

Methods

Intervention Protocol for Investigating Yoga Implemented During Chemotherapy

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Abstract

Objective: Fatigue and other treatment-related symptoms are critical therapeutic targets for improving quality of life in patients with colorectal cancer during chemotherapy. Yoga is a promising intervention for improving these therapeutic targets and has been primarily investigated in the group-class format, which is less feasible for cancer patients with high symptom burden to attend. Thus, we developed a protocol for implementing yoga individually in the clinic among patients receiving chemotherapy. **Methods:** We followed recommended domains for developing a yoga protocol to be used in an efficacy trial. These recommendations include consideration to the style, delivery, components of the intervention, dose, specific class sequences, facilitation of home practice, measurement of intervention fidelity, selection of instructors, and dealing with modifications. The intervention protocol was developed by an interdisciplinary team. **Protocol:** Yoga Skills Training (YST) consists of four 30-minute in-person sessions and was implemented while in the chair during chemotherapy infusions for colorectal cancer with recommended daily home practice for eight weeks. Therapeutic goals of the YST are to reduce fatigue, circadian disruption, and psychological distress. Elements of the YST are awareness meditation, gentle seated movement, breathing practice, and relaxation meditation. Attention, comfort, and ease are also highlighted. **Conclusion:** This description of a protocol for integrating yoga with conventional cancer treatment will inform future study designs and clinical practice. The design of the YST is novel because it implements yoga—most commonly stud-

ied when taught to groups outside of the clinical setting—individually during clinical care.

Keywords: mind-body therapy, integrative medicine, cancer, fatigue, stress, psychological distress, circadian disruption

Introduction

Colorectal cancer (CRC) is in the top three most prevalent cancers for both men and women (Howlader et al., 2013), and the number of CRC survivors continues to increase (American Cancer Society, 2014). Fatigue, a state of overwhelming and sustained exhaustion, is one of the most common (>50%) and severe symptoms reported in CRC patients (Aprile, Ramoni, Keefe, & Sonis, 2008; Cella, Peterman, Passik, Jacobsen, & Breitbart, 1998; Wang et al., 2012). Fatigue co-occurs with other common symptoms such as depression (Burkett & Cleeland, 2007; Dantzer, Meagher, & Cleeland, 2012; Medeiros, Oshima, & Forones, 2010) and is associated with a decline in quality of life (Gray et al., 2011; Steginga, Lynch, Hawkes, Dunn, & Aitken, 2009). A biobehavioral conceptual framework and data suggest that fatigue and depressive symptoms share underlying mechanisms including psychological stress, circadian disruption, and inflammation (Jim et al., 2011; Miller, Ancoli-Israel, Bower, Capuron, & Irwin, 2008; Rohleder, Aringer, & Boentert, 2012; Roscoe et al., 2002). Chemotherapy is efficacious for increasing survival among

CRC patients, yet produces secondary symptoms such as fatigue and depression. These symptoms peak approximately 3-5 days following treatment and then improve (de Jong, Kester, Schouten, Abu-Saad, & Courtens, 2006; Jim et al., 2011); however, fatigue and depressive symptoms do not return to pretreatment levels in a substantial subset of patients (Jansen, Koch, Brenner, & Arndt, 2010; Schneider et al., 2007). Thus, reducing fatigue and depressive symptoms during chemotherapy may improve short- and long-term quality of life in patients with CRC.

