

Clinical Practice Guidelines on the Use of Integrative Therapies as Supportive Care in Patients Treated for Breast Cancer

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Society for Integrative Oncology webinar series
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Previous SIO Clinical Guidelines

General

- Integrative Oncology Practice Guidelines, *JSIO* 2007
- Evidence-Based Clinical Practice Guidelines for Integrative Oncology: Complementary Therapies and Botanicals, *JSIO* 2009

Lung Cancer

- Complementary Therapies and Integrative Oncology in Lung Cancer: ACCP Evidence-Based Clinical Practice Guidelines (2nd Edition), *Chest* 2007
- Complementary Therapies and Integrative Medicine in Lung Cancer: Diagnosis and Management of Lung Cancer: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (3rd edition), *Chest* 2013



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New/Updated Guideline Summaries

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Announcements

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- The **Guidelines International Network North America (G-I-N NA)** continues to sponsor a monthly webinar series on topics of interest. Information on upcoming webinars is available on the [G-I-N Web site](#).

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Clinical Practice Guidelines

"Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (Institute of Medicine, 1990)

Issued by third-party organizations, and not NCCIH, these guidelines define the role of specific diagnostic and treatment modalities in the diagnosis and management of patients. The statements contain recommendations that are based on evidence from a rigorous systematic review and synthesis of the published medical literature.

These guidelines are developed and provided by third-party organizations. They are not developed by NCCIH or professional organizations.

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- [Exercise Guidelines for Cancer Survivors](#) (Med Sci Sports Exerc)
- [Integrative Oncology in Lung Cancer](#) (Chest)
- [Integrative Oncology: Complementary Therapies and Botanicals](#) (Society for Integrative Oncology)
- [Use of Integrative Therapies as Supportive Care in Breast Cancer Patients](#) (Journal of the National Cancer Institute) [391KB PDF]

Featured

- Standard
- Institut
- Nationa

Allergy and Immunology

- [Allergic Rhinitis and Its Impact on Asthma \(ARIA\) Guidelines: 2010 Revision](#) (Journal of Allergy and Clinical Immunology) [171KB PDF]
- [Diagnosis and Management of Food Allergy](#) (Journal of Allergy and Clinical Immunology) [165KB PDF]
- [Guidelines for the Diagnosis and Management of Asthma](#) (NHLBI)

Cardiology

- [Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults](#) (NHLBI)
- [Management of Stable Ischemic Heart Disease](#) (Annals of Internal Medicine) [PDF]

“Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”

