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Psychometric properties of the Insomnia Severity Index in cancer survivors

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Abstract

Objective: Insomnia is commonly associated with cancer treatment. Cancer treatments increase risk for numerous psychological and medical late effects, thus making cancer survivors psychologically and medically vulnerable. Prior research examined psychometric properties of the Insomnia Severity Index (ISI) with various populations, including the French version of the ISI, with participants undergoing active cancer treatment. However, no prior studies examined insomnia exclusively with cancer survivors, using the English version of the ISI.

Methods: This study examined internal consistency and factor structure of an English version of the ISI in 100 cancer survivors (M_{age} = 51.1; *SD* = 14.92). This final analytic sample was composed of participants from three different insomnia interventions. Survivors ranged from less than 1 year off treatment (17%) to 21+ years off treatment (6%), with most participants off treatment for 1 to 2 years (24%).

Results: The mean ISI score for the total sample was 16.69 (*SD* = 4.47), indicating clinical insomnia, with moderate severity. Principal Components Analysis (PCA) indicated two factors (five items loading on Factor I and two items loading on Factor II) and acceptable reliability (α = .73). Item-total correlations ranged from .15 to .63.

Conclusions: Findings support the reliability of the ISI in cancer survivors. However, its factor structure warrants additional research with larger samples of cancer survivors. Results suggest inconsistency across participant responses and that ISI items may be functioning differently with this unique population of cancer survivors. Findings indicate that sleep maintenance problems are central to the experience of insomnia in our survivor sample.

KEYWORDS

assessment, cancer, factor analysis, insomnia, Insomnia Severity Index, oncology, survivors

1 | INTRODUCTION

Insomnia is one of the most common disorders associated with cancer treatment[1] and is associated with greater overall symptom burden and decreased quality of life.[2] Although some cancer patients find their sleep improves after treatment completion, as many as 30% of long-term survivors report continued insomnia.[3] Further, a prior investigation of 26 breast cancer survivors revealed that periodic limb movements in sleep distinguished survivors with moderate to severe insomnia from those with no to mild insomnia.[4] Characteristics of cancer survivors, such as worry about recurrence,[5] and medical and psychological late effects of cancer treatment,[3] may contribute to this increased risk, underscoring the importance of studying insomnia in this population.[6] Remarkably, a study of 21 230 women found that those with sleep disturbance had worse cancer-specific survival compared with those with no sleep disturbance.[7] Finally, a qualitative

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study of survivors revealed that the effects of insomnia symptoms persisted long after treatment completion.[2]

The Insomnia Severity Index (ISI) is a widely used self-report measure of insomnia that has been applied across a broad range of patient groups. The ISI is commonly used as an outcome measure in randomized controlled trials of insomnia treatment in cancer patients.[8] Numerous studies have endorsed strong psychometric properties of the ISI in community (non-clinical) and primary care populations. Across these studies, internal consistency ranged from α = .87 to α = .92. For example, the ISI demonstrated good reliability in a large community sample of healthy adults.[9] Finally, internal consistency for the Spanish version was also good in a sample of older adults (α = .91, n = 230).[10]