There are few existing interventions that aim to proactively improve fatigue and depressive symptoms during chemotherapy for CRC (Goedendorp, Gielissen, Verhagen, & Bleijenberg, 2009; Kwekkeboom et al., 2012; Lin, Shun, Lai, Liang, & Tsao, 2013). Reviews find that both psychological and exercise interventions reduce fatigue and depressive symptoms in cancer patients and suggest that it may be optimal to combine psychological and exercise interventions and simultaneously target symptoms that co-occur (Craft, Vaniterson, Helenowski, Rademaker, & Courneya, 2012; Donovan & Jacobsen, 2007; Kangas, Bovbjerg, & Montgomery, 2008; Mishra et al., 2012). Yoga is a combined approach that consists of gentle movements, breathing practices, and meditation, and has shown efficacy for improving clinical outcomes of fatigue, depressive symptoms (Bower et al., 2012; Culos-Reed et al., 2012), and possible mediators (i.e., psychological stress, circadian disruption, and inflammation) (Beddoe, Lee, Weiss, Kennedy, & Yang, 2010; Cramer, Lange, Klose, Paul, & Dobos, 2012; Kiecolt-Glaser et al., 2010). However, studies have primarily been conducted with women diagnosed with breast cancer, and further research is needed to assess the generalizability of these results to men and other cancer types. Further, therapeutic applications of yoga systematically select practices to target specific symptoms (e.g., fatigue), which may improve upon interventions with more global targets (Kangas et al., 2008).

Yoga research conducted in the United States has been primarily investigated in the group-class format (Culos-Reed et al., 2012), yet participants with high symptom burden are less likely to attend these classes (Cohen, Warneke, Fouladi, Rodriguez, & Chaoul-Reich, 2004; Danhauer et al., 2008). For example, patients' experience of fatigue was associated with attending fewer yoga classes (Moadel et al., 2007). Another study of cancer patients attending group yoga classes found that there were some common barriers to participating in yoga classes including transportation, scheduling, and being too busy or too sick (Cohen et al., 2004). Further, a study of yoga classes specifically for patients with colorectal cancer (2-48 months post-surgery) found low enrollment, low intervention adherence, and high attrition rates due partially to scheduling problems

(Cramer et al., 2015). The authors of this study have concluded that yoga may be more valuable if offered during treatment when patients experience higher symptom burden. It is possible that patients who are burdened by fatigue or depressive symptoms during chemotherapy who could potentially benefit the most are inadvertently excluded from yoga or other behavioral interventions due to feasibility issues.

This study describes a novel Yoga Skills Training (YST) protocol designed to be implemented individually in the clinic among patients receiving chemotherapy and examined as part of a randomized controlled study that has a primary outcome of fatigue, a secondary outcome of depressive symptoms, and that investigates possible mediators (i.e., psychological stress, circadian disruption, and inflammation). Reviews of yoga intervention research emphasize the need for improving the rigor of protocol development and reporting to advance the field (Danhauer, Sohl, Addington, Chaoul, & Cohen, 2016; Sherman, 2012). Thus, we gave special consideration to the domains recommended for developing a robust yoga protocol for an efficacy trial (Sherman, 2012).

Method

The YST protocol was informed by behavioral researchers, expert yoga therapists, and clinicians. The following recommended domains were considered: style, delivery, components of the intervention, dose, specific class sequences, facilitation of home practice, measurement of intervention fidelity, selection of instructors, and dealing with modifications (Sherman, 2012).

Style. The content of the initial YST was informed by the PI's (SJS) training from the Integral Yoga Academy's Yoga for People with Cancer Teacher Training and the Urban Zen Integrative Therapy training (Sohl et al., 2012) and was modified for this study to further target fatigue, circadian disruption, and psychological distress by consulting with three expert yoga therapists from the Krishnamacharya tradition who were not involved with teaching yoga for the study. The process for modifying the protocol included several iterative group discussions to ensure the practices incorporated were optimal according to ancient Indian therapeutic principles (Bossart, 2007) as well as reflection on the therapists' personal experience when practicing and teaching the protocol (authors AW, DT, and KH). Each individual component of the course was discussed separately and then put together and evaluated for flow and timing. Individual practices and flow of the practices were discussed until the group reached consensus. A few weeks separated each meeting of the yoga therapists to allow time for teaching personal students and independent review of theoretical

effectiveness of the protocol. Clinicians also reviewed the protocol to ensure safety before it was put into practice.

