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Corresponding author: Youngmee Kim; Email: ykim@miami.edu

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Dyadic sleep intervention for adult patients with cancer and their sleep-partner caregivers: A feasibility study

Youngmee Kim, PH.D.¹ , Amanda Ting, PH.D.² , Thomas C. Tsai, M.S.¹ and Charles S. Carver, PH.D.¹

¹Department of Psychology, University of Miami, Coral Gables, FL, USA and ²Department of Psychology, Palo Alto VA, Palo Alto, CA, USA

Abstract

Objectives. Sleep disturbances are common among adult patients with cancer and their caregivers. To our knowledge, no sleep intervention to date has been designed to be provided to both patients with cancer and their caregivers simultaneously. This single-arm study aimed to pilot test the feasibility and acceptability, and to illustrate the preliminary efficacy on sleep efficiency of the newly developed dyadic sleep intervention, My Sleep Our Sleep (MSOS: NCT04712604).

Methods. Adult patients who were newly diagnosed with a gastrointestinal (GI) cancer and their sleep-partner caregivers (n = 20 persons: 10 dyads, 64 years old, 60% female patients, 20% Hispanic, 28 years relationship duration), both of whom had at least mild levels of sleep disturbance (Pittsburgh Sleep Quality Index [PSQI] \geq 5) participated in this study. MSOS intervention consists of four 1-hour weekly sessions delivered using Zoom to the patient–caregiver dyad together.

Results. We were able to enroll 92.9% of the eligible and screened patient–caregiver dyads within 4 months. Participants reported high satisfaction in 8 domains (average 4.76 on a 1–5 rating). All participants agreed that the number of sessions, interval (weekly), and delivery mode (Zoom) were optimal. Participants also preferred attending the intervention with their partners. Both patients and caregivers showed improvement in sleep efficiency after completing the MSOS intervention: Cohen's d = 1.04 and 1.47, respectively.

Significance of results. Results support the feasibility and acceptability, as well as provide the preliminary efficacy of MSOS for adult patients with GI cancer and their sleep-partner caregivers. Findings suggest the need for more rigorous controlled trial designs for further efficacy testing of MSOS intervention.

Introduction

Sleep disturbance – defined as difficulty falling asleep, difficulty staying asleep, and frequent and prolonged nighttime awakenings (Berger 2009; National Institutes of Health 2011) – is highly prevalent (33%–40%) among adult patients with cancer across all cancer sites/types and cancer trajectory, notably more so than a 15%–20% seen in the general population (Berger 2009; Harris et al. 2014; Lee et al. 2004). Sleep disturbance in patients with cancer has further been associated with poor quality of life, circadian dysregulation, development of major diseases, poor cancer prognosis and recurrence, and mortality (Berger 2009; Cappuccio et al. 2010; Cohen-Mansfield and Perach 2012; Gangwisch et al. 2007; Irwin 2015; Knutson 2010; Kudlow et al. 2013; Phillips et al. 2017; Stevens et al. 2014; Troxel 2010; Watanabe et al. 2010).

Sleep disturbance is also highly prevalent among family members who provide support to their relatives with cancer (hereafter caregivers). For example, 36%–95% of family caregivers report sleep disturbance by self-report or objective assessment, and 4 in 10 report at least 1 sleep problem (Dhruva et al. 2012; Kotronoulas et al. 2013). These rates and severity are higher than those in caregivers of patients with other diseases, such as AIDS and dementia (Kochar et al. 2007; Medic et al. 2017; Mills et al. 2009; Spira et al. 2010), chronic knee osteoarthritis (Martire et al. 2013), Parkinson's disease (Happe et al. 2002; Pal et al. 2004), and stroke (Rittman et al. 2009), as well as those seen among patients with dementia (Flaskerud et al. 2000) and in demographically similar healthy adults (Mills et al. 2009). Caregivers' sleep disturbance degrades the quality of care they provide for the patients, decreases their own quality of life (Irwin 2015; Katz and McHorney 2002), and increases their own risk for various morbidities (Berger 2009; Cappuccio et al. 2010; Cohen-Mansfield and Perach 2012; Gangwisch et al. 2007; Irwin 2015; Knutson 2010; Kudlow et al. 2013; Phillips et al. 2017; Stevens et al. 2014; Troxel 2010; Watanabe et al. 2010).



