




# Randomized Feasibility Study of Meditative Practices in Hospitalized Cancer Patients

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## Abstract

**Introduction:** There is limited research regarding the benefits of mind-body practices such as meditation in hospitalized patients with an active diagnosis of any cancer type. **Methods:** We conducted a prospective, randomized, clinical trial (NCT03445572) comparing 2 meditative practices—Isha Kriya (IK) and meditative slow breathing (MSB)—versus wait-list controls in hospitalized cancer patients. Our aim was to determine the feasibility of meditation practice in cancer inpatients. Feasibility was defined as recruitment of more than 50% of the eligible patients approached and at least 60% of the patients having meditated at least 4 days by day 7. Acceptability was assessed on day 7 as a positive response on at least 2 questions on the modified Global Symptom Evaluation (GSE) scale. **Results:** Forty patients (39% of the eligible patients approached) consented to participate in the study and were randomly assigned to the MSB (n = 13), IK (n = 14), or wait-list (n = 13) groups. Of the 27 patients assigned to receive MSB and IK meditations, day 7 data were available for 18 patients. Fifteen of the 18 patients meditated at least once in the first 7 days, and most (12/15) responded positively on the GSE. **Conclusion:** Both IK and MSB meditations were acceptable among the hospitalized cancer patients. Feasibility for enrollment and practice was likely not achieved due to limited uninterrupted time for daily meditation, high levels of morbidity in some participants, and limited research staff support. Shorter term outcomes should be explored in future meditation studies involving hospitalized cancer patients.

## Keywords

meditation, hospitalized cancer patients, inpatient, meditative slow breathing, Isha Kriya

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## Introduction

Hospitalized cancer patients experience high levels of anxiety caused by both physical symptoms and emotional distress due to fear of death, disability, and suffering.<sup>1</sup> In hospital settings, pharmacological management of anxiety often helps alleviate some of the psychological symptoms associated with cancer. In the outpatient setting, the use of mindfulness-based stress reduction is supported by a meta-analysis of 22 studies.<sup>2</sup> There is also evidence showing efficacy for other mind-body interventions, such as guided imagery, meditation, hypnosis, yoga, tai chi, and qi gong, in cancer patients.<sup>3–6</sup> In our experience, we have found

improvement in self-reported symptoms of cancer patients participating in an outpatient Tibetan meditation group program.<sup>7</sup> However, few studies have explored the use of

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mind-body interventions in hospitalized cancer patients. To date, limited data are available from only 1 such trial—published as an abstract—which explored the effects of mediation practice on newly hospitalized patients with acute leukemia.<sup>8</sup> There is a need for rigorous studies to learn more about the role of mind-body interventions provided to hospitalized cancer patients. We investigated the role of 2 interventions—meditative slow breathing (MSB) and Isha Kriya (IK) meditation, which are both simple to practice and have a short duration (15 minutes)—to assess the feasibility of these practices in hospitalized cancer patients. These 2 meditation techniques were specifically chosen to see if there was a difference in feasibility for our patients between a simple diaphragmatic breathing meditation technique that could be taught by anyone with a little training versus a 3-step meditation technique.

## Methods

This was a randomized clinical trial (NCT03445572) in hospitalized patients in a large comprehensive cancer center. The study was approved by the University of Texas MD Anderson Cancer Center Institutional Review Board, and all patients gave informed consent.

### Participants

Participants were recruited based on a review of inpatient service lists by study physicians and research staff and through referrals from attending physicians. Eligibility criteria included age 18 years or older, history of cancer, admission to hospital, ability to follow instructions, Eastern Cooperative Oncology Group status score of 3 or below, life expectancy greater than 2 months as assessed by the attending physician, and fluency in English. Patients dispositioned to transition to inpatient hospice or the palliative care unit were excluded, as were those with cognitive dysfunction, delirium, and Edmonton Symptom Assessment System (ESAS) scores greater than 4/10 for dyspnea; those requiring more than 2 L of oxygen and current meditation practitioners were also excluded.

