

RESEARCH ARTICLE

A population-based psychometric analysis of the insomnia severity index in black women with and without a history of cancer

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Abstract

Black women are under-represented in insomnia research. Further, cancer treatments increase the risk of late effects, thus affecting the sleep of psychologically and medically vulnerable cancer survivors. The Insomnia Severity Index (ISI) is widely used, but has not been researched in black women, and research in cancer survivors is limited. Prior studies demonstrate that psychometric properties of the ISI are not consistent across samples. This study examined the internal consistency and factor structure of the ISI in 29,500 participants from the Black Women's Health Study, an epidemiological study of black women in the United States. This cohort included 28,214 women without a cancer history and 1,286 cancer survivors. Exploratory, confirmatory and multigroup analyses were conducted to determine the psychometric properties of the ISI in these groups. The mean ISI score was 7.18 (standard deviation [SD] = 6.82). Findings supported the internal consistency reliability of the ISI in black women with ($\Omega = 0.896$) and without ($\Omega = 0.892$) a cancer history. Exploratory factor analyses supported a one-factor structure. Confirmatory factor analyses indicated that fit of this one-factor model was not robust in survivors (Satorra-Bentler chi-square [χ^2 SB²(14)] = 197.78, comparative fit index [CFI] = 0.928, root mean-square error of approximation [RMSEA] = 0.143) or in women with no cancer history (χ^2 SB²(14) = 2,887.93, CFI = 0.945, RMSEA = 0.121), but the alternative models we examined were not superior. Although factor structures in previous studies have varied considerably, we found a one-factor structure. Although internal consistency reliability was strong, factor analytic results did not further support the ISI. Inconsistencies in ISI measurement properties across studies may reflect differences in sample sizes and populations.

KEYWORDS

assessment, factor analysis, oncology, racial minorities, structural equation modeling

1 | INTRODUCTION

Women are disproportionately affected by insomnia for numerous reasons, including social and environmental factors, higher prevalence rates of anxiety and depression, and reproductive factors (Soares, 2005). Menopausal symptoms are strongly associated with insomnia, with research demonstrating that 40 to 60% of menopausal women struggle with insomnia (Baker et al., 2015). Taken together, this evidence warrants the advancement of research on insomnia in women.

Some studies have suggested that black women have a higher incidence of insomnia, although they report insomnia symptoms less frequently than white women (Foley et al., 1999). Prior research has also shown that insomnia is common in women with a history of cancer (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005). As many as 43% of long-term cancer survivors report continued insomnia symptoms following treatment completion (Taylor et al., 2012), with 18% meeting diagnostic criteria for insomnia disorder (Savard, Simard, Hervouet, et al., 2005). Compared to the general population, cancer survivors are at increased risk of insomnia due to the medical and psychological late effects of cancer treatment (Taylor et al., 2012). Of note, breast cancer patients reporting impaired sleep (e.g., poor sleep efficiency, duration and quality) have worse cancer-specific survival (Palesh et al., 2014; Phipps et al., 2016). Studies have posited mechanisms such as decreased immune function and impaired hormonal stress responses due to sleep quality (i.e., sleep disturbance) (Palesh et al., 2014), as well as accelerated tumour growth and metastasis (Phipps et al., 2016). Such findings underscore the need to assess and treat insomnia in individuals with a history of cancer.

The Insomnia Severity Index (ISI) is a commonly used, seven-item self-report measure of insomnia severity over the past 2 weeks (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005). It has been shown to detect cases of insomnia and has convergent validity with measures of fatigue and quality of life (Michaud et al., 2021; Morin et al., 2011). The ISI evaluates issues with sleep onset and maintenance, as well as issues with morning awakenings. It also measures sleep dissatisfaction ("How satisfied/dissatisfied are you with your current sleep pattern?"), interference with daytime functioning ("How noticeable to others do you think your sleep problem is in terms of impairing the quality of your life?") and insomnia-related distress ("How worried/distressed are you about your current sleep problem?") (Morin, 1993). Summing the seven ISI items yields a total score, ranging from 0 to 28, with higher scores reflecting greater insomnia severity. Total score interpretations are: "minimal" symptoms (0–7), subthreshold insomnia (8–14), moderate insomnia (15–21) and severe insomnia (22–28). The ISI has been translated into many languages, including Korean (Cho et al., 2014), Chinese (Chung et al., 2011) and Spanish (Sierra et al., 2008). It has been used as a primary outcome measure in trials of behavioural treatment of insomnia, including those among cancer patients and survivors (Savard, Simard, Ivers, et al., 2005; Zhou et al., 2020).