The empirical evidence underscores the need for sleep interventions for patients with cancer and their family caregivers. Cognitive Behavioral Therapy for Insomnia (CBT-I) is a gold standard psychobehavioral intervention endorsed by the American Academy of Sleep Medicine for treating sleep disturbance/insomnia in the general population (Bootzin and Epstein 2011). CBT-I has since been modified to address the unique experiences of sleep disturbance in patients with cancer. For example, decreasing the number of CBT-I sessions for patients with cancer from 6-8 to 2-4 or administering the intervention using a stepped care model has been found to be efficacious (Savard et al. 2021; Zhou et al. 2020). Modified CBT-I for patients with cancer also de-emphasizes sleep restriction, reflecting common characteristics of sleep disturbance seen in adult patients with cancer (Johnson et al. 2016; Palesh et al. 2012, 2020; Savard et al. 2021). The common characteristics of poor sleep between patients with insomnia and patients with cancer, however, have been kept in modified CBT-Is for patients with cancer. The efficacy of modified CBT-I for patients with cancer in comparison with standard CBT-I has been cumulating in recent years (Johnson et al. 2016; Palesh et al. 2012, 2020; Savard et al. 2021).

Although the efficacy of the modified CBT-I for adult patients with cancer has recently begun cumulating (Johnson et al. 2016; Ma et al. 2021; Savard et al. 2021), only 1 intervention study, to date, has targeted improving sleep quality for caregivers of adult patients with cancer. This intervention included stimulus control, relaxation, cognitive therapy, and sleep hygiene elements and was found to be effective in improving sleep quality and decreasing depressive symptoms in caregivers (Carter 2006).

The social support literature suggests possible broad pathways from social support to better sleep. Social support protects against social isolation (Cacioppo et al. 2002; Pressman et al. 2005), attenuates stress responses (Morin et al. 2003; Troxel et al. 2007), provides a sense of belonging and emotional support (Gunn and Eberhardt 2019; Troxel et al. 2007), encourages healthy sleep behaviors, and entrains circadian rhythms (Monk et al. 2004). This line of thought suggests that couples' relationship function and their sleep reciprocally affect each other via their shared psychobiological processes (Irwin 2015). This conceptual framework provides a basis for dyadic investigation of sleep and sleep disturbance, which thus far has been applied only to healthy young-to-middle-aged adults (Gunn et al. 2017, 2021; Hasler and Troxel 2010; Kane et al. 2014; Segrin and Burke 2015; Troxel et al. 2007; Walters et al. 2020a), patients with insomnia (Mellor et al. 2019; Walters et al. 2020b), or parents with newborn babies (Feinberg et al. 2016; Sadeh et al. 2011), whose sources of sleep disturbance exclusively differ from those in cancer patient-caregiver dyads.

Patients with cancer are at risk for sleep disturbance due in part to cancer-related distress and treatment-related cytokine-induced inflammation (Liu et al. 2012). Some sleep-partner caregivers are also at risk by sharing the cancer-related stress and possibly engaging in regulatory processes that compromise not only their sleep quality but also the sleep partner's. On the other hand, 1 member in the dyad may serve as an anchor to protect both themselves and their partners against disturbed sleep by engaging in sleep regulatory processes that enhance not only their sleep quality but also the sleep partner's. Intervening on both sleep partners who serve as each other's comrade to make desirable changes, as opposed to intervening on a sole member in the dyad or each member individually, is an optimal strategy that is highly likely to yield larger impact on improving sleep and general health. It would be particularly the case among at-risk dyads of adult patients with cancer and their sleep partners. Thus, this study pilot tested the feasibility and acceptability, and demonstrated the preliminary efficacy of a newly developed dyadic sleep intervention for adult patients with cancer and their sleep-partner caregivers.

Methods

Participants

Couples consisting of patients with gastrointestinal (GI) cancer and their sleep-partner family caregiver were recruited at the University of Miami Sylvester Comprehensive Cancer Center clinics in South Florida. Eligibility criteria for patients included having a diagnosis of stage I to IV of a GI cancer (anus, colon, esophagus, gallbladder, large and small intestine, liver, pancreas, rectum, stomach, and other biliary or digestive organs) in the past 5 years at the time of enrollment and having a consistent sleep partner. Eligibility criterion for *caregivers* was being a sleep partner of the patient. Additional eligibility criteria for both patients and caregivers included having at least mild-to-moderate sleep disturbance (PSQI \geq 5; Buysse et al. 1989), willing to change suboptimal sleep habits, 18 years or older, able to speak and read English, and if applicable, >4 weeks after surgery prior to enrollment because surgery affects sleep. Exclusion criteria for both patients and caregivers included having had a diagnosis of psychosis, major depressive disorder, or bipolar disorder that was not being treated; substance or alcohol dependency, or active suicidality in the past year; have narcolepsy or restless leg syndrome; have an extreme chronotype, or do shift work such that there is no overlap in sleep schedule between patients and caregivers; plan trans-meridian travel during the period of data collection; and have hearing or visual impairment, dementia, or cognitive dysfunction.

