
Meditation

**Thank you!**

If you have further questions, please feel free to contact:

**Karen Goldstein, MD MSPH**

919.286.0411 ext. 7764

karen.goldstein@va.gov

Full-length report and cyberseminar available on ESP website:

<http://www.hsrd.research.va.gov/publications/esp/>

# Discussants

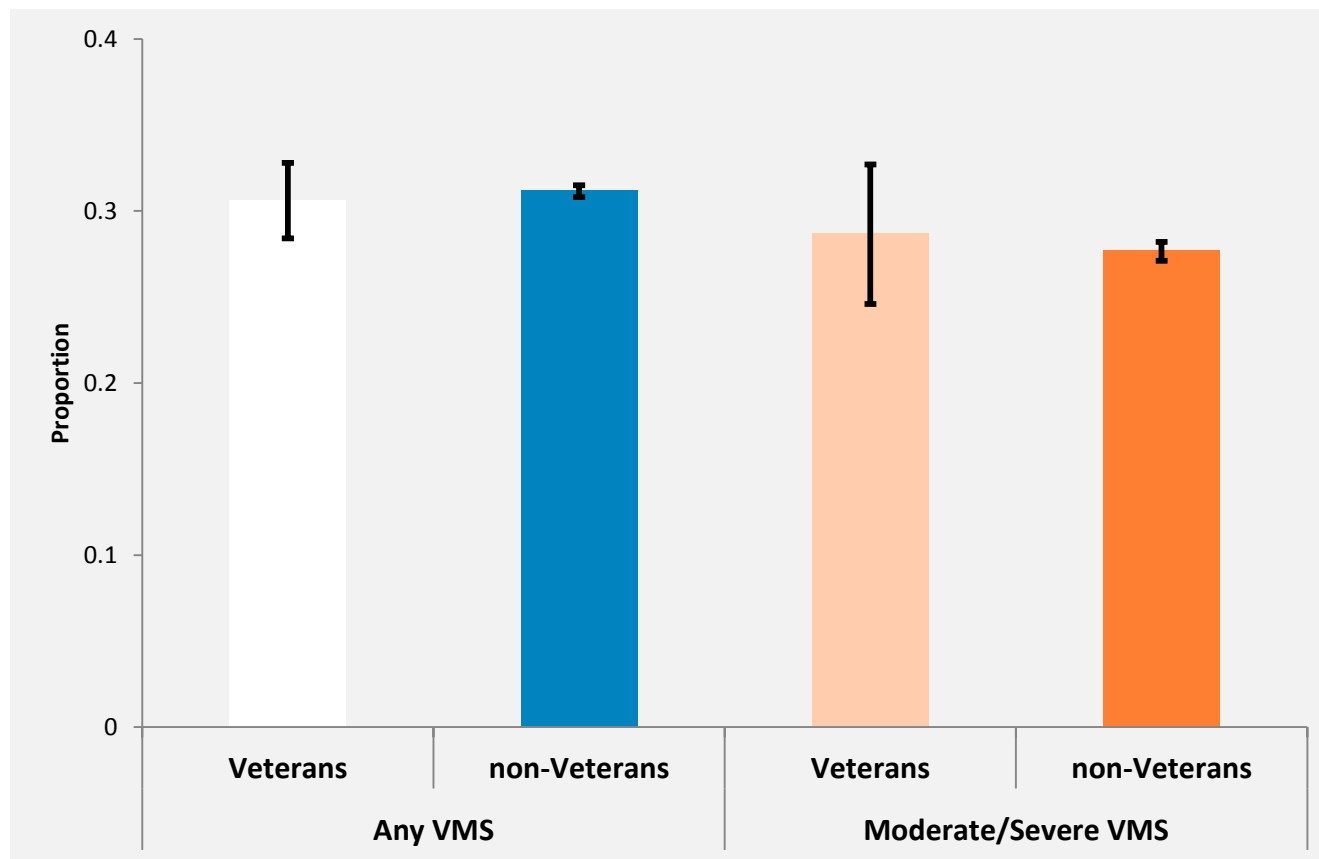
Dr. Alicia Christy

Deputy Director of Reproductive Health  
Women's Health Services

Dr. Jodie Katon

former Sr. Reproductive Epidemiology  
Consultant for Women's Health Services