In contrast to these reports, studies of clinical samples (ie, patients with insomnia disorders or other medical conditions) have reported more variability of the internal consistency of the ISI. For example, an internet-delivered intervention for insomnia revealed the ISI had low internal consistency at baseline (α = .61), but good internal consistency post-intervention (α = .88). Furthermore, although a study of sleep clinic participants demonstrated *acceptable* internal consistency (α = .74),[11] a study of cancer patients (α = .90)[8] and another of veterans with traumatic brain injury[12] both reported *excellent* internal consistency, (α = .90 and α = 0.92, respectively). Of note, the prior study of cancer patients used a mixed sample, composed of participants who were both, on and off treatment.[8] Further, a study of a Korean version of the ISI revealed excellent internal consistency (α = .92) in a sample of 614 patients with a variety of sleep problems, including primary insomnia (n = 169), comorbid insomnia (n = 133), and obstructive sleep apnea (n = 312).[13] This wide range of internal consistencies (α = .61 to α = .92) suggests the ISI may be less consistent in medical samples, including cancer patients and survivors. This would not be surprising because measures of reliability are limited by total score variance. Therefore, in clinical samples in which participants are more likely to have elevated insomnia scores, alpha estimates will tend to be lower. Although it is also possible that sample size could play a role as some of the clinical samples reporting on the ISI tend to be smaller (eg, *n* = 83),[12] studies of the alpha statistics indicate it can be reliably estimated even in moderate size samples and alpha values of the ISI have not been consistent even across large samples.[14,15] Although the initial development of the ISI did not include factor structure examination, numerous investigators have reported distinct differences in the structure of the ISI across samples. Two studies, one in a sample of veterans with traumatic brain injury[12] and the second in a community sample of 230 older adults,[10] supported a single-factor structure for the ISI. In contrast, Savard, Savard, and Ivers revealed a two-factor structure of the ISI in a large sample of French-speaking cancer patients, with the first four items loading onto Factor I and the last three loading onto Factor II[8] (see Table 3). Three additional studies also demonstrated a two-factor structure in 585 older adults (Chinese version),[16] 1516 adolescents (Chinese version),[17] and 1037 sleep clinic patients (Persian version).[15] Finally, Bastien, Vallières, and Morin first reported a three-factor structure in a sleep clinic sample.[11] Three later studies also reported a three-factor structure of the ISI in 272 insomnia patients (Italian version),[18] 345 Chinese individuals across schools, communities, and a hospital in Taiwan,[19] and 500 medical students and their social networks (Spanish version).[20] In sum, for the three prior studies that revealed a two-factor structure, items 1 to 4 encompassed Factor I and items 5 to 7 represented Factor II.[8,15,16] Another study that revealed a two-factor structure had items 1 to 3 represent one factor and items 4 to 7 represent another.[17] Other studies revealed three factor structures.[11,18-20] Notably, no prior studies labeled or described the factors. For a more detailed summary of prior studies reporting ISI psychometrics, see Table 3. These results suggest that the dimensionality of the ISI varies across samples and that understanding the factor structure in a specific population may be important for understanding how the ISI can be best used to evaluate insomnia in a particular group. Given that the ISI is being widely applied in studies of cancer survivors, it is important to evaluate its measurement properties in this population. However, studies of the ISI in oncology samples have not yet focused specifically on cancer survivors after treatment completion. This is a significant gap in the literature, as the growing population of cancer survivors is known to have unique physical and psychological vulnerabilities,[21,22] including high rates of insomnia,[3,23] even many years after treatment.[24] To address this, our study examined the internal consistency reliability and factor structure (ie, statistical approach to describing variability among variables)[25-28] of the ISI (English version) in a sample of cancer survivors after treatment completion.

2 | METHODS

2.1 | Participants and procedures

Participants were 100 cancer survivors (89% female) ranging in age from 18 to 84 years (*M* = 51.1, *SD* = 14.9). Most of the sample (57%) had been treated for breast cancer (Table 1). Survivors ranged from 1 to 2 years off treatment (24%) to 11 or more years off treatment (14%), with most participants off treatment for 1 to 2 years (24%).

Participants completed the ISI as part of their participation in one of three insomnia studies conducted at an academic medical cancer center in the northeastern region of the United States. Only baseline ISI assessments completed prior to any intervention were used for this analysis. ISI data were drawn from the three studies as follows[1]: data from 39 participants were taken from a previously reported group intervention for adult cancer survivors[29,2]; data from 10 participants were drawn from a previously reported individual intervention for young adult cancer survivors[30]; (3) and data from 51 survivors were taken from an ongoing stepped-care intervention trial (clinical trials.gov #NCT02756390). To be eligible for this trial, participants had to have a minimum total ISI score of 12. There was no minimum ISI score for study 1 and 2 eligibility. For all trials, participants provided written informed consent. Procedures for these three studies were approved by the cancer center Institutional Review Board (IRB), as was the subsequent plan to combine the data and assess the psychometric properties of the ISI (Protocol #17-564).