Although the ISI has demonstrated strong internal consistency reliability (i.e., the extent to which items in the questionnaire measure various aspects of the same construct) in community and primary care samples, with α levels ranging from 0.87 to 0.91 (Sierra et al., 2008), investigations of clinical samples have revealed substantial variability in its psychometric properties. Such studies report Cronbach's α ranging from 0.61 to 0.92 (Kaufmann et al., 2019), with >0.70 acceptable (i.e., >0.80 good; >0.90 excellent). In addition, the factor structure of the ISI has varied considerably, with a variety of one-, two- and three-factor solutions reported (Chen et al., 2015; Chung et al., 2011; Fernandez-Mendoza et al., 2012; Kaufmann et al., 2019; Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005; Sierra et al., 2008; Yu, 2010). Of note, of the seven studies that revealed a two-factor structure, three indicated that Items 1, 2, 3 and 4 reflected one factor, and Items 5, 6 and 7 reflected a second factor (Sadeghniaat-Haghighi et al., 2014; Savard, Savard, Simard, et al., 2005; Yu, 2010). However, two of these studies suggested that Items 1, 2 and 3 reflected one factor, whereas 4 to 7 indicated a second factor (Albougami & Manzar, 2019; Chung et al., 2011). Despite these differences, these solutions overlapped in that Items 1, 2 and 3 reflected one factor, whereas 5, 6 and 7 reflected a second factor. Next, three studies indicated a one-factor solution (i.e., all items loading onto one factor; Gerber et al., 2016; Kaufmann et al., 2019; Sierra et al., 2008) (see Table 1). Finally, four of the studies reported a three-factor solution (Bastien et al., 2001; Castronovo et al., 2016; Chen et al., 2015; Fernandez-Mendoza et al., 2012); although similar to those that indicated a two-factor solution, Items 5 through 7 reflected one factor, potentially suggesting conceptual overlap for this group of items.

The examination and identification of factor structure is crucial in that it explains relationships between variables in a measure, and describes the latent, underlying constructs (e.g., dissatisfaction, functional impairment, etc.) within that particular measure. By identifying how specific items are related to an underlying condition, such as insomnia, factor analysis aids interpretation of findings for both clinicians and researchers and can have implications for assessment and treatment of insomnia. Specifically, the psychometric properties of an assessment may provide information on how the assessment is used, which in turn can influence delivery of clinical services for individuals with insomnia.

Prior investigations of the ISI used racially and ethnically homogeneous samples with few members of minority groups (Kaufmann et al., 2019; Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005; Yusufov et al., 2019), and none reported specifically on black women. Psychometric investigations of the ISI in cancer samples have been limited to two studies (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005; Yusufov et al., 2019) and results have varied. A study of 1,670 cancer patients both on and off treatment revealed excellent internal consistency ($\alpha = 0.90$) (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005), and supported a

TABLE 1 Factor analytic structure in prior studies that used ISI

Study first author and year	Language	Study sample	α	% female	% black	No. of factors	Factor structure ^a
Cancer samples							
Savard, Savard, Simard, et al. (2005)	French-Canadian	1,670 cancer patients	0.90	48.6	NR	2	Factor I: Items 1–4; Factor II: Items 5–7 (EFA)
Yusufov et al. (2019)	English	100 cancer survivors	0.73	89.0	3	2	Factor I: Items 2, 4, 5–7; Factor II: Items 1, 3 (EFA)
Non-cancer samples							
Cho et al. (2014)	Korean	614 sleep-disorder patients	0.92	38	NR	N/A	N/A
Morin et al. (2011)	French-Canadian	959 community individuals; 245 study patients (n = 183 treatment; n = 62 controls)	0.90; 0.91	60.1 (61.2; 51.6)	NR	N/A	N/A
Kaufman et al. (2019)	English	83 veterans with history of traumatic brain injury	0.92	13.3	NR	1	N/A
Sierra et al. (2008)	Spanish	230 older adults	0.91	NR	NR	1	N/A
Gerber et al. (2016)	German	1475 adolescents; 862 students; 533 emergency responders	0.76; 0.77; 0.81	51; 74.1; 22.9	NR	1	N/A
Sadeghniai-Haghighi et al. (2014)	Persian	1,037 sleep-clinic patients	0.76	NR	NR	2	Factor I: Items 1–4; Factor II: Items 5–7 (PCA)
Yu (2010)	Chinese	585 older adults	0.81	81.0	0	2	Factor I: Items 1–4; Factor II: Items 5–7 (EFA)
Chung et al. (2011)	Chinese	1,516 adolescents from three schools	0.83	55.0	NR	2	Factor I: Items 4–7; Factor II: Items 1–3 (PCA)
Manzar et al. (2020)	English	406 substance-using adults	0.68–0.78	13.3	NR	2	Two-factor model with incorporation of modification indices (covarying error terms) (EFA and CFA)
Albougami and Manzar (2019)	English	134 Saudi Arabian nurses	0.75–0.78	65.7	NR	2	Factor I: Items 1–3; Factor II: Items 4–7 (CFA)
Bastien et al. (2001)	English	78 older adults	0.74	57.9	NR	3	Factor I: Items 5–7; Factor II: Items 2–3; Factor III: Items 1, 4, 5 (PCA)
Castronovo et al. (2016)	Italian	272 insomnia patients	0.75	60	NR	3	Factor I: Items 5–7; Factor II: Items 1, 4, 7; Factor III: Items 1–3 (CFA)
Chen et al. (2015)	Chinese	345 Taiwanese individuals from schools, communities and a hospital	NR	NR	NR	3	Factor I: Items 5–7; Factor II: Items 1–3; Factor III: Items 1, 4, 7 (EFA and CFA)
Fernandez-Mendoza et al. (2012)	Spanish	500 medical students and their social networks	0.82	61.4	NR	3	Factor I: Items 5–7; Factor II: Item 4; Factor III: Items 1–3 (CFA)