Procedure

This study was approved by the University of Miami Institutional Review Boards. The protocol was registered with ClinicalTrials.gov (NCT04712604). As shown in Fig. 1, potentially eligible patients were identified by their diagnosis of a GI cancer and diagnosis date, using medical records at oncology clinics. Pre-eligible patients by the medical records were contacted and screened for eligibility to participate in the study. Participants who were eligible and agreed to participated in the study signed an informed consent form individually on a web-based REDCap application before providing any study data. Participants (patient and caregiver as a unit) participated in the study together; the data were collected simultaneously from both members of the dyad individually. Data were collected from March to July 2021.

Participants completed the pre-intervention assessment (T1), which included a 1-time questionnaire on a web-based Qualtrics survey application and a 7-day daily sleep measure on a web-based REDCap application. This study employed a single-arm study design. The intervention was delivered via a HIPAA-compliant Zoom video platform once a week to both patients and caregivers together for 4 weeks. Participants completed an intervention satisfaction survey immediately after the end of each session on a web-based Qualtrics survey application. Project coordinator managed the intervention satisfaction survey, so that participants were informed that the interventionist was blind to the survey data. Seven days after the final intervention session, participants completed the post-intervention assessment (T2) that included another 1-time questionnaire and another 7-day daily sleep measure on a web-based Qualtrics survey and REDCap application, respectively



Figure 1. MSOS enrollment flowchart.

(Kim et al. 2023). Participating dyads were provided a US\$20 incentive at the end of the study.

Measures

Daily sleep assessment

Participants completed a sleep diary each morning for 7 consecutive days using a modified Consensus Sleep Diary (Carney et al. 2012). The sleep diary includes entries for bedtime, sleep onset, number and duration of awakenings, sleep offset, out-of-bed time, naps, physical activity, and caffeine or alcohol intake, from which sleep hygiene behaviors were assessed. The sleep diary also includes questions about the sleep environment and behaviors in the bed, from which stimulus control behaviors were assessed. The sleep diary data collected during the pre-intervention block served to tailor the behavioral module of the dyadic sleep intervention. Sleep efficiency derived from the sleep diary assessments at pre- and post-intervention blocks served as the primary outcome.

Questionnaire included 3 types of measures and demographic questions. One set of measure was to assess overall sleep disturbance. Subjective sleep quality and general sleep disturbance was assessed using the 19-item Pittsburgh Sleep Quality Index (PSQI)

at T1 and T2 (Buysse et al. 1989). Higher scores of overall sleep disturbance (range 0–21) and subjective sleep quality (range 0–3) indicate greater sleep disturbance and poorer sleep quality. The overall sleep disturbance score served as an eligibility criterion. Subjective sleep quality score served as a secondary outcome.

A second measure assessed dysfunctional beliefs and attitudes about sleep at T1 and T2 using the 16-item Dysfunctional Beliefs and Attitudes about Sleep (DBAS; Morin et al. 2007) on an 11-point Likert-type format (0: strongly disagree, 10: strongly agree). The total and subscale (5-item consequence, 6-item worry, 2-item sleep expectations, and 3-item sleep medication) scores of the DBAS served to tailor the cognition module of the dyadic sleep intervention for individual participants. The DBAS total and subscale scores had acceptable internal consistency in the present study at T1 (.76 < α < .84 for patients and .65 < α < .86 for caregivers), with the exception of the expectations subscale ($\alpha = .42$, *r* between the 2 items = .26, p = .46 for patients; and $\alpha = .35$, r between the 2 items = .27, p = .44 for caregivers) and the medications subscale ($\alpha = .51$ for patients; and $\alpha = .50$ for caregivers). The DBAS total and subscale scores remained to have acceptable internal consistency in the present study at T2 (.77 $< \alpha < .87$ for patients and .58 (consequences) $< \alpha < .91$ for caregivers), again with the exception of the expectations subscale ($\alpha = .40$, r between the 2 items = .251, p = .48 for patients; and $\alpha = .53$, r between the 2 items = .40,

p = .26 for caregivers) and the medications subscale ($\alpha = .50$ for patients; and $\alpha = .52$ for caregivers).