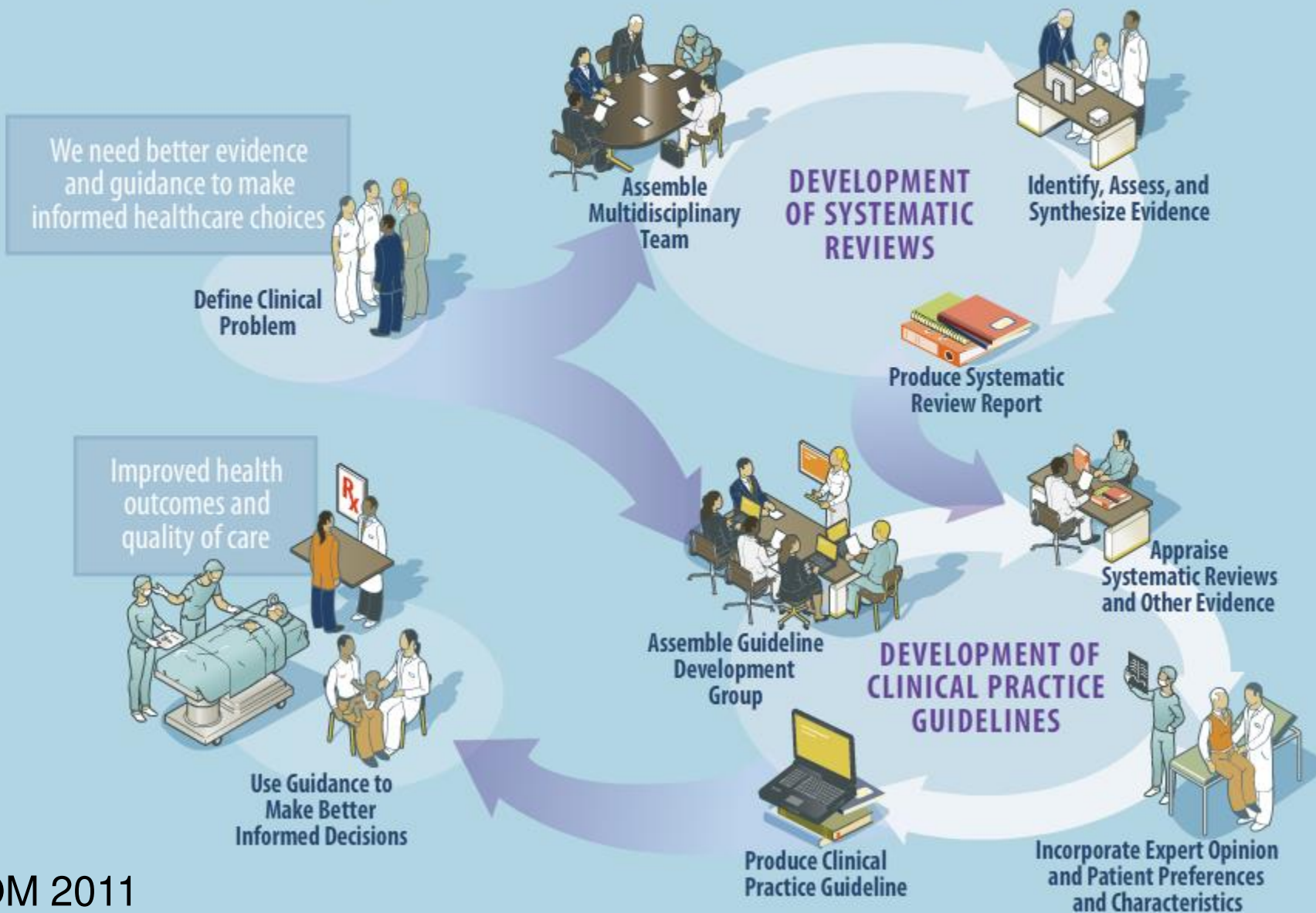
– 2011, *US Institute of Medicine*

Why bother with Clinical Practice Guidelines?

- Provide clinicians and patients with a trustworthy tool for managing clinical problems
- Represent the current state of science
- Help an organization increase visibility, credibility and impact in their professional community

Systematic Reviews and Clinical Practice Guidelines Improve Healthcare Decision Making

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IOM Standards for Developing Trustworthy Clinical Practice Guidelines

1. Establish transparency
2. Manage conflicts of interest (COI)
3. Guideline development group composition
4. Clinical practice guideline-systematic review intersection
5. Establish evidence foundations to rate strength of recommendations
6. Articulate recommendations in a standardized form and phrase so that compliance with the recommendation(s) can be evaluated
7. External reviewers should comprise a full spectrum of relevant stakeholders
8. Update on a regular basis

Phase I: SIO Guideline Task Force

- Assemble SIO Guideline Task Force (Spring 2013)
 - Gary Deng, MD, PhD, Memorial Sloan Kettering Cancer Center – SIO Past President
 - Heather Greenlee, ND, PhD, Columbia University – SIO President
 - Suzanna Zick, ND, MPH, University of Michigan – SIO President Elect
- Identify topic (Summer 2013)
- Establish process for developing SIO guidelines (Summer/Fall 2013)
 - Identify areas of expertise for representation
 - Identify multidisciplinary Working Group members
 - Develop process to manage Conflicts of Interest
 - Develop timeline

Complementary & integrative medicine (CIM) use among breast cancer survivors

- 2.8+ million breast cancer survivors in the US
- 48-80% of breast cancer patients use CIM
- Intended uses of CIM after diagnosis include:
 - Prevent & treat side effects of conventional therapies
 - Improve quality of life, functional status and emotional state
 - Increase efficacy of conventional cancer therapies
 - Secondary cancer prevention
 - Meet needs not addressed by conventional therapies
 - Treat comorbidities
 - Health promotion

