

# Designing Yoga Interventions to Transition from Research to Practice

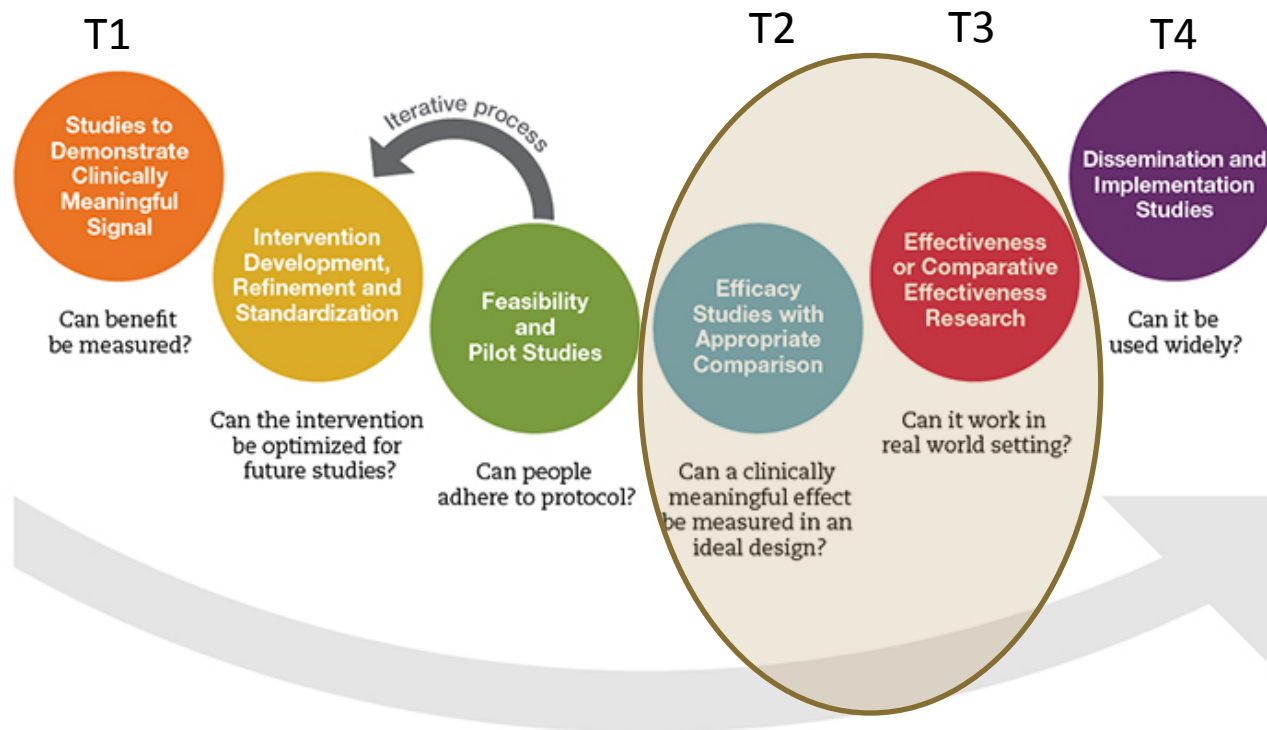
Stephanie J. Sohl, PhD

Symposium on Yoga Research, October 18, 2017



# Transitioning from Research to Practice

National Center for Complementary and Integrative Health (NCCIH)  
Framework for Developing and Testing Mind and Body Interventions



# Gap Between Research & Practice

- Results from research trials are often not applied in clinical practice
- Intervention elements to facilitate translation:
  - Low cost
  - Self-sustaining
  - Takes limited time
  - Can be implemented with little specific expertise
  - Simple to learn or understand
  - Packaged/manualized
  - Developed with consideration for consumer needs
  - Can be used across settings
  - Customizable