### Procedures

Eligible patients were approached and, after consent was obtained, randomly assigned to either the IK, MSB, or wait-list groups. Figure 1 summarizes the CONSORT flow chart. Background information and ESAS financial-spiritual (ESAS-FS) questionnaires were collected. Patients were then introduced to the interventions by either a physician or a research staff member. Seven days after baseline, participants completed the ESAS-FS, modified Global Symptom Evaluation (GSE), and compliance questionnaires via phone call by a research assistant.

## Interventions

Patients were introduced to IK and MSB with the help of audio recordings, written instructions, and verbal instructions by the research staff. Patients were asked to engage in their meditation or breathing practice for 15 minutes twice daily. Wait-list patients were provided access to the audio link of both meditations with instructions via an email sent to them after study completion.

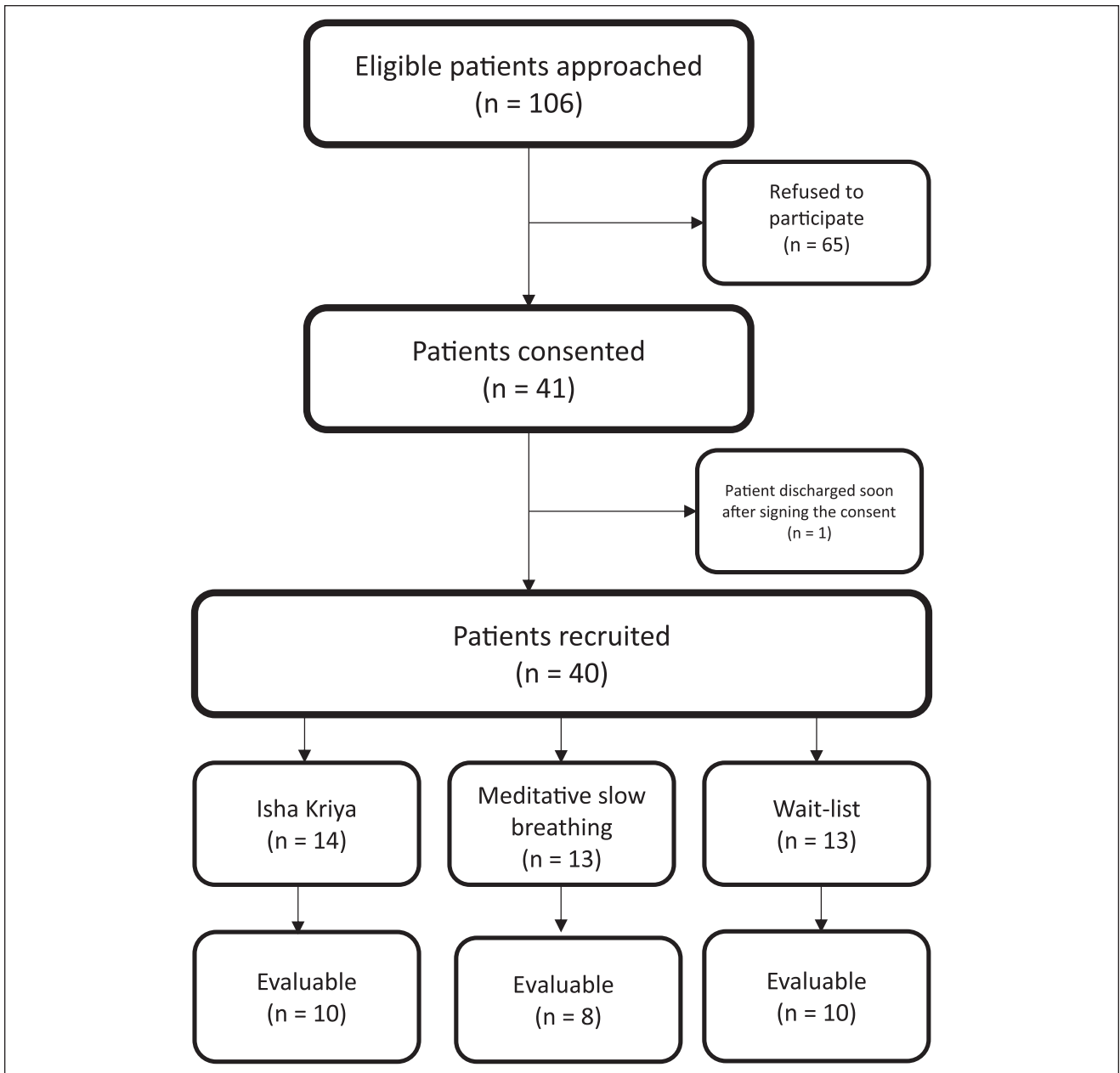
**Descriptions of IK and MSB.** Isha Kriya meditation involves a 3-step process over 15 minutes. Step 1 (9 minutes) involves a slow inhalation and exhalation. With each inhalation, participants are instructed to mentally say “I am not the body” and inhale for the whole duration of that thought. With each exhalation, participants are instructed to mentally say “I am not even the mind” and exhale for the entire length of that thought. Step 2 involves uttering a long “Ahh” sound (“Ahh” as in “father”) 7 times, exhaling fully into each sound. In step 3, patients sit for 5 minutes with eyes closed, with a slightly upturned face and a slight focus between the eyebrows.