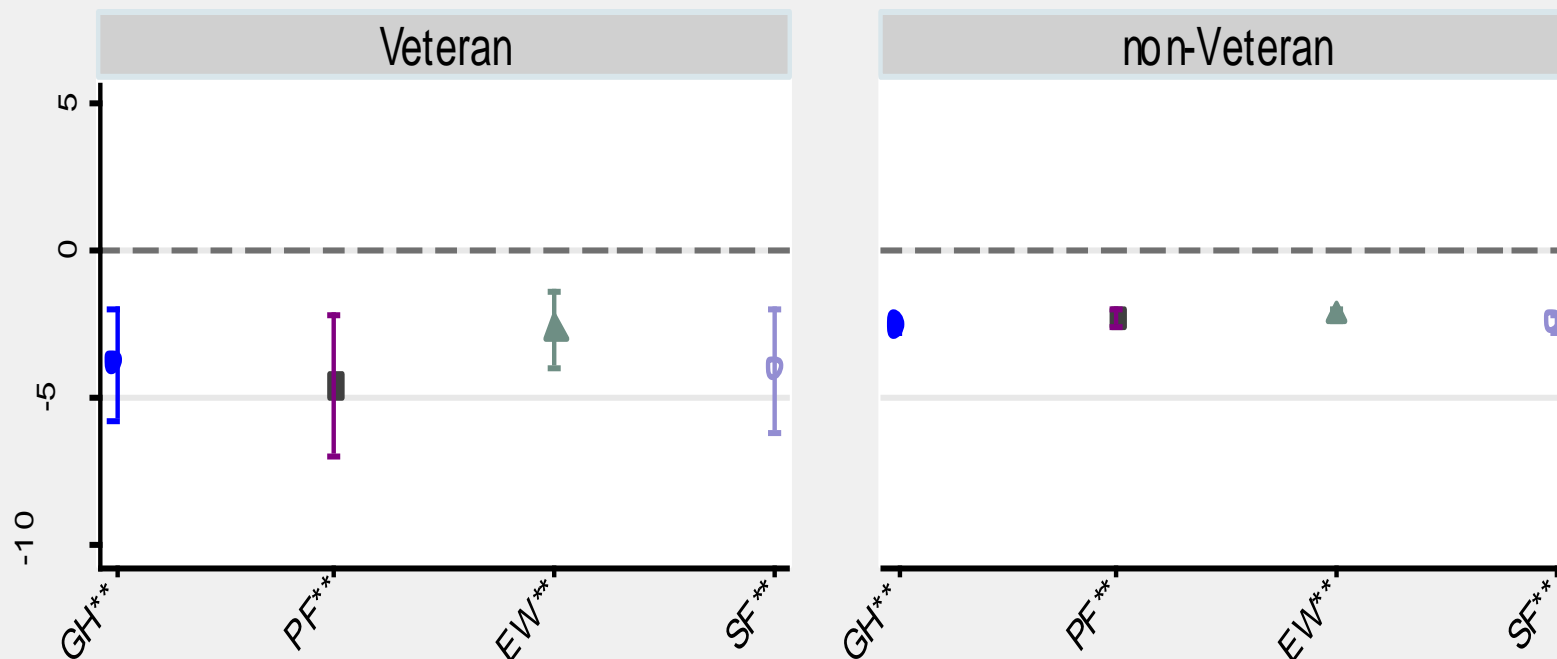
# Prevalence and severity of VMS among women Veterans



<sup>1</sup>Adjusted for age, race, education, time since menopause, obesity, pack years of smoking, depression, diabetes, hypertension and physical activity

Katon, J. G., et al. (2016). "Vasomotor Symptoms and Quality of Life Among Veteran and Non-Veteran Postmenopausal Women." Gerontologist **56 Suppl 1**: S40-53.

# VMS and Quality of Life



GH = general health, PF = physical function, EW = emotional well- being, SF = social function