TABLE 1 Demographic and clinical characteristics (N = 100)

Variable	Total *N* (%)
Sex	
Female	89
Male	11
Age	
18-34	16
35-49	21
50-64	45
65+	18
Race/ethnicity	
White	87
Multiracial/other	
Black	3
Native American	
Asian/Pacific Islander	7
Hispanic/Latino	1
Unknown	2
Cancer diagnosis	
Breast	57
Other solid tumors	21
Lymphomas	14
Leukemias	8
Time since treatment	
<1 year	17
1-2 years	24
3-4 years	16
5-7 years	17
8-10 years	12
11+ years	14

2.2 | Measures

2.2.1 | Insomnia Severity Index[31]

The ISI is a 7-item self-report checklist inquiring about insomnia symptoms over the two previous weeks. The first three items capture problems with falling asleep, maintaining sleep, and early morning awakening; the last four items capture sleep dissatisfaction, sleep-related problems in daytime functioning, noticeability of the daytime functioning problem, and insomnia-related distress. Participants rate each item on a 5-point Likert scale; for items 1 to 3 from "none" to "very severe"; for item 4 from "very satisfied" to "very dissatisfied"; and for items 5 to 7 from "not at all" to "very much." The total score, ranging from 0 to 28, is obtained by summing the seven items, with higher scores reflecting greater insomnia severity.

2.3 | Data analysis

Item frequency, mean, mode, and corrected item-scale correlations for the ISI were initially examined. Internal consistency reliability of the ISI was examined using the coefficient alpha (α), the relationship of each ISI item to the total score using corrected item-total correlations, and a calculation of alpha (α) with each item deleted. Factor structure was examined using Principal Components Analysis (PCA) with varimax rotation on item correlation matrices. Eigen values (≥1) and a scree test guided factor retention. Factor loadings >.40 were reported and interpreted.[25-27] Analyses were conducted using the Statistical Package for Social Sciences Version 24.0 (SPSS 24.0).

3 | RESULTS

3.1 | ISI items and internal consistency

The mean ISI score for the total sample was 16.69 (*SD* = 4.47), indicating clinical insomnia, with moderate severity.[31] The modal response for all items was 2 ("moderate" or "somewhat"), except item 4, which had a modal response of 3 ("severe", "dissatisfied", or "much"). Item response means ranged from 1.86 (Item 5; noticeability) to 3.25 (Item 4; dissatisfaction; Table 2).

Item-scale correlations ranged considerably, from .15 to .63. Items pertaining to staying asleep, satisfaction, interference, noticeability, and worry had the highest item-total correlations (.52 - .63), and items addressing problems with falling asleep (Item 1) and early awakening (Item 3) showed the lowest correlations (.15 and .25, respectively) indicating they had the least common variance with the total ISI score. The ISI demonstrated acceptable internal consistency (Cronbach's α = .73), lower compared with most non-clinical samples, but comparable to clinical samples. Analyses revealed that five of the ISI items contributed to the measure's internal consistency, with Cronbach's alpha found to decrease if they were eliminated. However, results for Item 3 (early awakenings) and Item 1 (problems falling asleep) again showed a different relationship with the total scale. Removing these items resulted in a scale with improved internal consistency (α = .77 or .74, respectively), again indicating these items did not contribute as much shared variance. Thus, it is possible that items 1 and 3 are

TABLE 2 Item-total correlations and descriptive statistics of the Insomnia Severity Index

ISI Item	Modal Response	Mean (SD)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
1. Problems falling asleep	2	1.99 (1.24)	0.146	0.774
2. Problems staying asleep	2	2.57 (0.99)	0.517	0.676
3. Early awakenings	2	2.15 (1.16)	0.250	0.744
4. Dissatisfaction	3	3.25 (0.67)	0.595	0.678
5. Noticeability	2	1.86 (1.14)	0.555	0.663
6. Distress	2	2.48 (0.96)	0.628	0.651
7. Functional impairment	2	2.39 (1.02)	0.591	0.657

not strongly tied to the remaining items and are potentially tapping into another dimension.