Delivery. To date, only preliminary research has been conducted to explore if yoga is safe and efficacious when taught in clinical settings (Kligler et al., 2011; Rao et al., 2008, 2009; Rao et al., 2008) and only those conducted by this study's co-authors have been implemented during an infusion (Birdee, Bossart, Sohl, Wheeler, & Wertenbaker, 2015; Sohl et al., 2012, 2016; Sohl et al., 2016). In addition, few studies have investigated yoga implemented individually, even though therapeutic yoga is traditionally taught in this format (Desikachar, 1995; Sherman, 2012). We previously demonstrated initial feasibility of implementing the YST individually in the clinical setting and short-term improvements in anxiety and relaxation with patients undergoing chemotherapy for ovarian cancer (Sohl et al., 2012). The current protocol built upon the previous YST by selecting practices more targeted to the therapeutic goals, increasing attention to treatment fidelity, and increasing focus on adherence to home practice.

Components of the Intervention. This intervention was designed to teach the key evidenced-based components of yoga for people with cancer (i.e., movement, breathing, and meditation) (Bower et al., 2012; Danhauer et al., 2016) with an additional and explicit emphasis on yogic philosophy. We chose to incorporate the full range of yoga skills in this study rather than one in isolation (e.g., breathing only; Dhruva et al., 2012) since we believe these components to be interconnected and synergistic (Birdee, Sohl, & Wallston, 2016; Bossart, 2007). We also only selected movements that could be practiced in a chair, which were low in intensity.

Dose. Although the optimal dose of yoga is unknown, a previous study reported that the greatest improvements in fatigue were found in cancer survivors who practiced yoga an average of three times per week (Littman et al., 2012) and a review of exercise interventions (including yoga) during chemotherapy found that 90-120 minutes of moderate activity per week was optimal (Carayol et al., 2013). Further, approximately 20 minutes of home yoga practice per day was found to be associated with an improvement in next-day fatigue (Carson et al., 2007). In addition, the median length of time for yoga interventions is 8 weeks (Sherman, 2012). Therefore, a reasonable suggested dose for yoga during chemotherapy could be 3–6 times per week for about 20 minutes per session for 8 weeks.

Specific Class Sequences. Therapeutic goals of the intervention, primarily identified through reviewing relevant research and an understanding of a biobehavioral conceptual framework, were to reduce fatigue, circadian disruption, and psychological distress. Thus, practices incorporated in

this protocol theoretically aimed to enhance relaxation and move energy flow (*prana*) throughout the body. Although the YST was taught individually, we selected the specific practices based on ancient Indian therapeutic principles as if they were going to be taught to a group. That is, although it is possible for yoga therapy to be further individualized, we chose to select practices targeted to the therapeutic goals and treatment setting with only slight modifications made based on individual characteristics (Birdee et al., 2015; Bossart, 2007). This approach created a broadly consistent protocol that is likely to be more generalizable.

Facilitation of Home Practice. We considered home practice to be an essential component of this yoga intervention. Standardized visits for chemotherapy are once every two weeks; thus, the in-person dose of the intervention is less than the dose implemented in studies that previously found yoga to be efficacious (Bower et al., 2012; Danhauer et al., 2016). Expert yoga therapists from the Krishnamacharya tradition were ideal for informing this approach because this tradition also places an emphasis on daily home practice (Desikachar, 1995).

Measurement of Intervention Fidelity. We took a number of steps to ensure treatment fidelity was also informed by guidelines for behavioral medicine research (Bellg et al., 2004; Borrelli et al., 2005; Sherman, 2012). These included development of a treatment manual and a checklist based on this manual to measure consistent implementation. Development of a treatment manual will ultimately also enable dissemination of the treatment protocol if the YST is found to be efficacious.

Selection of Instructors. We identified certified yoga instructors who had specific training and experience relevant to teaching yoga for people with chronic illness. These instructors were then trained to implement the study-specific protocol.

Dealing with Modifications. A prior yoga study (Cramer et al., 2015) that instructed more extensive physical movement in primarily post-treatment colorectal cancer survivors reported some minor adverse events (e.g., transient abdominal pain, muscle soreness, neck pain, vertigo, and hip pain) that recovered without treatment and no major adverse events. The current protocol is expected to have less risk of adverse events related to the intervention because the movements incorporated in the YST were selected to be gentle and all performed while seated. The manualized protocol for each YST session contains the same content, but the number of repetitions and the magnitude of movements are individualized based on how the participant is feeling that day.