\*\*\*  $p < 0.001$ , \*\*  $p < 0.01$ , \*  $p < 0.05$

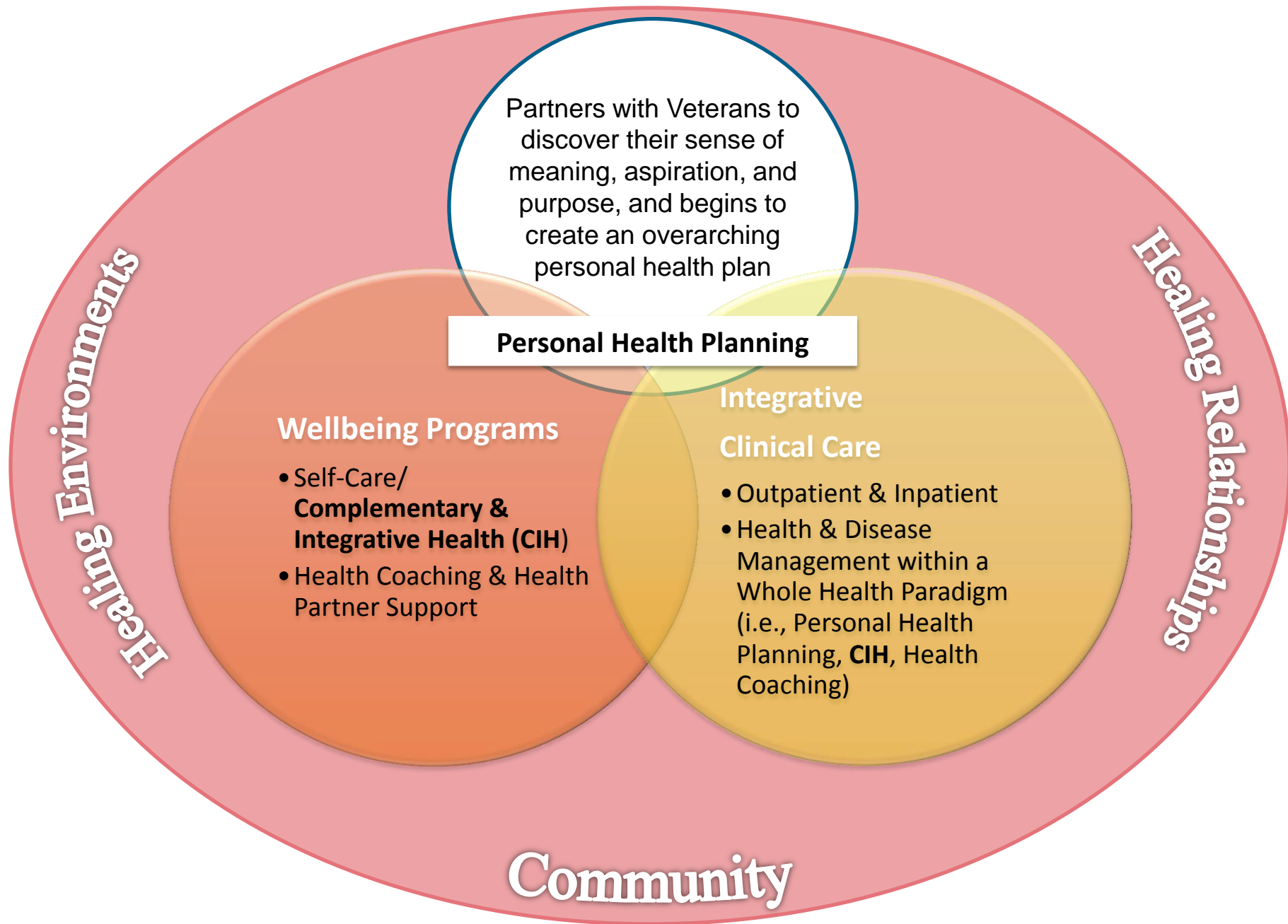
<sup>1</sup>Adjusted for age, race, education, overall QOL at baseline, obesity, pack years of smoking, depression, diabetes, hypertension and physical activity

Katon, J. G., et al. (2016). "Vasomotor Symptoms and Quality of Life Among Veteran and Non-Veteran Postmenopausal Women." Gerontologist **56 Suppl 1**: S40-53.

# Frequency of Menopausal Disorders

Age Group			
	18-44 years old	45-64 years old	≥65 years old
1	Menstrual disorders and endometriosis	<b>Menopausal disorders</b>	Osteoporosis
2	Other female reproductive organ conditions	Urinary conditions	Urinary conditions
3	STI and vaginitis	Other female reproductive organ conditions	<b>Menopausal disorders</b>
4	Urinary conditions	Benign breast conditions	Breast cancer
5	Pregnancy-related	STI and vaginitis	Benign breast conditions <i>and</i> other female reproductive organ conditions

Katon, J. G., et al. (2015). "Reproductive Health Diagnoses of Women Veterans Using Department of Veterans Affairs Health Care." Med Care **53 Suppl 4 Suppl 1**: S63-S67.



# DEFINITIONS

**Whole Health (WH)** : is an approach to health care that empowers AND equips people to take charge of their health and well-being, and live their life to the fullest.