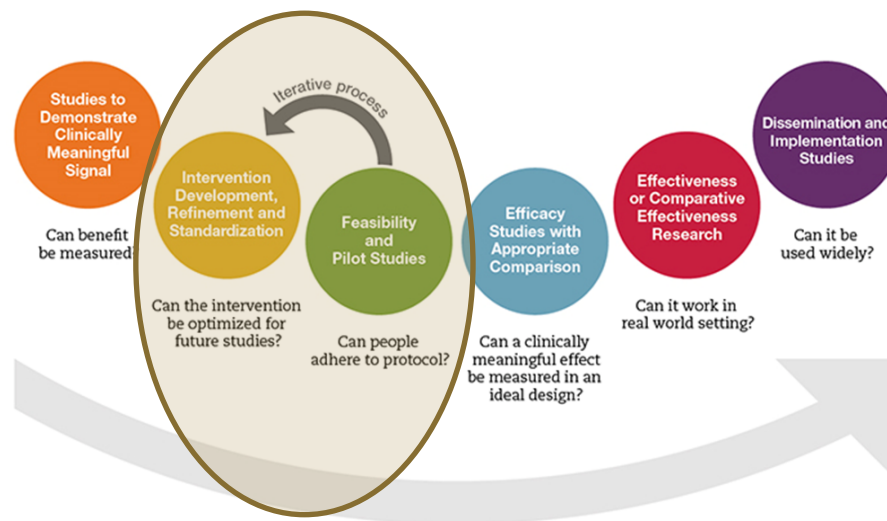
# Efficacy of Yoga During Cancer Treatment

- Evidence supports the efficacy of yoga for improving psychological outcomes, with potential for also improving physical symptoms
- Most participants are women with breast cancer (91%) attending primarily group classes
- Barriers to study participation include difficulties with scheduling and travel, changes in interest or symptoms, and health issues

(Danhauer, Addington, Sohl, Chaoul, & Cohen, 2017)

# Examples from Our Research

- Yoga coordinated with clinical care (i.e. during chemotherapy and around the time of surgery)
- Yoga implemented via eHealth



# Outline

## Yoga in the clinic during chemotherapy

- One-arm feasibility study
- Small randomized pilot study
- Ongoing larger randomized pilot study
  - Intervention protocol publication

## Yoga around the time of surgery

- Feasibility questionnaire
- One-arm feasibility study
- Ongoing adaptation to eHealth
  - Stakeholder input on intervention refinement

# Aims of Coordinating Yoga with Clinical Care

- Increase representativeness of cancer patients
- Reach those who have barriers to participation
- Include elements to facilitate translation:
  - Takes limited time
  - Simple to learn or understand
  - Packaged/manualized
  - Developed with consideration for consumer needs
  - Can be used across settings
  - Customizable

# FEASIBILITY OF A BRIEF YOGA INTERVENTION DURING CHEMOTHERAPY FOR PERSISTENT OR RECURRENT OVARIAN CANCER

Stephanie J. Sohl, PhD,<sup>1#</sup> Suzanne C. Danhauer, PhD,<sup>1</sup> Julie B. Schnur, PhD,<sup>2</sup> Leslie Daly, MS,<sup>2</sup>  
Kathryn Suslov, MD,<sup>2</sup> and Guy H. Montgomery, PhD<sup>2</sup>

**Objective:** To present feasibility data and a preliminary exploration of a Yoga Skills Training (YST) for patients undergoing chemotherapy for ovarian cancer

# Results

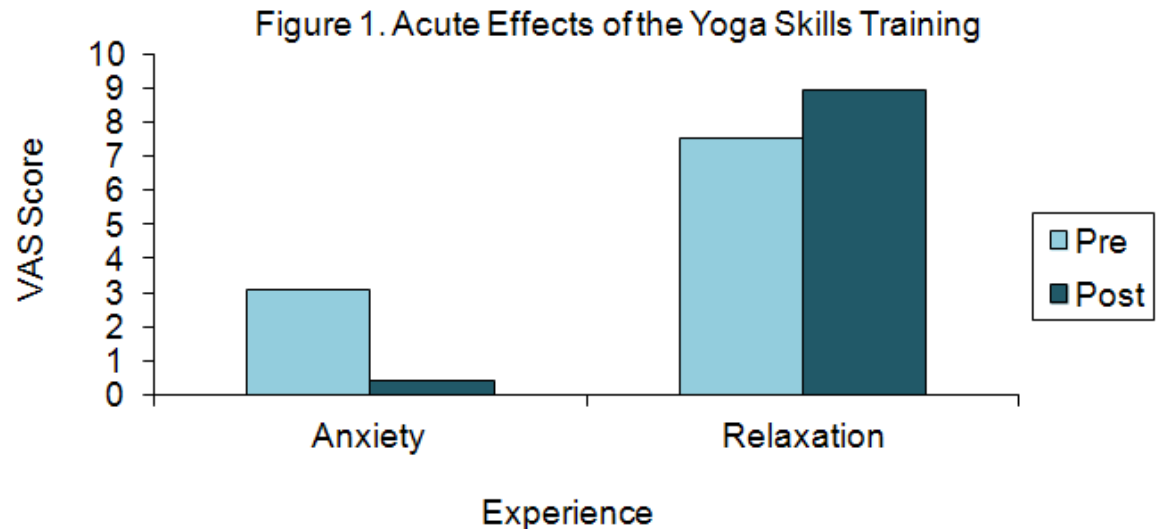
Participants: 7 women undergoing chemotherapy for ovarian cancer