A third measure was used to assess relationship quality at T1, which included the 14-item Measures of Attachment Quality (MAQ; Carver 1997) that assesses 3 adult attachment orientations: security, anxiety, and avoidance; and the 4-item Dyadic Adjustment Scale (DAS; Sabourin et al. 2005) that assesses relationship satisfaction. The 3 attachment orientation and relationship satisfaction composite scores had overall acceptable internal consistency in the present study (.67 < α < .93 for patients and .56 (anxiety) < α < .89 for caregivers). The MAQ and DAS scores served to tailor the relationship module of the dyadic sleep intervention. Finally, demographic questions included self-reported age, gender, education, income, race/ethnicity, and relationship duration.

Dyadic sleep intervention

My Sleep Our Sleep (MSOS: NCT04712604) consists of four 1-hour weekly sessions that were delivered via HIPAA-compliant Zoom video platform. The MSOS intervention was developed by (a) adapting the behavioral (sleep hygiene and stimulus control) and cognitive (monitoring and managing maladaptive thoughts about sleep) modules of CBT-I, for adult patients with cancer by relaxing sleep restriction; (b) accommodating the symptoms and experience of cancer and treatment that are attributable to their disturbed sleep; (c) targeting both sleep partners; and (d) educating sleep partners about relationship-enhancing communication and working together effectively to sleep well. In addition, the MSOS intervention acknowledged the significant close relationship nature of sleep and cancer experience. These principles adapting CBT-I for patients with cancer and their sleep-partner caregivers are fundamental and are applicable to each of the 4 intervention sessions. The intervention can be delivered by a master's level interventionist who has been trained in psychology, behavioral medicine, or related field via HIPAA-compliant video platform to the patient and caregiver simultaneously.

The session content includes 4 modules – sleep behavior, sleep cognition, sleep in relationship, and relapse prevention – which are presented in Table 1. Session 1 introduces the intervention and focuses on providing psychoeducation about the 2-process model of sleep, sleep hygiene, and stimulus control. Each partner's current habits of sleep hygiene and stimulus control are reviewed, and goals for relevant behavioral changes are collaboratively discussed and negotiated.

During Session 2, progress with behavior changes for sleep hygiene and stimulus control is reviewed and barriers adhering to behavior changes are addressed. Session 2 also focuses on providing psychoeducation on the connection between thoughts, emotions, and behaviors, as well as identifying and discussing automatic thoughts that are cancer-related and sleep-specific that contribute to each partner's sleep disturbance. In addition to practicing behavior changes for sleep hygiene and stimulus control, partners practice together monitoring their automatic thoughts that contribute to their sleep disturbance.

Session 3 focuses on providing psychoeducation on challenging unhelpful automatic thoughts, which involves identifying the unhelpful thinking style and reframing the automatic thought to produce a more balanced alternative thought. In addition to practicing behavior changes for sleep hygiene and stimulus control, and monitoring their maladaptive thoughts, partners practice together challenging their automatic thoughts that contribute to their sleep disturbance.

Table 1. MSOS intervention session content

Session	Content	
#1: Sleep Behavior	MSOS introduction	
	Review individuals' sleep habits	
	Psychoeducation on sleep behaviors : 2-process model of sleep, sleep hygiene, sleep control	
	Setting goals for sleep behavior changes	
	Homework assignment – sleep behaviors	
#2: Sleep Cognition	Review homework of Session 1	
	Psychoeducation on sleep cognition : identify noisy thoughts, active mind, automatic negative thoughts, worries, with focus on cancer-related cognition	
	Setting goals for monitoring sleep cognition	
	Homework assignment – sleep behaviors & monitoring sleep cognition	
#3: Sleep Cognition	Review homework of Session 2	
	Psychoeducation on sleep cognition : challenging and reframing noisy thoughts, active mind, auto- matic negative thoughts, worries, with focus on cancer-related cognition	
	Setting goals for reframing sleep cognition	
	Homework assignment – sleep behaviors & monitoring and reframing sleep cognition	
#4: Sleep in Relationship	Review homework of Session 3	
	-Psychoeducation on sleep in relationship : effective communication; behaviors, thoughts, and emotions in the cancer journey	
	-Psychoeducation on good sleep maintenance and relapse prevention	
	Setting goals for effective communication, good sleep maintenance, and relapse prevention	
	Homework assignment – sleep behaviors, monitoring and reframing sleep cognition, effec- tive communication with partner, good sleep maintenance	

Session 4 focuses on discussing aspects of the close relationship and shared cancer experiences that also contribute to the couples' sleep problems. Psychoeducation on effective communication, including self-disclosure, partner responsiveness, and relationship engagement is provided. Behaviors, thoughts, and emotions throughout the cancer journey, such as those related to fear of recurrence, cancer prognosis, caregiving stress, etc., are collaboratively discussed. Psychoeducation on maintaining changed healthy sleep habits and relapse prevention collaboratively is also discussed.

