Planning Pilot Studies: Considering Feasibility, Study Design and Next Steps

Stephanie J. Sohl, PhD
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Developing and Testing Yoga Interventions

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

- Studies to Demonstrate Clinically Meaningful Signal
  - Can benefit be measured?

- Intervention Development, Refinement and Standardization
  - Can the intervention be optimized for future studies?

- Feasibility and Pilot Studies
  - Can people adhere to protocol?

- Efficacy Studies with Appropriate Comparison
  - Can a clinically meaningful effect be measured in an ideal design?

- Effectiveness or Comparative Effectiveness Research
  - Can it work in real world setting?

- Dissemination and Implementation Studies
  - Can it be used widely?

Iterative process
Outline – Planning Pilot Studies

• Feasibility and Pilot Studies
• Intervention Development, Refinement and Standardization
• Specific Example
Selecting a Research Topic

FINER principles

• Feasible
• Interesting
• Novel
• Ethical
• Relevant

Hulley et al., 2001
Feasibility and Pilot Studies

• Used to determine whether an intervention is appropriate for further testing

• Reasons for conducting a feasibility study:
  • Process
  • Resources
  • Management
  • Scientific

Thebane et al., 2015
**Feasibility and Pilot Studies**

**It is important to state the criteria for success**

- Process – Recruitment examples

  *We hypothesize that we will enroll at least 50% of eligible patients.*

  *We hypothesize that we will enroll one participant per center per week can be recruited.*

  Thebane et al., 2015
Feasibility and Pilot Studies

• Resources examples

*We hypothesize that we will obtain complete follow-up data in at least 70% of all recruited.*

*We hypothesize that participants will adhere to 70% of the intervention sessions.*

Thebane et al., 2015
Feasibility and Pilot Studies

• Management examples

Is the equipment readily available when and where it is needed?

What are the challenges that participating centers have with managing the study?

Thebane et al., 2015
Feasibility and Pilot Studies

• Scientific examples

*Do data show too much or too little variability?*

*What is the estimate of the variance of the treatment effect?*

**Pilot studies are not powered for hypothesis testing.**

Leon, Davis, & Kraemer, 2011; Thebane et al., 2015
Outline – Planning Pilot Studies

• Feasibility and Pilot Studies
• Intervention Development, Refinement and Standardization
• Specific Example
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

(Sherman, 2012)
Example from Our Research

Yoga in the clinic during chemotherapy

• **One-arm feasibility study**
• **Small randomized pilot study**
• **Ongoing larger randomized pilot study**
  • **Intervention protocol publication**
Feasibility of a Brief Yoga Intervention During Chemotherapy for Persistent or Recurrent Ovarian Cancer

Stephanie J. Sohl, PhD,1* Suzanne C. Danhauer, PhD,1 Julie B. Schnur, PhD,2 Leslie Daly, MS,2 Kathryn Suslov, MD,2 and Guy H. Montgomery, PhD2

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
\[ d = 0.83 \]
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
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)
Framework for Developing and Testing Mind and Body Interventions

YST: Refined to be more targeted to fatigue, attention to treatment fidelity, focused on adherence to home practice (K01 AT008219-01A1)

https://nccih.nih.gov/research/blog/r34?nav=upd
Methods

Intervention Protocol for Investigating Yoga Implemented During Chemotherapy

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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.
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).

• Considered when developing the yoga intervention, so that it will ultimately be implemented consistently in a larger trial and practical to disseminate

(Bellg et al., 2004; Proctor et al., 2011)
# Measurement of Intervention Fidelity

<table>
<thead>
<tr>
<th>Overall Relationship</th>
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<tbody>
<tr>
<td>Allowed student to ask questions</td>
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<tr>
<td>Had a one-pointed focus on the student</td>
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<tr>
<td>Emphasized attention, comfort and ease throughout the practice</td>
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<tr>
<td>Allowed space for the student to have his/her own “experience of the practice” during and after each instruction</td>
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<tr>
<th>Skill 1: Awareness</th>
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<tbody>
<tr>
<td>Guided awareness consistent with the protocol</td>
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<tr>
<td>Encouraged openness to the experience of the present moment</td>
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<th>Skill 2: Movement</th>
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<tr>
<td>Instructed synchronized breath and movement</td>
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<tr>
<td>Allowed for individual to self-determine movement and modifications</td>
</tr>
<tr>
<td>Taught all movements (or appropriate modifications) in the protocol</td>
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(Sohl, Birdee, Ridner, et al., 2016)
Summary of Planning Pilot Studies

• Feasibility indicators are essential for planning larger studies

• Plan early for intervention standardization needed in larger studies

• Pilot studies require problem solving and persistence
Questions or Comments?
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References


References