Results: Yoga Skills Training (YST) Protocol

Style. The resulting YST can be taught by certified yoga instructors from different traditions that have a consistent understanding of yoga healing principles and experience teaching people with chronic conditions.

Delivery. The YST is implemented in the clinic during patients' already-scheduled visits for chemotherapy to lessen identified barriers to participation. This mode of delivery may be more inclusive of patients most in need of intervention and may proactively address patients' acute symptoms that have the potential to persist.

Components of the Intervention. The YST incorporates meditation, movement and breathing practices. The intention to maintain attention (*sthira*), comfort and ease (*sukha*) is also highlighted throughout the YST.

Dose. The dose of the YST when including home practice is consistent with the optimal dose deduced from the literature. The YST consists of four in-person 30-minute sessions offered in the clinic every two weeks along with daily home practice. Participants are given a paper handout describing the YST (Figure 1), an audio recording of the YST, and devices to play the recording to facilitate home practice. The intervention period from the time the first intervention is implemented to the post-treatment assessment spans eight weeks.

Specific Class Sequences. The instructor takes the first 5 minutes of the session to address any questions and inquire about the participant's current physical status. Skills included in the YST with approximate times for each skill are: (a) Awareness Meditation—2 minutes to check in and notice the current state of the body, breathing, emotions, energy level, and mind; (b) Movement (*asana*)—10 minutes of gentle movements coordinated with the breath chosen to increase mental attention and energy flow (*prana*) to each area of the body; (c) Breathing Practice (*pranayama*)—3 minutes of inhaling cool air as if through a straw (modified *sitali*). *Sitali* was chosen because this practice enhances the qualities of moist and cool to balance the effects of chemotherapy, which is considered dry and hot; and (d) Relaxation Meditation (*dhyana*)—5 minutes of focus on letting go of tension in the body, mind, and breath with the goal of exploring the possibility of a peaceful place deep inside that is unchanging, regardless of the outer circumstances.

Facilitation of Home Practice. The last approximately 5 minutes of the session are used to review a handout describing the YST and to encourage participants to practice daily. To optimize adherence to home practice we incorporate brief coaching methods based on motivational interviewing as used to encourage yoga practice and walking in other

studies of cancer patients (Littman et al., 2012; Swenson, Nissen, & Henly, 2010). Specifically, the instructors ask open-ended questions to inquire about goals, specific times planned for home practice, and strategies to ensure home practice of the interventions. Confidence in the ability to practice at home is verbally assessed and reports of low confidence discussed. We ask participants to record their home practice daily, which may also increase adherence.

Measurement of Intervention Fidelity. The instructors document the degree to which they successfully followed the manual with a checklist after each in-person session (Table 1). In addition, we video record all YST sessions (using a small device pointed at the instructor that does not record the patient) and review a video from the first participant for each instructor and a random selection of 10% of the remaining recordings. The checklist is also used when observing videos to evaluate consistency of implementation. We consider a score of 30 or greater on this checklist indicative of high treatment fidelity (> 80%; range of scores 0 to 36; Borrelli et al., 2005).

Selection of Instructors. The PI and an expert yoga consultant (AW) trained instructors in implementation of the YST according to a treatment manual during an initial training. The instructors then each completed a written evaluation and were observed teaching the protocol to confirm their understanding. The PI and an expert yoga consultant also have ongoing monthly meetings with the instructors to support them in maintaining familiarity with the protocol and staying up-to-date with any modifications made. In addition, instructors are expected to have a personal yoga practice since it is traditionally believed that one cannot teach the experiential knowledge instructed through yoga unless one has experienced it.

Dealing with Modifications. Each session begins with an awareness meditation to increase participants' attention to and awareness of the state of their physical body and thus encourage their ability to ensure that they move with comfort and ease. We suggest that participants prioritize the breathing component of the YST during home practice if time is limited based on clinical experience and promising results of a pilot study (Dhruva et al., 2012). Any additional adaptations made to movements and adverse events related to the intervention that may occur in this novel setting are documented by the instructors and incorporated into the treatment manual. For example, for patients who have limited arm movement (e.g., IV, shoulder pain), we suggest that they keep the arm low and primarily move from below the elbow.