3.2 | Factor analysis

A PCA with orthogonal rotation (varimax method) revealed two factors with eigenvalues greater than 1 (3.02 for Factor I; 1.28 for Factor II), and the Scree plot supported a two-factor solution, accounting for 61.32% of the total variance (Factor I = 43.11%; Factor II = 18.21%). The first factor corresponded to difficulty staying asleep, satisfaction, noticeability, worry/distress, and functional impairment (items 2 and items 4-7), while the second factor reflected problems falling asleep (item 1) and early awakenings (item 3; Figure 1). Notably, item 1 (problems falling asleep) had a negative loading on Factor II (−0.79), so that individuals would score high on Factor II if they reported *more* early awakenings and *fewer* problems falling asleep.

4 | DISCUSSION

Although the ISI is widely used in oncology samples, its psychometrics have not been extensively studied in cancer survivors specifically. Analysis of its measurement properties in cancer patients during treatment is largely limited to a study of the French language version.[14] To our knowledge, no prior studies examined the measurement properties of the ISI in cancer survivors. Regarding reliability, the internal consistency we found (α = .73) is within the range observed in other clinical samples (α = .61 to α = .92), eg, Savard et al,[14] but below the range commonly reported in general or non-clinical samples (α = .87 to α = .92), eg, Morin et al.[9] This difference in reliability across samples converges with prior ISI studies and with studies indicating internal consistency of personality measures is lower when applied to clinical samples as opposed to general population samples.[32-34] At the item level, our observed range of item-scale correlations is much more variable (0.15 to 0.63) compared with prior studies. For example, in their study of primary care patients, Gagnon, Bélanger, Ivers, and Morin found that item-scale correlations ranged from 0.65 to 0.84. Items inquiring about problems falling asleep (item1) and early awakenings (item 2) had particularly weak associations with the total ISI scale in our sample. In contrast, the item capturing problems staying asleep (item 3) was more highly endorsed by our participants and more strongly associated with their overall ISI scores. These findings indicate that problems with sleep maintenance are central to insomnia in our survivor sample. This is consistent with previous reports that middle insomnia is more prevalent in populations with chronic medical conditions,[35,36] like those commonly diagnosed in cancer survivors.[37] Thus, differences in types of insomnia symptoms may account for variability in ISI scores across populations.

Descriptions of the ISI factor structure have not been consistent, with one-factor, two-factor, and three-factor solutions supported in prior studies (Table 3). The present factor analysis indicates that the ISI operates somewhat differently in our cancer survivor sample than in these other groups. We might have expected the factor structure of the ISI in our sample to be consistent with that reported in a sample of cancer patients during treatment,[8] but that was not the case—although both studies revealed a two-factor structure. Savard and colleagues (2005) found that their Factor I was associated with items measuring all three types of insomnia (difficulty falling asleep, difficulty staying asleep, early awakenings) as well as overall satisfaction, whereas their Factor II was associated with the last three ISI items (noticeability, distress, functional impairment).[8] In contrast, we found that the first Factor reflected all the sleep interference items (dissatisfaction, noticeability, distress, functional impairment) along with symptoms of middle, but not early or terminal insomnia. Initial and terminal insomnia symptoms loaded on a second factor but with opposite valence.

Findings underscore that these symptoms play a different role in the experience of insomnia in our sample than the other symptoms measured by the ISI. While both cancer patients and survivors are at risk for medical and psychological morbidity, symptom acuity and burden are typically much greater for patients in active therapy. Additionally, compared with survivors, patients often experience interruptions in sleep and activity schedules because of hospitalizations and treatment regimen demands. Future research on insomnia