In MSB, participants are introduced to a diaphragmatic breathing technique by instructing them to breathe slowly, extending their breath into their diaphragm, and that if their mind wanders to bring their attention back to their breath. The practice takes approximately 15 minutes.

## Measures

Feasibility was defined as the following: (1) recruitment of more than 50% of the eligible patients who were approached and (2) an adherence rate of at least 60%, that is, of the patients having engaged in mind-body practice on at least 4 days by day 7.

Acceptability was assessed on day 7 as a positive response on at least 2 questions on the modified GSE.<sup>9</sup> The GSE has 2 parts. In the first part, patients are asked whether they report their symptom as worse, about the same, or better after starting the treatment. The second part consists of 5 questions that evaluate whether participating in the study was worthwhile, whether they would participate in the study if they had to do over again, whether they would refer the study to others, and whether it had a positive or negative impact on quality of life. The answers consist of yes, no, and uncertain. These questions helped determine if participating in the study was burdensome or beneficial to the patients. Additionally, we asked 5 questions regarding their perception of meditation such as feeling more peaceful, hopeful, relaxed, in more control of life after meditation, and if they would continue to participate in the study. The ESAS-FS scores were collected at baseline and on day 7. The ESAS-FS is a 12-item symptom tool that asks the participant to rate the severity of their symptoms in the prior 24



**Figure 1.** Flow chart of study analysis.

hours on a scale from 0 to 10, where 10 is the worst possible expression of each symptom. The ESAS-FS is based on the original 9-item ESAS tool, which has been widely used for symptom assessment in the cancer patient population,<sup>10</sup> with 3 additional questions to assess sleep, financial distress, and spiritual pain. The total symptom distress score is a combination of ESAS individual symptom scores including all 12 items.

Demographic information and clinical characteristics were obtained at the time of consent.

### Statistical Analysis

The primary outcome of feasibility was defined by both recruitment and adherence rates. The secondary outcomes were acceptability of the study, measured by the modified GSE scores of the participants in each intervention group, and effect of the intervention, measured by pre- and post-test intervention ESAS scores.

