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Short communication

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

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ABSTRACT

Objectives: Fatigue and other treatment-related symptoms (e.g., sleep disturbance) are critical targets for improving quality of life in patients undergoing chemotherapy. Yoga may reduce the burden of such symptoms. This study investigated the feasibility of conducting a randomized controlled study of a brief yoga intervention during chemotherapy for colorectal cancer.
Design: We randomized adults with colorectal cancer to a brief Yoga Skills Training (YST) or an attention control (AC; empathic attention and recorded education).
Setting: The interventions and assessments were implemented individually in the clinic while patients were in the chair receiving chemotherapy.
Interventions: Both interventions consisted of three sessions and recommended home practice.
Main outcome measures: The primary outcome was feasibility (accrual, retention, adherence, data collection). Self-reported outcomes (i.e., fatigue, sleep disturbance, quality of life) and inflammatory biomarkers were also described to inform future studies.
Results: Of 52 patients initially identified, 28 were approached, and 15 enrolled (age Mean = 57.5 years; 80% White; 60% Male). Reasons for declining participation were: not interested ($n = 6$), did not perceive a need ($n = 2$), and other ($n = 5$). Two participants were lost to follow-up in each group due to treatment changes. Thus, 75% of participants were retained in the YST and 71% in the AC arm. Participants retained in the study adhered to 97% of the in-person intervention sessions and completed all questionnaires.
Conclusions: This study demonstrated the feasibility of conducting a larger randomized controlled trial to assess YST among patients receiving chemotherapy for colorectal cancer. Data collected and challenges encountered will inform future research.

1. Introduction

Fatigue and sleep disturbance are symptoms often experienced by patients receiving chemotherapy for colorectal cancer (CRC). Based on the biobehavioral conceptual framework and research data, fatigue and sleep disturbance co-occur because of shared underlying mechanisms including inflammation.[1–3] Treating fatigue and sleep disturbances may improve the quality of life of patients during chemotherapy.[4] Yet, there are few behavioral interventions designed for CRC patients that aim to proactively improve fatigue and sleep disturbances during treatment.

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. Research supports that yoga is a promising intervention for reducing fatigue and sleep disturbances when implemented as group classes.[5–7] Preliminary evidence also supports that yoga reduces inflammation.[8] However, barriers limit patients' participation in group classes such as scheduling or feeling too sick to attend.[7,9] The proposed YST was designed to lessen these barriers by integrating yoga into the clinic during patients' visits for chemotherapy. We indicated a priori that a retention rate of 65% would support feasibility for a larger trial.

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2. Methods

2.1. Participants

We recruited adults at the Comprehensive Cancer Center of Wake Forest University who were within 2 weeks of initiating a new course of chemotherapy for CRC and willing and able to provide informed consent in English (June 2011–January 2013; ClinicalTrials.gov Identifier: NCT01590147). Ethical approval was obtained from this University's local institutional review board (IRB00016716). Enrolled participants were randomized using a computer generated table. Allocation was concealed until participants were assigned (1:1) to YST or an attention control (AC). Both interventions consisted of three fifteen-minute sessions delivered in-person once every two weeks while patients sat in a chair during chemotherapy treatments with recommended home practice.

2.2. Interventions

The three in-person YST sessions were designed to teach the same set of skills: (a) awareness meditation; (b) movement; (c) breathing and relaxation. Patients were given an audio recording of a 15-min YST session and asked to practice four times per week at home (A.1 Audio Recording of the YST by Lynn Felder, RYT). The YST was informed by the Principal Investigator's training in adapting yoga for people with cancer (http://www.yogaforpeoplewithcancer.com/) and to the clinical setting (http://www.urbanzen.org/uzit/). All movements were taught while patients were seated during chemotherapy.

The AC sessions included empathic attention to account for non-specific effects of the YST. An interventionist allowed patients to direct the conversation and provided supportive comments. Additionally, patients were given audio recordings of freely available podcasts related to coping with cancer similar in length to the suggested YST home practice time (Podcasts selected from: http://www.cancercare.org/connect_workshops#past_workshops).

2.3. Measures

Rates of accrual, adherence to the interventions (in person attendance, length of practice, home practice [yes/no]), completion of questionnaires, and satisfaction with the interventions (0 not at all to 4 very much) were documented to assess feasibility. Patient-reported outcomes and inflammation were also assessed during clinic visits for chemotherapy at baseline (week 0) and post-intervention (week 8).

2.3.1. Patient-reported outcomes

The Functional Assessment of Cancer Therapy-Fatigue subscale assessed fatigue,[10] the Patient-Reported Outcomes Measurement Information System—Sleep Disturbance Short Form 4a assessed sleep quality,[11] and The Functional Assessment of Cancer Therapy-Colorectal assessed quality of life.[12] Higher scores indicate lower fatigue, more sleep disturbance and a better quality of life.

2.3.2. Inflammation

Inflammatory cytokines (Interleukin 6, Interleukin 1 receptor agonist, soluble tumor necrosis factor receptor 1, tumor necrosis factor alpha, and C-reactive protein) were collected via plasma samples along with routine blood draws prior to chemotherapy.

Patients also provided demographic information and their medical charts were reviewed.

Table 1
Patient characteristics ($N = 15$).

Baseline characteristics	*N*
Sex	
Male	9
Female	6
Race	
White	12
Black	3
Other	0
Hispanic	0
Marital status	
Married or living with partner	13
Separated, divorced or widowed	2
Education	
High school education or less	2
Some post-high school	4
College/post-graduate degree	8
Primary diagnosis	
Colon cancer	10
Rectal cancer	5
Stage at diagnosis	
0–II	4
III	6
IV	5
Treatment for recurrent disease	
Yes	6
No	9
Performance status (ECOG)	
0	3
1	11
2	1
	Median (inter quartile range)
Age	61.0 (44.0–67.0)
Fatigue (possible range: 0–52.0)	43.0 (36.0–49.0)
Sleep quality (possible range: 0–16.0)	10.0 (5.0–12.0)
Quality of life (possible range: 0–136.0)	104.0 (87.5–112.0)
Interleukin 6	2.17 (1.47–3.90)
Interleukin 1 receptor agonist	309.5 (248.22–367.47)
Soluble tumor necrosis factor receptor 1	1124.10 (856.28–1529.20)
Tumor necrosis factor alpha	1.11 (0.81–1.82)
C-reactive protein	4.6 (2.2–7.0)

Note. Numbers may not add up to 15 due to missing data. ECOG = Eastern Cooperative Oncology Group.

2.4. Analyses

We conducted descriptive statistics to assess feasibility, patient-reported outcomes, and inflammation and Mann–Whitney *U* tests to compare groups.

3. Results

Of 52 patients identified, 28 were approached, and 15 (54%) enrolled (Fig. 1). Twenty-four of those initially identified could not be contacted. Participants had a median age of 61.0 years, and a majority were White and male (Table 1).

Two participants were lost to follow-up in each arm due to cancer treatment changes (73% retention). Intervention adherence to the three in-person sessions for both groups was 76% (of those consented: YST: 18 of 24 sessions; AC: 16 of 21 sessions) or 97% (of those retained in study). The median length of each intervention session was significantly different by arm with a median of 30.0 min (interquartile range [IQR] = 25.0–37.5) for the YST arm and 20.0 min (IQR = 20.0–27.5) for the AC arm ($p < 0.05$). A higher proportion of the participants indicated that they used the home practice recording in the past two weeks (yes/no) in the YST arm (week 4 [4 of 5]; week 8 [4 of 6]) as compared to the AC arm (week