Phase II: Guidelines Working Group

Co-Chairs

- **Heather Greenlee**, ND, PhD, MPH – naturopathic medicine, acupuncture, natural products, epidemiology, clinical trials
- **Debu Tripathy**, MD – breast medical oncology, natural products, clinical trials

Members

- **Lynda Balneaves**, PhD, RN – nursing, natural products, clinical trials
- **Linda Carlson**, PhD, Rpsych – clinical psychology, mind-body, clinical trials
- **Misha Cohen**, OMD, LAc – acupuncture, Chinese herbal medicine, clinical trials
- **Gary Deng**, MD, PhD – integrative med, acupuncture, Chinese med, clinical trials
- **Dawn Hershman**, MD, MS – breast medical oncology, natural products, epidemiology, clinical trials
- **Matthew Mumber**, MD – radiation oncology, mind-body interventions
- **Jane Perlmutter** – patient advocacy
- **Dugald Seely**, ND, MS – naturopathic med, research methods, systematic reviews, clinical trials
- **Ananda Sen**, PhD - biostatistics
- **Suzanna Zick**, ND, MPH – naturopathic med, natural products, acupressure, epidemiology, clinical trials

Conflicts of Interest

- Financial conflicts of interest, including research support, were reviewed for all authors
- No financial conflicts of interest to disclose
- We noted that some authors have conducted/authored some of the studies included in the review

Interventions of interest

- Natural products (e.g., botanicals, vitamins, minerals)
- Mind-body practices
 - Meditation
 - Yoga
 - Hypnosis
 - Imagery/Relaxation
 - Creative Therapies
 - Stress Management
 - Tai Chi/Qigong
- Acupuncture, acupressure, electroacupuncture
- Massage therapy
- Whole systems

Due to previous excellent reviews by *American Cancer Society*, *American Institute for Cancer Research*, and *American College of Sports Medicine*, decision not to include: **Diet, Physical activity, Energy balance**

Clinically relevant outcomes of interest

- Fatigue
- Gastrointestinal
- Gynecological
- Hematological
- Lymphedema
- Neurological
- Neuromuscular
- Pain
- Psychological
- Quality of life
- Renal
- Skin
- Sleep
- Vasomotor symptoms

Note: Immune parameters were not included

Search criteria

9 Databases: EMBASE, MEDLINE, PubMed, CINAHL, PsychINFO, Web of Science, SCOPUS, AMED, Acutrial

- Randomized controlled trial, AND
- Published January 1, 1990 - December 31, 2013, AND
- Breast cancer, AND
- Breast cancer treatment, AND
- Side effects/toxicities, AND
- Complementary/integrative therapies

Inclusion criteria

1. Randomized controlled trial
2. Available in English
3. Included $\geq 50\%$ breast cancer patients and/or reported results separately for breast cancer patients
4. Used an integrative modality as an intervention during standard treatment with surgery, chemotherapy, radiation therapy, and/or hormonal therapy, or addressed long-term side effects resulting from diagnosis and/or treatment
5. Assessed an outcome of interest

Other systematic reviews and meta-analyses were excluded.

Search results

- 4,900 unique articles
- Article titles and abstracts were initially screened by at least 2 reviewers for inclusion for full review
- Full-text of articles that met criteria were assembled in online database accessible to the working group (Mendeley)
- Second round of screening consisted of a full-text scan to further remove articles that did not meet the inclusion criteria
- 203 articles met the criteria for final inclusion