For other information, data were summarized using standard descriptive statistics such as mean, standard deviation,

**Table 1.** Demographic and Clinical Characteristics.

Characteristic	All (N = 40)	IK (N = 14)	MSB (N = 13)	WL (N = 13)	P
Median age (min-max), years	40 (25-79)	54 (29-79)	62 (28-71)	54 (25-71)	.76
Gender, n (%)					.31
Female	24 (60)	6 (42.9)	9 (69.2)	9 (69.2)	
Male	16 (40)	8 (57.1)	4 (30.8)	4 (30.8)	
Race, n (%)					.65
Caucasian	30 (75)	11 (78.6)	8 (61.5)	11 (84.6)	
African American	5 (12.5)	2 (14.3)	1 (7.7)	2 (15.4)	
Asian	3 (7.5)	1 (7.1)	2 (15.4)	0 (0)	
Other	2 (5)	0 (0)	2 (15.4)	0 (0)	
Primary cancer diagnosis, n (%)					
Brain and CNS	2 (5)	0 (0)	1 (7.7)	1 (7.7)	
Breast	2 (5)	1 (7.1)	0 (0)	1 (7.7)	
GI	12 (30)	3 (21.4)	4 (30.8)	5 (38.5)	
GU	3 (7.5)	1 (7.1)	1 (7.7)	1 (7.7)	
GYN	2 (5)	2 (14.3)	0 (0)	0 (0)	
Head and neck	2 (5)	1 (7.1)	1 (7.7)	0 (0)	
Leukemia	2 (5)	1 (7.1)	1 (7.7)	0 (0)	
Lung	5 (12.5)	0 (0)	1 (7.7)	4 (30.8)	
Lymphoma	4 (10)	2 (14.3)	2 (15.4)	0 (0)	
Myeloma	2 (5)	0 (0)	1 (7.7)	1 (7.7)	
Sarcoma	4 (10)	3 (21.4)	1 (7.7)	0 (0)	

Abbreviations: CNS, central nervous system; GI, gastrointestinal; GU, genitourinary; GYN, gynecologic; IK, Isha Kriya meditation; MSB, meditative slow breathing; WL, wait-list.

median, and range for continuous variables, and frequency and proportion for categorical variables. Association between categorical variables was examined by the  $\chi^2$  test or Fisher's exact test when appropriate. The Wilcoxon signed rank test was used to examine the change on ESAS from baseline to day 7 within each intervention group. The Kruskal-Wallis test was used to examine differences in baseline ESAS scores as well as changes of ESAS scores from baseline to day 7 among intervention groups.

## Results

One hundred six eligible patients were approached for the study (Figure 1), of whom 41 signed consent forms, for a final recruitment rate of 39%. For the first 31 patients who chose not to participate, we did not ask about reasons for nonparticipation. For the next 34 patients who declined, 17 (50%) reported that they were overwhelmed with their schedule, which did not permit time for meditation or research study participation. Other reasons for nonparticipation were pain and symptom distress (8 of 34, 23%) and no reason (8 of 34). One patient reported having tried meditation in the past and found it unhelpful.

Of the 41 patients who provided consent, 1 was discharged soon after signing the consent and was not evaluable. Of the remaining 40 patients, 14 were randomly

assigned to the IK group, 13 to the MSB group, and 13 to the wait-list group. Patient characteristics are summarized in Table 1. Majority of enrolled patients (34 out of 41) had advanced cancer. Because of the small sample size, *P* values were not calculated for the cancer types. The median length of stay from the day of study enrollment to the day of discharge was 3 days (with interquartile range 1-6.50).

Of the 27 patients assigned to mind-body groups, day 7 data were available for 18 patients. Patients in the IK group meditated for a median of 1.5 (range = 0-7) sessions per week, and those in the MSB group engaged in the breathing practice for a median of 4 (range = 0-14) sessions per week. Fifteen patients in the mind-body groups engaged in their practice at least 1 time in the first 7 days (8 in the IK group and 7 in the MSB group). Only 1 patient (7%) in the IK group and 4 (31%) in the MSB group were adherent to their practice schedule 4 times in 7 days. For the wait-list group, only ESAS-FS data were collected. Only 10 of the 13 patients in the wait-list group were evaluable.