Measures: Visual Analogue Scale items of anxiety and relaxation immediately before and after the YST

Effect Sizes:

Anxiety  
 $d = -0.82$

Relaxation  
 $d = 0.83$





Contents lists available at ScienceDirect

## Complementary Therapies in Medicine

journal homepage: [www.elsevierhealth.com/journals/ctim](http://www.elsevierhealth.com/journals/ctim)



Short communication

### A brief yoga intervention implemented during chemotherapy: A randomized controlled pilot study



Stephanie J. Sohl<sup>a,b,\*</sup>, Suzanne C. Danhauer<sup>b</sup>, Gurjeet S. Birdee<sup>a</sup>, Barbara J. Nicklas<sup>b</sup>, George Yacoub<sup>b</sup>, Mebea Aklilu<sup>b</sup>, Nancy E. Avis<sup>b</sup>

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- This study aimed to establish the feasibility of conducting a randomized controlled trial of a Yoga Skills Training (YST) among patients receiving chemotherapy for colorectal cancer
- We indicated *a priori* that a retention rate of 65% would support feasibility for a larger clinical trial

# Results: Accrual and Completion Rates

- Of 52 patients identified, 28 were approached, and 15 (54%) enrolled
- Participants had a median age of 61 years, and a majority were white (80%) and male (60%)
- Two participants were lost to follow-up in each arm due to cancer treatment changes (73% retention)
- Participants retained in the study also completed all questionnaires with one exception

# Results: Adherence and Satisfaction

- Intervention adherence to 3 in-person sessions = 76%
- The length of each intervention was 30 minutes
- All participants indicated that they liked the interventions and found them helpful

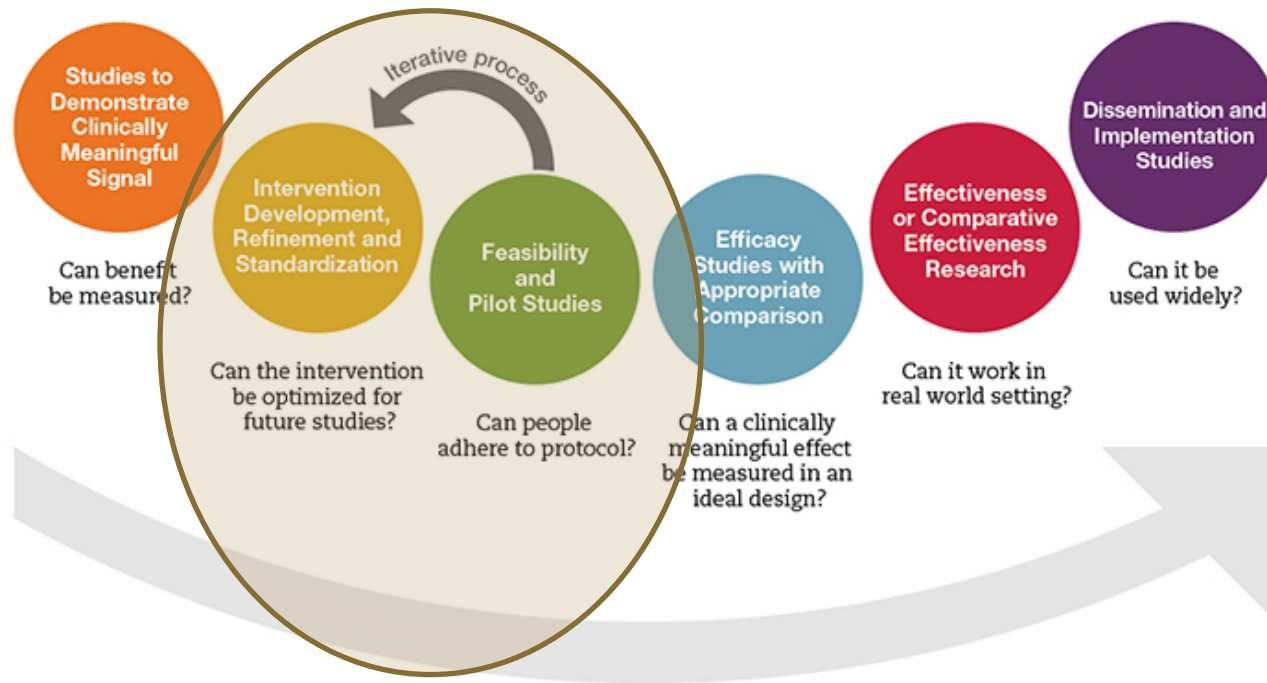
# Results: Qualitative Feedback

What participants liked best about the study:

- *“Learning to relax and be in control more.”*
- *“The sessions while being treated in the hospital.”*
- *“Special attention placed on emotional wellness in addition to physical.”*

# Larger Pilot of an Enhanced Yoga Skills Training

National Center for Complementary and Integrative Health (NCCIH)  
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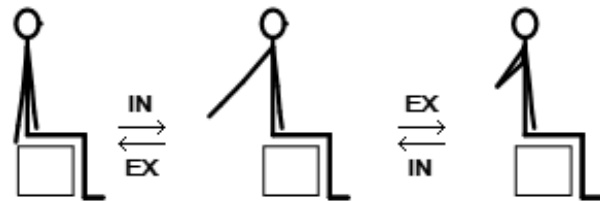
**YST: More targeted to fatigue, attention to treatment fidelity, focused on adherence to home practice (K01 AT008219-01A1)**

# Methods

## Intervention Protocol for Investigating Yoga Implemented During Chemotherapy

Stephanie J. Sohl, PhD,<sup>1,2</sup> Gurjeet S. Birdee, MD, MPH,<sup>1</sup> Sheila H. Ridner, PhD, RN, FAAN,<sup>3</sup> Amy Wheeler, PhD,<sup>4</sup> Sandra Gilbert,<sup>1</sup> Danielle Tarantola,<sup>5</sup> Jordan Berlin, MD,<sup>1</sup> Russell. L. Rothman, MD, MPP<sup>1</sup>

Inhale raise your arm out to the side keeping it relaxed. Exhale cross the same arm over the body to touch the opposite shoulder, turning the head slightly in the same direction. Inhale bring the arm back out to the side, exhale lower the arm down. Repeat 3-6x alternating sides.



# Recommended Domains for Yoga Protocol Development

- Style
- Delivery
- Dose
- Components of the Intervention
- Specific Class Sequences
- Facilitation of Home Practice
- Selection of Instructors
- Measurement of Treatment Fidelity
- Dealing with Modifications

# Treatment Fidelity

- Treatment fidelity is “the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers” (p. 69, Proctor 2011).
- Outcome assessed to evaluate successful implementation of an intervention into practice
- Considered when developing the yoga intervention, so that it will ultimately be reproducible and practical to disseminate

(Bellg et al., 2004; Proctor et al., 2011)

# Measurement of Intervention Fidelity

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## **Overall Relationship**

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**Allowed student to ask questions**

**Had a one-pointed focus on the student**

**Emphasized attention, comfort and ease throughout the practice**

**Allowed space for the student to have his/her own “experience of the practice” during and after each instruction**

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## **Skill 1: Awareness**

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**Guided awareness consistent with the protocol**

**Encouraged openness to the experience of the present moment**

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## **Skill 2: Movement**

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**Instructed synchronized breath and movement**

**Allowed for individual to self-determine movement and modifications**

**Taught all movements (or appropriate modifications) in the protocol**

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(Sohl, Birdee, Ridner, et al., 2016)

# Measurement of Intervention Fidelity

## **Skill 3: Breathing**

**Allowed for individual to self-determine breathing and modifications**

**Instructed breathing technique (or appropriate modifications) from the protocol**

## **Skill 4: Relaxation**

**Instructed relaxation technique**

**Instructed guided meditation**

**Suggested noticing of any shifts in current state**

**Led transition to alertness**

## **Closure: Home Practice**

**Reviewed understanding of handout on home practice**

**Discussed home practice goals**

**Inquired about confidence in ability to reach practice goals**

# Outline

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- Ongoing adaptation to eHealth
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# Significance

Improved management of acute perioperative pain and co-morbid symptoms may proactively reach an at-risk population and reduce the burden of chronic pain.