Introduction: *The more you practice these skills, like any other skill, the easier they will be for you to use when you will need them the most. Remember to be patient and gentle with yourself when practicing these skills. There is no 'right' way to do them. It is most important that you are comfortable and do your best to keep your attention in the present moment. If at any time your breathing is strained or you are uncomfortable, stop what you are doing and take a few easy breaths. Return to the practice as you feel comfortable.*

Skill 1: Awareness

Adjust how you are sitting using a footrest or pillow so that your feet rest firmly on the floor.

1a. Close your eyes (or fix your gaze toward a set spot if you prefer).

1b. Take a few comfortable deeper breaths.

1c. Place your hands on your abdomen. Check in with how your body is physically feeling just as it is, without changing anything.

1d. Place your hands on your chest. Notice any feelings you have at this moment and your energy level. Notice the subtle movements that happen in your body when you breathe.

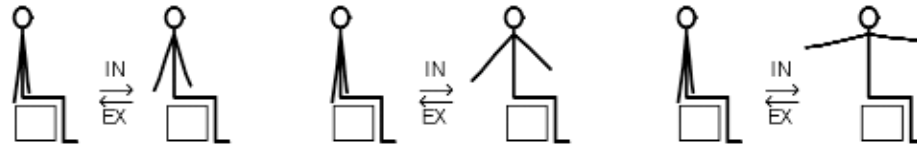
1e. Cup your hands over your eyes. Notice the activity of your mind (if it is active and busy, focused or still, or anywhere in between). Let it be just as it is.

Skill 2: Movement

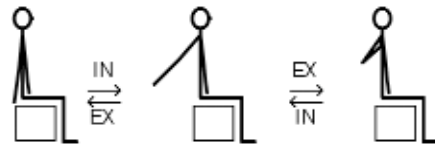
Keep your breathing relaxed and comfortable as you let your breath guide each movement. Your capacity may vary. The number of repetitions that feels right for you may vary by day. Take the time to pause and notice how you feel after each series of movements.

2a. Inhale, raise your arms from the sides and up a few inches. Exhale, lower your arms back down.

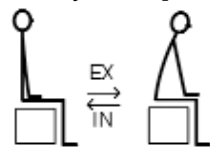
Repeat 3–6x, gradually raising your arms to a slightly higher level each time until you reach shoulder level (*samasthiti modified with slight lateral extension*).



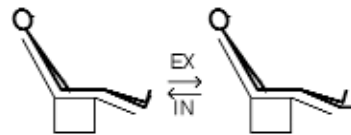
2b. Inhale, raise your arm out to the side, keeping it relaxed. Exhale, cross the same arm over your body to touch the opposite shoulder, turning your head slightly in the same direction. Inhale, bring your arm back out to the side. Exhale, lower the arm down (*samasthiti modified with twist*). Repeat 3–6x, alternating sides.



2c. Inhale, sit tall in the chair with the palms resting on the legs. Exhale, slide your hands down the thighs to the knees and gently bend forward. Inhale, return to an upright position while sliding your hands back to the original position (*uttanasana seated in a chair-modified*). Repeat 3–6x with a one-breath rest in between each one.



2d. Recline the chair and use the leg rest or lie down. Inhale, point your toes on one foot. Exhale, flex the same foot (*tadasana seated in a chair-modified*). Repeat 3–6x on each foot.



Skill 3: Breathing

3a. Inhale through your mouth as if through a straw, noticing the coolness of the air. Close your mouth and exhale smoothly through the nose (9–12x).

Skill 4: Relaxation

4a. Place your hands on your abdomen and bring your attention there as you breathe 3–6 breaths. Exhale the arms down, soften and relax the body.

4b. Place your hands on your chest and bring your attention there for 3–6 breaths. Exhale the arms down, letting go from the heart and breath, soften and relax.

4c. Cup your hands over your eyes and bring your attention there for 3–6 breaths. Exhale the arms down, soften and relax the mind.

4d. Explore the possibility of noticing a quiet place inside of you as you continue breathing comfortably.