Table 2 summarizes the patients' overall perception or acceptance of the study. Of the 18 evaluable patients in the mind-body groups, who were asked the question, "Was it worthwhile to participate in the study?" 12 answered "Yes," 6 answered "Uncertain," and none answered "No." Eight (2/10 IK and 6/8 MSB) reported improvement in quality of life, others answered "Uncertain," and none answered "No."

**Table 2.** Responses to the Modified Global Symptom Evaluation and Meditation Perception Questionnaire on Day 7.

Questions	Patient Responses	N = 18, n (%)	Intervention Type		P
			IK, n = 10, n (%)	MSB, n = 8, n (%)	
After starting your new treatment, how are your symptoms?	About the same	14 (78)	9 (90)	5 (63)	.27
	Better	4 (22)	1 (10)	3 (37)	
Was it worthwhile to participate in this research study?	<b>Yes</b>	<b>12 (67)</b>	<b>4 (40)</b>	<b>8 (100)</b>	<b>.01</b>
	Uncertain	6 (33)	6 (60)	0 (0)	
	No	0 (0)	0 (0)	0 (0)	
If you had to do it over again, would you participate in this research study?	Yes	13 (72)	6 (60)	7 (88)	.31
	Uncertain	5 (28)	4 (40)	1 (12)	
	No	0 (0)	0 (0)	0 (0)	
Would you recommend participating in this research study to others? <sup>a</sup>	Yes	14 (82)	6 (67)	8 (100)	.21
	Uncertain	3 (18)	3 (33)	0 (0)	
	No	0 (0)	0 (0)	0 (0)	
Did your quality of life get better by participating in this research study?	<b>Yes</b>	<b>8 (44)</b>	<b>2 (20)</b>	<b>6 (75)</b>	<b>.05</b>
	Uncertain	10 (56)	8 (80)	2 (25)	
	No	0 (0)	0 (0)	0 (0)	
Did your quality of life get worse by participating in this research study?	Yes	0 (0)	0 (0)	0 (0)	<b>.04</b>
	Uncertain	5 (28)	5 (50)	0 (0)	
	<b>No</b>	<b>13 (72)</b>	<b>5 (50)</b>	<b>8 (100)</b>	
I will continue with participating in the study	Strongly Agree/agree	16 (88)	8 (80)	8 (100)	1.0
	Neutral	1 (6)	1 (10)	0 (0)	
	Disagree	1 (6)	1 (10)	0 (0)	
I felt more at peace after meditation.	Strongly Agree/agree	13 (72)	6 (60)	7 (88)	.50
	Neutral	5 (28)	4 (40)	1 (12)	
I felt more relaxed after meditation.	Strongly Agree/agree	13 (72)	6 (60)	7 (88)	.14
	Neutral	4 (22)	4 (40)	0 (0)	
	Disagree	1 (6)	0 (0)	1 (12)	
I feel more hopeful after meditation.	Strongly Agree/agree	9 (50)	4 (40)	5 (62)	.45
	Neutral	9 (50)	6 (60)	3 (38)	
I feel like I am more in control of my life after meditation.	Strongly Agree/agree	7 (39)	3 (30)	4 (50)	.42
	Neutral	11 (61)	7 (70)	4 (50)	

Abbreviations: IK, Isha Kriya meditation; MSB, meditative slow breathing.

<sup>a</sup>Total N = 17; IK n = 9.

Bold values represent positive responses which are of statistical significance.

These results indicate a favorable trend toward MSB, with a *P* value of .0536. None of the participants reported worsening in quality of life as a result of participating in the study. Patients also responded mostly positive or neutral when asked if they felt more peaceful, hopeful, relaxed, in more control of life after meditation.