Quality scoring system

Scoring system	Question	Score
Jadad	1. Was the study described as randomized?	1=Yes, 0=No
	2. Was the method of randomization described in detail and appropriate?	1=Yes; 0=Not described in detail; 1=Described but not appropriate
	3. Was the study described as double-blinded?	1=Yes; 0=No
	4. Was the method of double-blinding described appropriate to maintain a double-blinding	If Q3=1 and double-blinding as described is appropriate, then Q4=1; If Q3=1 and double-blinding is not described, then Q4=0; If Q3=1 and double-blinding is inappropriate, then Q4=-1; If Q3=0, then Q4=0
	5. Was there a description of dropouts /withdrawals?	1=Yes/NA; 0=No
Modified Scale	1. Was there a description of dropouts /withdrawals?	1=Yes/NA; 0=No
	2. Was the method of randomization specified?	1=Yes; 0=No
	3. Was the eligibility criterion clearly laid out?	1=Yes; 0=No
	4. Is the Patient Blind to Study Arm?	1=Yes/N/A; 0.5=Don't Know; 0=No
	5. Is the Provider and/or Assessor Blinded to Study Arm?	1=Yes/N/A; 0.5=Don't Know; 0=No
	6. Is the sequence of study arm allocation concealed to the treatment assigner?	1=Yes/N/A; 0.5=Don't Know; 0=No
	7. Was there an objective strategy followed for treating missing data?	1=Yes; 0=No
	8. Was the study adequately powered for the primary outcomes?	1=Yes; 0.5=Don't Know; 0=No
	9. Point estimates and associated variability estimates (CI) presented for the primary outcome measures?	1=Yes; 0=No

USPSTF grades

Grade	Definition	Suggestions for Practice
A	Recommends the modality. There is high certainty that the net benefit is substantial.	Offer/provide this modality.
B	Recommends the modality. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this modality.
C	Recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this modality for selected patients depending on individual circumstances.
D	Recommends against the service. There is moderate or high certainty that the modality has no net benefit.	Discourage the use of this modality.
H	Recommends against the service. There is moderate or high certainty that the harms outweigh the benefits.	Discourage the use of this modality.
I statement	Concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

*Adapted from U.S. Preventive Services Task Force

<http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm>.

Clinical Practice Guidelines on the Use of Integrative Therapies as Supportive Care in Patients Treated for Breast Cancer

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Background The majority of breast cancer patients use complementary and/or integrative therapies during and beyond cancer treatment to manage symptoms, prevent toxicities, and improve quality of life. Practice guidelines are needed to inform clinicians and patients about safe and effective therapies.

Methods Following the Institute of Medicine's guideline development process, a systematic review identified randomized controlled trials testing the use of integrative therapies for supportive care in patients receiving breast cancer treatment. Trials were included if the majority of participants had breast cancer and/or breast cancer patient results were reported separately, and outcomes were clinically relevant. Recommendations were organized by outcome and graded based upon a modified version of the US Preventive Services Task Force grading system.

Results The search (January 1, 1990–December 31, 2013) identified 4900 articles, of which 203 were eligible for analysis. Meditation, yoga, and relaxation with imagery are recommended for routine use for common conditions, including anxiety and mood disorders (Grade A). Stress management, yoga, massage, music therapy, energy conservation, and meditation are recommended for stress reduction, anxiety, depression, fatigue, and quality of life (Grade B). Many interventions ($n = 32$) had weaker evidence of benefit (Grade C). Some interventions ($n = 7$) were deemed unlikely to provide any benefit (Grade D). Notably, only one intervention, acetyl-L-carnitine for the prevention of taxane-induced neuropathy, was identified as likely harmful (Grade H) as it was found to increase neuropathy. The majority of intervention/modality combinations ($n = 138$) did not have sufficient evidence to form specific recommendations (Grade I).

Conclusions Specific integrative therapies can be recommended as evidence-based supportive care options during breast cancer treatment. Most integrative therapies require further investigation via well-designed controlled trials with meaningful outcomes.

80+ pages of supplemental materials

Supplementary Table 2: Summary of randomized controlled integrative therapy trials in breast cancer patients with anxiety and stress outcomes