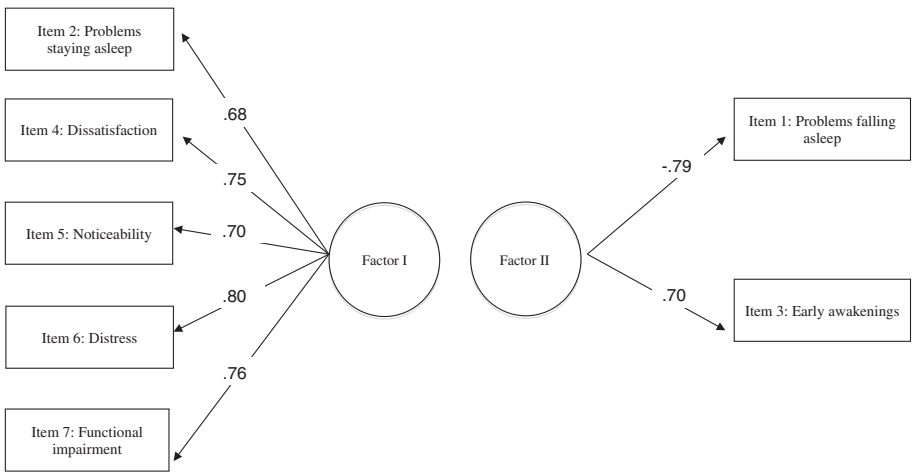

FIGURE 1 Factor structure of the Insomnia Severity Index in cancer survivors (*N* = 100) *Note*. Factor loadings < .40 not depicted.

TABLE 3 Factor analytic structure in prior studies

Study	Language	Sample Description	α	# of Factors	Item Loading
Cho 2014	Korean	614 sleep disorder patients	.92	N/A	N/A
Morin 2011	French-Canadian	959 community individuals; 245 study patients (n = 183 treatment; n = 62 controls)	.90; .91	N/A	N/A
Kaufman 2017	English	83 veterans with history of traumatic brain injury	.92	1	N/A
Sierra 2008	Spanish	230 older adults	.91	1	N/A
Savard 2005	French-Canadian	1670 cancer patients	.90	2	Factor I: Items 1-4; factor II: Items 5-7
Sadeghniiat-Haghighi 2013	Persian	1037 sleep clinic patients	.76	2	Factor I: Items 1-4; factor II: Items 5-7
Doris 2010	Chinese	585 older adults	.81	2	Factor I: Items 1-4; factor II: Items 5-7
Chung 2011	Chinese	1516 adolescents from three schools	.83	2	Factor I: Items 4-7; factor II: Items 1-3
Bastien 2001	English	78 older adults	.74	3	Factor I: Items 5-7; factor II: Items 2-3; factor III: Items 1,4,5
Castronovo 2016	Italian	272 insomnia patients	.75	3	Factor I: Items 5-7; factor II: Items 1,4,7; factor III: 1-3
Chen 2015	Chinese	345 Taiwanese individuals from schools, communities, and a hospital	†	3	Factor I: Items 5-7; factor II: Items 1-3; Factor III: Items 1,4,7
Fernandez-Mendoza 2012	Spanish	500 medical students and their social networks	.82	3	Factor I: Items 5-7; factor II: Item 4; Factor III: Items 1-3

Note.

†Cronbach alpha (α) for the ISI total not reported.

symptoms in oncology patients—as they transition from treatment to survivorship—may be particularly helpful in understanding these differences.

4.1 | Limitations

In evaluating these findings, study limitations should also be noted. For example, results of any study of modest sample size or a convenience sample require replication with larger samples. Nonetheless, the present investigation had more than 10 times as many subjects (n = 100) as variables (7 items). Our sample size exceeds most "rules of thumb" in factor analyses, eg, Bryant and Yarnold[28] and Nunnally[38] and empirical analyses have shown that clear and reproducible factor structure can be found with considerably smaller samples and subject-to-variable ratios, eg, Kline, Bryant and Yarnold, and Nunnally.[25,28,38] Simulation studies indicate that with the first factor explaining a moderate amount of variance, as in our case with an Eigenvalue of 3.02, alpha can be reliably estimated with samples as small as 100.[39]

Of note, our sample consisted mostly of White females drawn from a single center, raising generalizability questions that should be addressed in future research. Psychometric properties of a test are never independent of the sample under study (see Table 3) and are probably best conceptualized as properties of the test when applied in a specific population. Evaluating how the ISI items operate in a sample of cancer survivors seeking treatment for insomnia is critical, as these patients are similar to survivors who complete the ISI in intervention studies or in clinical assessment. However, we cannot know how well these findings will generalize to other groups of cancer survivors with different demographic, disease, or insomnia characteristics. Thus, it is difficult to know how much the ISI differences we note between on- and off-treatment cancer patients are not due to other differences (eg, language, culture, cancer type). Future studies using the English language version of the ISI with larger samples of both on- and off-treatment cancer patients will be particularly valuable in shedding light on this question.