The sequence and duration of the MSOS intervention session contents can be tailored for individual dyads based on information obtained from the pre-intervention questionnaire and the daily sleep measures. For example, for a dyad whose member scores less than 13 on the 4-item Dyadic Adjustment Scale (ranges 0–21: \leq 13 indicate distressed relationship; Sabourin et al. 2005), the topic of sleep in the relationship that is the content of Session 4 can

Table 2. Sample descriptives (n = 10 patient-caregiver dyads)

	T1		Т2			
	Patients	Caregivers	$t ext{ or } \chi^2$	Patients	Caregivers	$t \text{ or } \chi^2$
Age	64.53 (9.89)	63.51 (12.42)	0.88			
Gender (female)	60%	40%	10.0**			
Education			21.33			
High school/GED	20%	10%				
College	50%	80%				
Graduate degree	30%	10%				
Household Income (US\$)						
0-\$70,000	0%					
70,000–119,999	30%					
120,000–159,999	20%					
160,000–209,999	20%					
>300,000	10%					
Prefer not to answer	20%					
Ethnicity			4.53			
Hispanic	20%	10%				
Non-Hispanic White	80%	90%				
Employment			2.74			
Paid full-time employed	30%	20%				
Paid part-time employed	0%	10%				
On leave with pay	10%	0%				
Retired	50%	60%				
Unemployed	10%	10%				
Cancer Type	Anus (1), Appendix (1),	Colon (2),	Esophagus (1),	Jejunum (1),	Liver (1),	Pancreas (3)
On treatment	70%	-		80%		-
Relationship duration	28.04 (17.07) years					
Dysfunctional belief on sleep						
Consequences	4.08 (2.51)	2.46 (1.64)	2.08 (p = .067)	3.92 (2.21)	3.20 (1.48)	0.74
Worry	4.67 (2.62)	2.23 (2.29)	2.83*	3.58 (2.37)	2.30 (2.31)	1.93 (p = .086)
Expectation	5.40 (3.26)	6.05 (2.01)	-0.51	5.05 (2.60)	5.85 (2.08)	-0.89
Medications	3.37 (2.38)	1.93 (1.51)	1.98 (p = .079)	2.70 (2.10)	2.10 (1.28)	0.90
Attachment security	3.63 (0.55)	3.77 (0.35)	-0.58	-	-	
Attachment anxiety	1.45 (0.62)	1.38 (0.42)	0.57	-	-	
Attachment avoidance	1.44 (0.69)	1.30 (0.49)	0.67	-	-	

*p < .05, ** p < .01.

be discussed in the first session after the general introduction of the MSOS intervention. In other words, the psychoeducation on effective communication and general aspects of the close relationship and shared cancer experiences, which contribute to their sleep problems, can be discussed in the first session, and its progress can be monitored throughout the entirety of the MSOS intervention. The MSOS intervention protocol and measures are available (Kim et al., 2023).

Intervention satisfaction survey

After each intervention session, participants completed a total of 8 brief questions on a 5-point Likert format (1: strongly disagree, 5: strongly agree), regarding the extent to which the intervention session was engaging, easy to understand, comprehensive, useful, relevant, motivated sleep behavior changes, motivated sleep cognition changes, and helped to prepare for making sleep-related changes.

Statistical analysis

Demographic characteristics of the sample, and means and standard deviations or percentages of study variables are reported in Table 2. The feasibility criteria were as follows: \geq 75% of eligible dyads enrolled within the 4-month enrollment period, $\geq 80\%$ of enrolled dyads completing the intervention (1 week after the last intervention session and assessment), and no adverse events reported. The acceptability criterion was $\geq 80\%$ of participants reporting satisfaction (≥ 4 on the 5-point rating scale) across all 8 intervention satisfaction survey questions. Differences in demographics and study variables between patients and caregivers at T1 and T2 were tested using paired t-tests. Changes in study variables from pre-intervention (T1) to post-intervention (T2) were also tested using paired *t*-tests and reported using Cohen's *d*, which is a more informative effect size statistic than t-values for a pilot study with small sample. Statistical significance was set at a 2-tailed *p*-value <.05.