**Complementary and Integrative Health (CIH):**

- **Complementary health** is a group of diverse medical and health care systems, practices, and products that are not considered to be part of conventional or allopathic medicine. Most of these practices are used together with conventional therapies. (*NCCIH Strategic Plan 2016*).
- **Integrative medicine and health** reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic and lifestyle approaches, healthcare professionals and disciplines to achieve optimal health and healing. (*Academic Consortium for Integrative Medicine and Health 2016*)

## WH/CIH Highlights 2016

- OPCC&CT launches 11 new Whole Health Design sites for FY 17, now working with a total of 18 WH sites
- VISN Directors commit to 18 full-scale implementation WH demonstration sites in FY 18
- IHCC Advisory Group approves acupuncture, massage, tai chi, yoga, meditation>>>more to come!
- OSI/Pain memo released for VISN CIH POC

# Integrative Health Coordinating Center

- The IHCC is charged with developing and implementing complementary and integrative health (CIH) strategies in clinical activities, education, and research across the system.
- **Two major functions:**
  - Identify and address barriers to providing CIH across the VHA system.
  - Serve as a resource for clinical practices and education for Veterans and VA staff

# Core IHCC Staff

- Core IHCC Staff:
  - **National Director**, Benjamin Kligler (MD, MPH)
  - **Program Manager**: Alison Whitehead, MPH, RYT, PMP
  - **Project Manager**: Belinda Collingbourne, MBA, PMP
  - **Lead Clinical Champion**: Kavitha Reddy MD  
FACEPABoIM
- In addition to core staff, IHCC works closely with other OPCC&CT staff, Clinical Champions and other partners across the VA and in the community.

## Current IHCC Focus Areas

- Policy and Guidance Development
  - Planned release of CIH instruction manual FY 17 Q2
  - IHCC Advisory Committee
  - Workgroups (yoga, tai chi, nutraceuticals, acupuncture)
- Coding, Tracking, Billing
- New Occupations
  - Acupuncturists
  - Massage Therapists
- Access/Community Care
- Strategic Partnerships
- Metrics/Outcome evaluation
- Comprehensive Addiction and Recover Act 2016

# CARA 2016

## **S.524 - Comprehensive Addiction and Recovery Act of 2016 - Subtitle C— Complementary and Integrative Health (CIH)**

- **Sec. 931 & 932. Expansion of research and education on and delivery of CIH to veterans.**
  - Establishment of “Creating Options for Veterans’ Expedited Recovery” Commission
  - **Development of plan** to expand research, education, and delivery of CIH to Veterans (within 180 days)
- **Sec. 933. Pilot program on integration of CIH and related issues for Veterans and family members of Veterans.**
- <https://www.congress.gov/bill/114th-congress/senate-bill/524/text>

QUERI

## Evidence Map of Acupuncture

January 2014

Prepared for:  
Department of Veterans Affairs  
Veterans Health Administration  
Quality Enhancement Research Initiative  
Health Services Research & Development Service  
Washington, DC 20420

Prepared by:  
Evidence-based Synthesis Program (ESP) Center  
West Los Angeles VA Medical Center  
Los Angeles, CA  
Paul G. Shekelle, MD, PhD, Director

Investigators:  
Principal Investigators:  
Susanne Hempel, PhD  
Paul G. Shekelle, MD, PhD

Co-Investigators:  
Stephanie L. Taylor, PhD  
Michelle R. Solloway, PhD

Research Associates:  
Isomi M. Mlake-Lye, BA  
Jessica M. Beroes, BS  
Roberta Shanman, MS  
Marika J. Booth, MS  
Andrew M. Siroka, BS



QUERI

## Evidence Map of Tai Chi

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Department of Veterans Affairs  
Veterans Health Administration  
Quality Enhancement Research Initiative  
Health Services Research & Development Service  
Washington, DC 20420

Prepared by:  
Evidence-based Synthesis Program (ESP) Center  
West Los Angeles VA Medical Center  
Los Angeles, CA  
Paul G. Shekelle, MD, PhD, Director

Principal Investigators:  
Susanne Hempel, PhD  
Paul G. Shekelle, MD, PhD

Co-Investigator:  
Stephanie L. Taylor, PhD  
Michelle R. Solloway, PhD

Research Associates:  
Isomi M. Mlake-Lye, BA  
Jessica M. Beroes, BS  
Roberta Shanman, MS



# HSR&D QUERI Evidence Maps

QUERI

## Evidence Map of Yoga for High-Impact Conditions Affecting Veterans

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Department of Veterans Affairs  
Veterans Health Administration  
Quality Enhancement Research Initiative  
Health Services Research & Development Service  
Washington, DC 20420