On the first part of the GSE, 14 of 18 patients reported that their symptoms were about the same and 4 of 18 reported that their symptoms improved, when asked about the effects of the meditation intervention. There were no statistical differences in individual ESAS variable scores or symptom distress scores among the 3 intervention groups measured at baseline or day 7. Also, changes in ESAS variable scores or symptom distress scores from baseline to day 7 were not significantly different among the 3 groups. In the MSB group, the sleep score in ESAS decreased an average 2.4 points from baseline to day 7,

which indicated a marginally significant improvement in sleep (*P* = .0625), with an effect size of 0.97.

## Discussion

Our study suggests that the 2 meditation interventions, IK and MSB, were not feasible in hospitalized cancer patients due to the low recruitment and adherence rates. The results were surprising because of the presumed low burden of the interventions and the known benefits associated with mind-body practices. In addition, the average length of stay for our institution's hospitalist service (largest referral source for our study) is 5 days.<sup>11</sup> The median number of days patients stayed hospitalized after study enrollment was 3 days (interquartile range = 1-6.50), and majority of enrolled patients had advanced cancer. During this period, the

frequency of diagnostic and therapeutic interventions, along with frequent visits by multidisciplinary teams, may have made it difficult to participate in a study that required time to be set aside for mind-body practice twice daily. Frequent interruptions may in part explain the lower-than-expected adherence rate. Study enrollment may have been higher if patients had been approached during evening hours when interventions and visits by medical teams are likely less frequent. Determining the most appropriate time to approach patients for recruitment and introduction to meditation will need to be explored in future studies.

It is encouraging to note that more than half of the patients who were enrolled in the mind-body arms practiced their assigned mind-body intervention at least 1 time. Among the 2 mind-body interventions, our findings suggest that MSB had better overall adherence in hospitalized cancer patients. However, these findings are preliminary owing to the very low number of respondents. As a 1-step method, MSB may have been perceived as easier to perform than 3-step IK, contributing to our observation of overall better adherence. The complexity of meditation practice may have a role in adherence, which must be considered when designing future studies. For example, one could consider focusing on less complex meditation techniques in the inpatient setting and more complex, multistep meditation practices such as IK in the outpatient setting.

There was a trend toward improvement in sleep in patients participating in MSB. Future studies of meditation in hospitalized cancer patients should also include an assessment of the effects of meditation on cancer-related symptoms such as insomnia and fatigue. Such assessments should include the use of validated patient-reported outcome measures such as the ESAS.

Our study was a small-scale pilot study of the feasibility of conducting meditation for cancer patients in an inpatient setting. There are several limitations to note. Approaching cancer patients in an inpatient setting is likely more complicated than in an outpatient environment. Our study introduced meditation practices via audio recordings. An in-person teaching method by the research team might have helped with adherence. We decided to measure the primary outcome on day 7 assuming that patients may be able to get discharged, continue the meditation practice at home, and report the results from home. However, hospitalized cancer patients usually have low performance status and high symptom burden, which may contribute to decreased adherence after discharge. They may also have multiple follow-up appointments after discharge, which may have contributed to our high rate of patients lost to follow-up on day 7. High attrition was also seen in a meditation study in patients with acute leukemia.<sup>12</sup> The trial enrolled 90 participants, but only 42 participants remained in the trial throughout the 6-month follow-up period. A shorter term outcome

for evaluating meditation practice, such as day 5 or day of discharge rather than day 7 of hospitalization, may be better suited to a study of hospitalized patients. Last, follow-up with the wait-list patients after they were sent the link to the meditation audios would have given us information on their motivation to start meditation practices and adherence in this setting.

## Conclusion

Our randomized controlled trial of MSB and IK mind-body practices in hospitalized cancer patients was not feasible due to low recruitment and adherence. However, both MSB and IK were acceptable mind-body practices for cancer inpatients. Despite the unexpected low rates of recruitment and adherence, this pilot study can help in the design of future randomized controlled trials. We recommend adding shorter term outcomes for future meditation studies in cancer inpatients. It is important to take into account disease burden, care coordination, and multiple appointments after discharge as factors potentially contributing to decreased adherence with a mind-body intervention such as meditation.

## Declaration of Conflicting Interests

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