Results

Sample characteristics

As shown in Table 2, participants were primarily middle-aged, non-Hispanic White, and retired, and had some degree of college education and middle-class household income. Most patients were on treatment at both T1 and T2 for various types of GI cancer. On average, patients and caregivers had been in a relationship for over 28 years and reported mild-to-moderate levels of sleep disturbance and dysfunctional belief about sleep. Both patients and caregivers also reported on average high levels of attachment security and relationship satisfaction, and low levels of attachment anxiety and avoidance, on the measures we used. At T1, 40%, 10%, and 10% of patients had subthreshold, moderate, and severe levels of insomnia, respectively; at T2, 70% had subthreshold levels of insomnia, and none had moderate or severe levels of insomnia. Among caregivers, 50% at T1 and 60% at T2 had subthreshold levels of insomnia, and none had moderate or severe levels of insomnia at either timepoint.

Enrollment feasibility

As shown in Fig. 1, a total of 241 patients with GI cancer were identified as potentially eligible for the study. We were able to contact 77.5% of patients who met the eligibility criteria by medical records. Of those, 30.3% refused to be screened. Among those who were screened, 81.6% were ineligible after screening: 45.2% were single, 24.2% reported PSQI < 5, 8.1% were divorced/separated, and 4.8% had a partner who was out of the country for the unforeseeable future. Of those eligible and screened, 92.9% (13 out of 14 dyads) enrolled during the 4-month enrollment period. Among 13 dyads enrolled, 3 dyads (23.1%) withdrew after the first intervention session due to cancer recurrence or becoming too busy, leaving 10 dyads who completed the intervention.

Intervention fidelity

The fidelity to the intervention protocol was ensured by YK who reviewed 100% of the intervention sessions. Based on individuals' sleep hygiene and stimulus control data obtained from daily sleep diary, DBAS total score, and attachment orientations and relationship satisfaction scores at T1, the behavior, cognition, and relationship modules, respectively, of the MSOS intervention sessions were tailored for each dyad. On average, Session 1 took

	Patients <i>M</i> (SD)	Caregivers <i>M</i> (SD)
Engaging	4.88 (0.32)	4.87 (0.32)
Easy to understand	4.98 (0.07)	5.00 (0.00)
Comprehensive	4.86 (0.31)	4.78 (0.38)
Useful	4.80 (0.37)	4.59 (0.44)
Relevant	4.89 (0.29)	4.83 (0.29)
Motivating sleep behavior changes	4.54 (0.74)	4.53 (0.50)
Motivating sleep cognition changes	4.77 (0.32)	4.63 (0.43)
Helpful prepared for making sleep-related changes	4.48 (0.62)	4.77 (0.43)
Average	4.76 (0.29)	4.75 (0.28)

slightly over 1 hour (1 hour 16 minutes) but all other sessions took 1 hour (1 hour 4 minutes each for Sessions 2 and 3; and 1 hour 2 minutes for Session 4). No adverse events were reported.

Intervention acceptability

Participants reported high satisfaction with the MSOS intervention in 8 domains, with an average of 4.76 on a 1 (not satisfied) to 5 (completely satisfied) scale, ranging from 4.53 to 5.00 (Table 3). Levels of satisfaction remained consistently high throughout the intervention sessions (p > .34), except for 2 domains. First, the levels of agreement on the intervention motivating participants for making changes in sleep behaviors slightly decreased at the third session (means = 4.42, 4.67, 4.58, and 4.92 at Sessions 1 through 4, respectively, F = 6.06, p = .032). Second, the levels of agreement on the intervention motivating participants for making changes in sleep cognitions gradually improved (means from 4.43 to 4.79 across the 4 sessions, F = 7.22, p = .19).

All participants (20 persons) agreed that the number of sessions (4), the interval (weekly), the delivery mode (Zoom as opposed to in-person or telephone), and the interaction mode with the interventionist (live as opposed to non-interactive or internet-based animated interaction) of the MSOS intervention were optimal. All participants preferred attending all sessions with their partners (as opposed to alone or with someone else). One participant (out of 20) suggested reducing the number of days requested for completing the daily sleep diary.