Prepared by:  
Evidence-based Synthesis Program (ESP) Center  
Durham Veterans Affairs Healthcare System  
Durham, NC  
John W. Williams, Jr., M.D., M.H.Sc., Director

Investigators:  
Principal Investigator:  
Remy B. Concha, M.D., Ph.D.  
Co-Investigators:  
Jennifer McDuffie, Ph.D.  
Adam Goode, D.P.T., Ph.D.  
Sarah Conrad, B.A.  
Wei-Duan Porter, M.D.  
Poonam Sharma, Ph.D.  
Suzanne Marshall, Ph.D.  
Hillary Winkler, B.A.  
John W. Williams, Jr., M.D., M.H.Sc.  
Research Associates:  
Aashish Nagi, M.S.



QUERI

## Evidence Map of Mindfulness

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Prepared for:  
Department of Veterans Affairs  
Veterans Health Administration  
Quality Enhancement Research Initiative  
Health Services Research & Development Service  
Washington, DC 20420

Prepared by:  
Evidence-based Synthesis Program (ESP) Center  
West Los Angeles VA Medical Center  
Los Angeles, CA  
Paul G. Shekelle, MD, PhD, Director

Investigators:  
Principal Investigators:  
Susanne Hempel, PhD  
Paul G. Shekelle, MD, PhD  
Co-Investigators:  
Stephanie L. Taylor, PhD  
Neil J. Marshall, PhD  
Michelle R. Solloway, PhD  
Research Associates:  
Isomi M. Mlake-Lye, BA  
Jessica M. Beroes, BS  
Roberta Shanman, MS



Evidence Map of Tai Chi:  
Click [here](#)

Evidence Map of Yoga:  
Click [here](#)

Evidence Map of Mindfulness:  
Click [here](#)

Intranet Only:  
[Massage for Pain: An Evidence Map](#)

# Resources

- **Whole Health Library:**  
<http://projects.hsl.wisc.edu/SERVICE/curriculum/index.html>
  - **Module 25: Women's Health**
    - **Clinical Tools**
      - [Menopause](#)
      - [Hormone Replacement Therapy](#)
      - [Endometriosis](#)
      - [Fibroids](#)
      - [Phytoestrogens](#)
      - [Dysmenorrhea, Menstrual Cramping](#)
      - [Estrogen Dominance](#)
      - [Polycystic Ovarian Syndrome](#)
- **OPCC&CT SharePoint:**  
<http://vaww.infoshare.va.gov/sites/OPCC/default.aspx>
- **IHCC SharePoint:**  
<http://vaww.infoshare.va.gov/sites/OPCC/sitePages/IHCC-home.aspx>

## Healthy Aging in Women's Health Services

### Healthy aging priorities

- Develop capacity and improve care coordination (e.g. menopausal symptom management, pelvic floor disorders)
- Improve access
- Build partnerships around specialty specific reproductive health care needs
- Ensure adequate resources for providers
- Develop models of Best Practices for healthy aging
- Develop strategies to reach high risk subgroups

## Healthy Aging in Women's Health

- Evidence –based clinical management
  - Optimize medication management
  - Prioritize the impact of mental health and postmenopausal management
- Develop resources for providers and patients through the North American Menopause Society and ACOG
  - Patient Education
  - MenoPro Mobile App
  - Position statements (NAMS)
  - Practice bulletins (ACOG)

## Healthy Aging in Women's Health

- Incorporation of research to ensure access to current evidence-based treatment
- Recognition of unique characteristics of menopausal age Veterans and medical care within VHA (Katon 2015)
- Systematic reviews to evaluate non-pharmacologic and non-traditional therapies
  - SSRIs
  - Complimentary and alternative medications
  - Mind/body practices

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- References for included Systematic Reviews and Randomized Controlled Trials mentioned in this report can be found in the full report:  
<http://www.hsrd.research.va.gov/publications/esp/reports.cfm>

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Please include the following correction:

In response to the question about effect size for estrogen-based hormone therapies on vasomotor symptoms: according to the recent AHRQ systematic review by Grant and colleagues (see link below), the effect size for estrogen based hormone therapy on VMS is -0.50 for high dose estrogen compared to placebo, -0.64 for standard dose estrogen compared to placebo, and -0.55 for low dose estrogen compared to placebo.

<https://www.effectivehealthcare.ahrq.gov/ehc/products/353/2052/menopausal-executive-150304.pdf>

In response to the question about the role of estrogen based hormone therapy for the treatment of osteoporosis: While it is a treatment option, it is generally not first-line therapy for prevention or treatment of osteoporosis due to associated risks.