Intervention	Author, Year	Population	Sample Size	Intervention Details	Comparison Group	Study Conclusions	Study Quality score (scale 0-9)	Primary or Secondary Outcome?	Recommendation	Grade
Music Therapy	Binns-Turner, 2011 (35)	BC patients undergoing surgery	30	Music therapy	SC	Greater decline in anxiety in treatment group over control	5.0	Primary	Music therapy is recommended for reducing anxiety during RT and CT sessions.	B
	Bulfone, 2009 (36)	Stage I-II BC patients 40-60 yo post-surgery	60	Music therapy	SC	Anxiety scores in the experimental group decreased after music, but increased in control waiting for CT	3.5	Primary		
	Hanser, 2006 (37)	Stage IV BC patients	70	Music therapy	SC	Significant immediate effects of music therapy were observed on relaxation, but no differences between conditions were found over time on anxiety	6.0	Secondary		
	Li, 2012 (38)	BC patients post-surgery	120	Music therapy	SC	Music therapy decreased state anxiety score more than control at all three time points	5.0	Primary		
Meditation	Crane-Okada, 2012 (40)	BC patients 50+ yo post-treatment	49	Mindful Movement Program	SC	No group differences in anxiety symptoms	5.5	Secondary	Meditation is recommended for reducing anxiety in BC patients and those undergoing RT.	B
	Kim, 2013 (41)	BC patients post-surgery receiving RT	102	Brain wave vibration meditation	RT only	Anxiety improved more in treatment group than control	6.0	Primary		
	Lengacher, 2009 (42)	BC patients within 18 months post-treatment	84	MBSR	SC	Greater improvements in anxiety at 6 weeks in MBSR group	6.5	Primary		
	Würtzen, 2013 (43)	Stage I-III BC patients 3-18 months post-surgery	336	MBSR	SC	Greater decrease in anxiety in MBSR group after 12 months	5.5	Primary		
Stress Management	Aguado Loi, 2012 (52)	Newly diagnosed BC patients pre-CT	220	Self-administered stress management training	SC	No significant improvements in either group on anxiety	7.0	Primary	Stress management is recommended for reducing anxiety during treatment, but longer group programs are likely better than self-administered home	B
	Carlson, 2013 (56)	Stage I-III BC patients	271	MBSR, supportive-expressive therapy	Stress management	Women in MBSR improved more over time in stress	6.5	Primary		

Anxiety / stress reduction

Grade B

- **Music therapy** is recommended for reducing anxiety during radiation therapy (RT) and chemotherapy (CT) sessions.
- **Meditation** is recommended for reducing anxiety in BC patients and those undergoing RT.
- **Stress management** is recommended for reducing anxiety during treatment, but longer group programs are likely better than self-administered home programs or shorter programs.
- **Yoga** is recommended for reducing anxiety in BC patients undergoing RT +/- CT and suggested for fatigued patients.

Grade C

- **Acupuncture** can be considered for reducing anxiety in fatigued BC patients.
- **Massage** can be considered for short-term reduction of anxiety in BC patients.
- **Relaxation** can be considered for treating anxiety during treatment.

Depression / mood

Grade A

- **Meditation**, particularly MBSR, is recommended for treating mood disturbance and depressive symptoms in BC patients undergoing RT.
- **Relaxation** is recommended for improving mood and depressive symptoms when added to SC.
- **Yoga** is recommended for improving mood in women undergoing RT +/- CT and for fatigued BC patients in addition to SC.

Grade B

- **Massage** is recommended for improving mood disturbance in post-treatment BC patients.
- **Music therapy** is recommended for improving mood in newly diagnosed BC patients.

Grade C

- **Acupuncture** can be considered for improving mood in postmenopausal women experiencing hot flashes or fatigue.
- **Healing touch** can be considered for improving mood in BC patients undergoing CT.
- **Stress management** interventions with or without exercise can be considered for improving mood in BC patients.

Fatigue

Grade B

- **Energy Conservation Counseling** is recommended for the treatment of fatigue.

Grade C

- **American Ginseng** is recommended as an herbal approach for the treatment of fatigue in BC patients.
- **Acupuncture** can be considered for the treatment of fatigue after the completion of cancer treatments.
- Modified **qigong** can be considered for the treatment of fatigue in BC patients.

Grade D

- **Acetyl-L-carnitine** is not recommended for the treatment of fatigue due to lack of effect.
- **Guarana** is not recommended as an herbal for the treatment of fatigue due to lack of effect.

Sleep

Grade C

- **Stress management** techniques can be considered for the treatment of sleep disruption.
- Gentle **yoga** can be considered for the treatment of sleep disruption.

Quality of life & physical functioning

Grade A

- **Meditation** is recommended for improving quality of life among BC patients.