4e. Notice any shifts in your body, energy level, or breathing.

4f. Take your time gently stretching as needed, open eyes, move into the day.

Figure 1. Yoga Skills Training home practice guide.*

*Sanskrit names for movements are provided for publication only and not given to participants.

| | Done Well (2) | Needs Improvement (1) | Not Done (0) | N/A |
|--|---------------|-----------------------|--------------|-----|
| Overall Relationship | | | | |
| 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 | | | | |
| Skill 1: Awareness | | | | |
| Guided awareness consistent with the protocol | | | | |
| Encouraged openness to the experience of the present moment | | | | |
| Skill 2: Movement | | | | |
| Instructed synchronized breath and movement | | | | |
| Allowed for individual to self-determine movement and modifications | | | | |
| Taught all movements (or appropriate modifications) in the protocol | | | | |
| 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 | | | | |

Table 1. Yoga Skills Training treatment fidelity checklist.

Discussion

This study focused on how the YST, which integrates yoga with conventional cancer treatment, may inform the design of future studies and clinical practice. A strong interdisciplinary team collaborated to address each domain recommended for developing a robust yoga protocol for an efficacy trial (style, delivery, components of the intervention, dose, specific class sequences, facilitation of home practice, measurement of intervention fidelity, selection of instructors, and dealing with modifications). We considered reducing participant burden, including instructions for ensuring safety, simplicity of the practice, and attention to treatment fidelity. We created a manual for this protocol that can be implemented by instructors from various therapeutic yoga

traditions to facilitate dissemination of the YST, if it is found to be efficacious.

Despite a growing number of yoga studies in the literature, few other publications have explained the rationale and development of a yoga practice for a specific patient population (Birdee et al., 2015; Sherman, 2012). It is important to understand this rationale because the selection of techniques may influence the therapeutic outcomes of a yoga practice. For example, another study of yoga for people diagnosed with colorectal cancer, who were primarily post-treatment, showed promising results for improving sleep disturbances and psychological distress. The yoga practices implemented in this prior study, which included theoretically invigorating practices such as *surya namaskar* and *kapalabhati pranayama*, were selected with the goal of

positively influencing the intestinal organs (Cramer et al., 2015). The current study, implemented during treatment, selected yoga practices with the goals of reducing fatigue, circadian disruption, and psychological distress. Invigorating practices would not be consistent with the yoga principles applied in the current study based on the specific therapeutic goals, current receipt of treatment, and location considered in developing the protocol. However, the framework applied in the current study might also consider applying invigorating practices following treatment when people are ready to resume maintenance of their health. Thus, the outcomes of implementing these protocols during treatment may differ. The nascent yoga research field has not yet examined if certain yoga techniques are more efficacious than others for specified populations or therapeutic targets.

Although it is a strength that the YST applied ancient Indian therapeutic principles, these were selected to be targeted to specific therapeutic goals and the treatment setting rather than individually tailored to each participant. Future research may investigate if individually tailoring of yoga practices results in stronger effects than a more general approach (Bossart, 2007). Another future direction is to evaluate how to make the YST optimally generalizable. For example, it would be interesting to determine if the YST could be further simplified if one component of yoga is the most active (e.g., just breathing), or if it is effective when implemented remotely such as via videoconferencing (Cramer et al., 2015; Danhauer et al., 2016). A possible limitation of the YST is that the in-person intervention time is not sufficient to see differences in the targeted outcomes. Future research could also investigate the optimal dose of instructor-facilitated YST sessions needed to see desired effects.

In conclusion, the design of the YST is novel because it shifts the more commonly studied paradigm of yoga taught to a group outside of the clinical setting to the individual during clinical care. In addition, the YST's emphasis on implementing a self-directed yoga practice (e.g., encourages patient to decide on appropriate number of repetitions during each practice, recommends daily home practice) also may enhance patients' engagement in their healing process. If future studies support its efficacy, the YST has the potential to reach and empower people receiving cancer treatment with self-regulation strategies that may continue to support them after completion of the intervention. Results of studying the YST could also apply to managing symptoms from other treatments.

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