Preliminary intervention efficacy

Prior to receiving the MSOS intervention (T1), the most prevalent sleep hygiene behaviors for which participants did not meet the recommendation was lack of exercise (60% of patients and 30% of caregivers were inactive), which was followed by alcohol intake (40% of patients and 30% of caregivers) and caffeine intake (10% of patients and 20% of caregivers). The most prevalent problematic sleep stimulus control behavior was doing non-sleep activities in bed (70% of patients and 90% of caregivers) and having an inconsistent waking time (the range of waking time reported in the daily sleep diary across the 7 consecutive days was greater than 2 hours:

		Patients			Caregivers		
	T1	T2	d	T1	T2	d	
Sleep efficiency	77.61 (15.48)	87.04 (9.55)	-1.04**	81.66 (8.02)	90.92 (8.67)	-1.47***	
PSQI subjective sleep quality	1.10 (0.99)	0.90 (0.57)	0.22	1.10 (0.57)	0.70 (0.48)	0.78*	
Dysfunctional belief on sleep	4.33 (1.94)	3.71 (1.78)	0.32	3.18 (1.45)	2.96 (1.26)	0.17	
DAS	15.20 (3.94)	15.30 (3.77)	-0.09	16.20 (3.55)	15.60 (3.75)	0.30	

Table 4. Intervention effects

* *p* < .05, ** *p* < .01, *** *p* < .001.

Note. PSQI = Pittsburgh Sleep Quality Index; DAS = Dyadic Adjustment Scale.

80% of patients and 50% of caregivers), which was followed by napping (40% of patients and 30% of caregivers).

As shown in Table 2, both patients and caregivers had moderate levels of dysfunctional beliefs about sleep and poor sleep efficiency (< 81%) that was assessed using the 7-day daily sleep diary at T1. Patients reported higher levels of total dysfunctional beliefs about sleep and worry than their caregivers, but both reported comparable levels of overall sleep disturbance, subjective sleep quality, sleep beliefs on consequences, expectations, and medications, as well as attachment orientations, relationship satisfaction, and sleep efficiency at T1.

After receiving the MSOS intervention (T2), the majority increased the duration of engaging in moderate exercise (50% of inactive patients and 66% of inactive caregivers at T1) and either reduced the amount or adjusted the time for last alcoholic beverage intake to be earlier in the evening (75% of patients who did not meet the recommendation and 66% of caregivers who did not meet the recommendation at T1). Also, the majority reduced the time in bed doing non-sleep activities (86% of patients and 89% of caregivers who did non-sleep activities in bed at T1), woke up within a more consistent time frame across days (63% of patients and 60% of caregivers who had various waking time at T1), and reduced the duration of naps (50% of patients and 100% of caregivers napped at T1). At T2, both patients and caregivers reported mild levels of dysfunctional beliefs about sleep and had good sleep efficiency (> 87%). Patients reported comparable levels of sleep patterns with their caregivers at T2.

As shown in Table 4, sleep efficiency, the primary outcome that was derived from the sleep diary, of both patients and caregivers, significantly improved after the MSOS intervention (Cohen's d = 1.04 and 1.47 for patients and caregivers, respectively, t > 3.28, p < .01). Among secondary outcomes, caregivers' subjective sleep quality also significantly improved (Cohen's d = .78, t = 2.45, p = .037). Effect sizes of the MSOS intervention on reducing other indicators of sleep disturbance for patients and caregivers were small-to-medium.

Discussion

The results of this pilot study support the feasibility and acceptability, as well as provide the preliminary efficacy of the newly developed sleep intervention, called MSOS, for both adult patients with GI cancer and their sleep-partner caregivers. Specifically, among adult patients with cancer who are not single, divorced, or separated, approximately half had at least mild-to-moderate sleep disturbance and a sleep-partner caregiver who also had mildto-moderate sleep disturbance, supporting the high prevalence of sleep disturbance in both adult patients with cancer and their caregivers. In addition, most of our participants were willing to make changes in even their sub-optimal, as opposed to severely disturbed, sleep habits. Furthermore, in a study of spousal caregivers of patients with dementia, the caregivers continued to have significant ongoing sleep problems after the death or institutionalization of their demented spouses (Gao et al. 2019). This result suggests, sleep disturbance, once developed, has lasting effects even after ceasing the caregiver role. Thus, a rather lenient intervention inclusion criterion for the levels of sleep disturbance particularly for vulnerable populations, such as adult patients with cancer and their sleep-partner caregivers, may be desirable to yield a broader impact.

Our results support high feasibility of providing a dyadic sleep intervention to patients who are mainly on treatment. Treatment status was not an inclusion or exclusion criterion for this pilot study. However, MSOS accommodates the symptoms and experience of cancer as well as potential treatment effects on the patients' disturbed sleep. Thus, the MSOS intervention can be useful for those who manage current and lasting cancer-related symptoms, in which both the patients and their family caregivers are often collaboratively involved. However, the effects of MSOS intervention on treatment adherence, prognostic outcomes, health-care utilization, and quality of life need to be tested in future studies.