# Preliminary Research

Initial survey supported:

- Interest
- Length of intervention session
- Name
- Modality of implementation

# Mindful Movement and Breathing

- Implemented perioperatively
- Supports usual care goals:
  - Pain management
  - Ambulation
  - Deep breathing

## Research

# Feasibility of a Brief Yoga Intervention for Improving Acute Pain and Distress Post Gynecologic Surgery

Stephanie J. Sohl, PhD,<sup>1,2</sup> Nancy E. Avis, PhD,<sup>2</sup> Kimberly Stanbery, MSN, RN, OCN,<sup>2</sup> Janet A. Tooze, PhD,<sup>2</sup> Kelly Moormann, BA,<sup>2</sup> Suzanne C. Danhauer, PhD<sup>2</sup>



# Preliminary Research

- One-arm pilot:
  - 55% recruitment rate
  - Feasibility of testing an in-person MMB
  - Challenges to implementation before surgery
- eHealth approach to improve feasibility

Sohl, Avis, Stanbery, Tooze, Moormann, & Danhauer, *Int J Yoga Therap*, 2016

# EHealth Mindful Movement and Breathing to Improve Gynecologic Cancer Surgery Outcomes



R34 AT009546, Planning Grant

# Aim I

**Develop the eHealth interventions.** This aim will be accomplished with input from stakeholders that include healthcare providers, mind-body experts, clinical informatics professionals, patients, and research staff.

Stakeholders were asked to give their opinions of 2 mock videos that demonstrated intervention activities in a hospital bed and on proposed implementation strategies.

# Examples of Stakeholder Feedback

| Feedback                                                                                                                                                                                            | Resulting Modification                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pillow under knees could facilitate blood clots.                                                                                                                                                    | We modified movements so they do not require pillows under the knees or movement of the bed.                                                                          |
| Asking the patient to do the exercises at the same time each day may help with adherence.                                                                                                           | We incorporated additional guidance in instructions for both groups.                                                                                                  |
| Give the patient an opportunity to use the restroom or have water prior to the start of the session.<br><br>Match all that was said and done to create patient comfort to the active control group. | We added instructions at the beginning of the intervention protocols regarding creating a space for undisturbed focus on the intervention and comfort in both groups. |

# Next Steps

- **Aim II:** Field-test implementation strategies
- **Aim III:** Determine feasibility and acceptability of the interventions.

# Outline – Next Steps

## Yoga in the clinic during chemotherapy

- Ongoing larger randomized pilot study (K01AT008219)
  - Intervention protocol published (more targeted to fatigue, attention to treatment fidelity, focused on adherence to home practice)
  - Implements daily and qualitative assessment

## Yoga around the time of surgery

- Ongoing adaptation to eHealth (R34 AT009546)
  - Stakeholder input on intervention refinement
  - One-arm test of implementation strategies
  - Randomized pilot study

# Discussion

- Implementing yoga so that it is coordinated with clinical care and/or via eHealth may facilitate translation of research to practice
- Future directions for yoga research include seeking an optimal balance between clinical efficacy and public health impact when designing interventions in order to reduce the gap between research and practice

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# Questions or Comments?



# References

Bellg, A.J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D.S., Ory, M., Ogedegbe, G., Orwig, D., Ernst, D., Czajkowski, S., 2004. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol.* 23, 443–451. doi:10.1037/0278-6133.23.5.443

Glasgow, R.E., Emmons, K.M., 2007. How can we increase translation of research into practice? Types of evidence needed. *Annu. Rev. Public Health* 28, 413–433.

Lenfant, C., 2003. Clinical Research to Clinical Practice — Lost in Translation? *N. Engl. J. Med.* 349, 868–874. doi:10.1056/NEJMsa035507

Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., Griffey, R., Hensley, M., 2011. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm. Policy Ment. Health* 38, 65–76. doi:10.1007/s10488-010-0319-7

Sherman, K. J. (2012). Guidelines for Developing Yoga Interventions for Randomized Trials. *Evidence-Based Complementary and Alternative Medicine*, 2012.

# References

**Sohl SJ**, Avis NE, Stanbery K, et al. Feasibility of a brief yoga intervention for improving acute pain and distress post gynecologic surgery. *Int J Yoga Therap*. 2016; 26: 43-47.

**Sohl SJ**, Birdee GS, Ridner SH, et al. Intervention protocol for investigating yoga implemented during chemotherapy. *Int J Yoga Therap*. 2016; 26: 103-111.

**Sohl SJ**, Danhauer SC, Birdee GS, et al. A brief yoga intervention implemented during chemotherapy for colorectal cancer patients: A randomized controlled pilot study. *Complement Ther Med*. 2016;25:139-142.

**Sohl SJ**, Danhauer SC, Schnur JB, et al. Feasibility of a brief yoga intervention during chemotherapy for persistent or recurrent ovarian cancer. *Explore*. 2012;8:197-198.

Danhauer SC, Addington EL, **Sohl SJ**, Chaoul A & Cohen L. Review of yoga therapy during cancer treatment. *Support Care Cancer*. 2017; 25; 1357-1372.