Grade C

- **Acupuncture** can be considered for improving quality of life among cancer patients.
- **Guided imagery** can be considered for improving quality of life among BC patients.
- **Mistletoe** can be considered for improving quality of life among BC patients.
- **Qigong** can be considered for improving quality of life in cancer patients.
- **Reflexology** can be considered for improving quality of life among BC patients.
- **Stress management** can be considered for improving quality of life among BC patients.
- **Yoga** can be considered for improving quality of life among BC patients.
- **Exercise/ awareness** can be considered for improving functioning among BC patients.

Grade D

- **Energy conservation** is not recommended for improving functioning among BC cancer patients due to lack of effect.

Chemotherapy induced nausea and vomiting (CINV)

Grade B

- **Acupressure** can be considered for BC patients receiving CT as an addition to antiemetics to help control nausea and vomiting during CT.
- **Electroacupuncture** can be considered for BC patients as an addition to antiemetics to control vomiting during CT.

Grade C

- **Ginger** can be considered for BC patients receiving CT, without concurrent RT as an addition to antiemetics for the control of acute nausea.
- **Progressive muscle relaxation** can be considered for BC patients receiving CT as an addition to antiemetics to help control nausea and vomiting during CT.

Grade D

- **Glutamine** is not recommended for use by BC patients receiving CT for the treatment of CINV due to lack of effect

Pain

Grade C

- **Energy and Sleep Enhancement** can be considered for pain associated with CT among unemployed individuals.
- **Massage** and **healing touch** can be considered for pain associated with CT.
- **Music therapy** can be considered to relieve pain associated with surgery.
- A **physical training program** that includes a mind-body modality can be considered for relieving pain associated with surgery among BC patients.
- **Hypnosis** can be considered for relief of associated with surgery in BC patients.
- **Acupuncture** can be considered as a non-pharmacologic approach to the short-term treatment of aromatase inhibitor-associated musculoskeletal symptoms (AIMSS).
- **Electroacupuncture** can be considered as a non-pharmacologic approach to the short-term treatment of AIMSS.

Neuropathy

Grade H

- **Acetyl-L-carnitine** is not recommended for prevention of neuropathy in BC patients due to harm.

Insufficient evidence

- Electroacupuncture, vitamin B, omega-3 fatty acid, vitamin E

Lymphedema

Grade C

- **Laser therapy** can be considered as a treatment for lymphedema in BC patients.
- **Manual lymphatic drainage (MLD)** and compression bandaging have been shown to be equivalent. MLD can be considered for treatment of lymphedema in BC patients who have sensitivity to bandaging.

Hot flashes

Grade C

- **Acupuncture** can be considered for decreasing the number of hot flashes in BC patients.
- **Electroacupuncture** can be considered for decreasing the number of hot flashes in BC patients.

Grade D

- **Soy** is not recommended for the treatment of hot flashes in BC patients and patients due to lack of effect.

Acute radiation skin reaction

Grade D

- **Aloe vera** is not recommended as a standard therapy to prevent or treat acute radiation skin reaction due to lack of effect.
- **Hyaluronic acid cream** is not recommended as a standard therapy to prevent or treat acute radiation skin reaction due to lack of effect.

Strengths, Limitations and Caveats

- Up to date summary of RCTs with defined grading system
- Excluded older literature, meta-analyses and reviews
- Excluded trials that had a minority of breast cancer patients
- May have missed some trials using different keywords, not associated with cancer therapy
- Not all modalities (e.g., spirituality) were included
- Future trials need to standardize therapies, defined symptoms/eligibility, outcome measures, toxicity assessments
- Use of guidelines requires judgment, shared decision-making, risk/benefit analysis depending on situation (e.g., curability), follow-up/surveillance and adjustments

Dissemination plan

- Published in Journal of the National Cancer Institute Monograph – open access
- Press releases to media outlets
- Submit to national guidelines repositories
- Develop patient and provider friendly materials
- Advocate for high quality integrative oncology research
- Post slidedeck on SIO website

Conclusions

- Clinical practice guidelines provide an aid to making complex clinical decisions
- Improve the ability for patients and clinicians to make healthcare decisions
- SIO aims to be the leader in developing trustworthy guidelines focused on integrative oncology

Many thanks

Research Assistants

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Thank you for participating in this SIO webinar!

Questions?

SIO Guidelines can be accessed via:

<http://www.integrativeonc.org/index.php/docguide>