The high acceptability is also achieved by high satisfaction with the intervention content, procedure, and measurement, and the interventionist. MSOS intervention delivers key components of CBT-I (sleep behavior change and addressing sleep-related cognition) in the context of close relationship for both patients and caregivers, whose sleep disturbances were equally addressed. Our results suggest that the MSOS intervention, which was delivered comprehensively and compactly in a minimum number of sessions, is highly feasible and acceptable. eHealth intervention delivered by a trained interventionist, which gained popularity and familiarity through the COVID-19 pandemic, was also considerably acceptable as it capitalizes on the human-side of the technology, as opposed to non-interactive or animated interactions. Furthermore, the finding that all participants preferred attending the intervention with their sleep-partner caregivers, as opposed to alone or with someone else, supports the exceptional acceptability of dyadic sleep intervention. However, a potential bias in sampling for couples who agreed to participate in a study together should also be noted. In addition, the efficacy and effectiveness of dyadic format, as opposed to that of individual or group, for reducing individuals' sleep disturbance should also be tested in future studies.

Our results hint that the MSOS intervention is particularly effective in modifying sleep stimulus control behaviors that were the most prevalent problematic sleep behaviors among both patients with cancer and caregivers. Furthermore, a few studies with medical populations showed that medical characteristics of 1 member of a dyad affected the partner's sleep. For example, osteoarthritis patients' pain affected their spouse's sleep (but not the other way around: Martire et al. 2013); poorer condition of dementia patients related to husband caregivers' increased time awake after sleep onset (Mills et al. 2009); and caring for a patient with a more severe type of cancer related to chronic sleep disturbance of the caregivers (Fletcher et al. 2008; Passik and Kirsh 2005). None of these studies, however, has intervened on both sleep partners simultaneously. On the other hand, the large effects of the MSOS intervention on improving sleep efficiency of both patients and caregivers, as well as enhancing caregivers' subjective sleep quality and reducing caregivers' overall sleep disturbance, clearly illustrate that the efficacy of the MSOS intervention are promising. Our preliminary findings should be replicated with a larger sample for further adequate interpretation.

Our findings also suggest that intervening on both sleep partners who serve as each other's comrade to make desirable changes, as opposed to targeting a sole member in the dyad, may be an optimal strategy that is highly likely to yield a larger impact on improving sleep and general health. In addition, existing studies have shown that the husband's loneliness was related to his wife's poor sleep (Segrin and Burke 2015), and the wife's perception of partner interactions during the day predicted her husband's better sleep (Troxel 2010). Thus, investigating MSOS's efficacy in improving mutual sleep regulatory patterns where partners influence the reduction of each other's sleep disturbance is highly warranted. It will be particularly critical among at-risk dyads of adult patients with cancer and their sleep partner's. Examining the potential role of close relationship factors (i.e., intimacy and self-disclosure) as the pathway of sleep intervention is also warranted.

Several limitations of this study should be noted. First, we employed a single-arm study design as the first step of this feasibility study, which lacks a control or comparison group that would have provided a stronger conclusion regarding the efficacy of the MSOS intervention. Similarly, the current design, small sample size, and potentially biased sample prevented the ability to test the superiority of novelty involving patient-caregiver dyadic intervention, as opposed to a small, 2-person stranger group format intervention. Second, our current enrollment criterion of having at least mild-to-moderate sleep disturbance (PSQI \geq 5) may contribute to a floor effect. Third, the generalizability of the current findings to different types of cancer, time since diagnosis, treatment trajectory, and language proficiency as well as to patients without a consistent sleep partner and patients without at least mild sleep disturbance, which are not included in the current study, is limited. Fourth, testing gender, race and ethnicity, and other group differences as well as dyadic (e.g., relationship duration, relationship satisfaction) and individual (e.g., personality, coping strategies) differences in the intervention efficacy was not feasible. These limitations should be addressed in larger future studies with diverse participants.

In summary, although sleep disturbance is common in both patients with cancer and their family caregivers, no studies to date have investigated the efficacy of dyadic sleep interventions involving both patients with cancer and their caregivers simultaneously. Our findings of this pilot study suggest that testing the efficacy of MSOS, an innovative and timely intervention for couples/dyads who are facing cancer, in a randomized controlled trial with a larger sample is warranted. The knowledge from this line of investigation may have substantial implications for traditional sleep research and practice with medical populations, shifting the emphasis from individual- to dyad/family-based approaches. 233

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Data availability statement. The data that support the findings of this study are available from the corresponding author upon reasonable request.

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