Finally, the three source studies that provided ISI data did not collect data about psychiatric symptoms that may have affected results. Thus, future studies should incorporate psychiatric data to examine the potential impact of such symptoms in insomnia. Nonetheless, although the DSM-IV distinguished between primary and secondary insomnia, the DSM-5 has eliminated this, in part to underscore that insomnia warrants independent clinical attention.

Despite its limitations, these results can help evaluate the utility of the ISI in cancer survivors and shed light on the experience of insomnia in this population. Specifically, our result that internal consistency of the ISI was in the acceptable range[33,34,40] and similar to reports in other clinical samples supports its use in cancer survivors. This may help guide interpretation of the ISI in cancer survivors by informing users that a substantial proportion of the variability in their scores will be driven by items capturing trouble staying asleep and the impact of these symptoms on functioning.

Finally, our findings contribute to the literature demonstrating that the ISI's measurement properties vary considerably across different populations. Part of this variability is likely due to meaningful differences in these populations (ie, clinical versus non-clinical) but may also reflect the measure and the psychometric methods used to evaluate it. Specifically, item-scale correlations and Cronbach's alpha (α) are most meaningfully applied to measures where all survey items reflect some aspect of a consistent latent construct. For example, on a measure of introversion, each item would each be expected to reflect an aspect of introverted personality that cannot be directly measured. In these types of measures, items can be thought of as "effect indicators"[33] because each item manifests the effect of the

otherwise unmeasured (latent) variable, and measuring the association of the items to each other is useful in understanding how well they do so. In contrast, when items do not reflect a latent variable, but more directly define a variable, such items can be considered "causal indicators," as they capture the causes of the variable they measure. An example of this would be a life events inventory asking about recent divorces, marriages, births, deaths, job loss, and job promotion. Though summing these items may be a useful measure of capturing exposure to potentially stressful events, it is unlikely that the items themselves would be even modestly correlated and measures of internal consistency would not be meaningful.[33,34]

With this distinction in mind, the ISI may be considered a "hybrid measure" including items that Streiner[33] would describe as "effect" and "causal" indicators. Specifically, the first three ISI items can be conceived as causal indicators that define insomnia, and the last four items as effect indicators of insomnia's functional impact. Though additional research across patient groups would be needed to evaluate this conceptualization of the ISI, it appears consistent with the items themselves and with the present study's findings. Including both causal and effect indicators in a single measure is not necessarily problematic but has implications for assessment of measurement properties.[33,34] If the ISI includes causal indicators, this may depress item correlations and overall measures of internal consistency. Furthermore, if different populations vary in prevalence of initial, middle, and terminal insomnia symptoms, then this could account for the significant variability in psychometric properties of the ISI across groups. Evaluating other measures of reliability, such as test-rest reliability, could be a useful alternative, as would evaluating validity against accepted criterion measures. For those using the ISI in cancer survivors, data supporting the validity of the ISI against diagnostic interview measures of insomnia may be useful, particularly because they could determine sensitivity and specificity of ISI cut-off scores specific to this population.

4.2 | Clinical implications

Given the widespread use of the ISI with cancer populations in both, clinical and research settings, as well as the psychological and medical consequences on insomnia, the present study offers numerous clinical implications. First, this study underscores that sleep maintenance is more central to cancer survivors, compared with sleep initiation and termination. Second, although we may have expected the ISI in cancer survivors to have performed similarly to patients on active cancer treatment, the present psychometric investigation suggests that sleep impairment is different in survivors, compared with individuals on active treatment. Third, psychometric findings suggested the importance of evaluating both, contributors to and functional impact of insomnia. Specifically, clinicians may wish to assess factors contributing to insomnia (particularly sleep maintenance) separately from the impact that insomnia has on patients' daily functioning, with an emphasis on the impact of symptoms. In sum, the present investigation highlights the distinct struggles that cancer survivors have with sleep, as well as the importance of evaluating and addressing middle insomnia.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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