Abbreviations: NR, not reported; N/A, not applicable.

^aParentheses indicate whether the factor structure was determined using exploratory factor analysis (EFA), confirmatory factor analysis (CFA) or principal components analysis (PCA).

two-factor structure of the ISI. This two-factor structure, evaluated using exploratory factor analysis only, indicated that Items 1–4 reflected one factor, whereas Items 5–7 reflected a second factor. In contrast, a prior study of 100 cancer survivors revealed substantially lower internal consistency ($\alpha = 0.73$) and a substantially different two-factor structure (Yusufov et al., 2019), such that only Items 1 and 3 reflected one factor, whereas 2, 4, 5, 6 and 7 reflected another. However, given that the sample in the Yusufov et al. (2019) study was small, the two-factor structure could not be evaluated using confirmatory factor analysis.

Understanding the measurement properties of the ISI is important for advancing research and clinical practice. In the present study, we analysed ISI data from the Black Women's Health Study (BWHS), a large nationally representative follow-up study of black women in progress since 1995 that includes a substantial number of cancer survivors. Our goal was to examine the psychometric properties of the ISI in black women with and without a history of cancer.

2 | METHODS

2.1 | Study cohort

Participants were enrolled in the BWHS, an ongoing, prospective study of black women in the United States established in 1995. This study was approved by the Institutional Review Board of Boston University and written informed consent was obtained from human participants. Women aged 21–69 were enrolled through questionnaires mailed to subscribers of *Essence* magazine, members of professional organizations, and friends and relatives of early respondents. This cohort comprises approximately 59,000 participants, who have been followed with biennial questionnaires (Rosenberg et al., 1995; Russell et al., 2001). The overarching goal of the BWHS is to understand the causes of health problems that affect black women.

Selection of participants for inclusion in the present analysis began with 31,593 women who completed the Insomnia Severity Index (ISI) included in the BWHS 2015 questionnaire. Women who reported a cancer diagnosis for the first time on the 2015 questionnaire ($n = 551$) were excluded, as they may have been undergoing active cancer treatment at the time they completed the ISI. Women who reported cancer at baseline (1995 questionnaire; $n = 512$) were excluded as we were unable to determine the accuracy of diagnoses made before baseline. We also excluded 850 women whose cancers were diagnosed in the 5 years before completion of the ISI (2010–2015) because their treatment or active cancer could have interfered with their usual sleep patterns and this analysis was focused exclusively on women who had completed treatment, except for endocrine therapy. We also excluded 181 women who reported a “tumour” of unknown type. Specifically, the sample of cancer survivors was comprised of women who reported a cancer diagnosis during follow-up (1995–2010) and had to be off treatment by 2015. “Cancer” was defined as any cancer identified by self-report, cancer registries or medical record. For participants reporting more than

one cancer, we considered their most recent diagnosis (i.e., that occurred closest to 2015). After these exclusions, 29,500 women had ISI data available for analysis, including 1,286 with a history of cancer and 28,214 with no cancer history (Figure 1).

2.2 | Measures

2.2.1 | Insomnia severity index

The ISI is a seven-item self-report checklist inquiring about insomnia symptoms over the two previous weeks. The first three items capture problems with falling asleep (#1), maintaining sleep (#2) and early morning awakenings (#3); the last four items capture sleep dissatisfaction (#4), sleep-related problems in daytime functioning (#5), noticeability of daytime functioning problems (#6) and insomnia-related distress (#7). 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. Total scores are interpreted as: 0–7, no or “minimal” symptoms; 8–14, subthreshold insomnia; 15–21, moderate insomnia; 22–28, severe insomnia (Morin, 1993).

2.2.2 | Data analysis

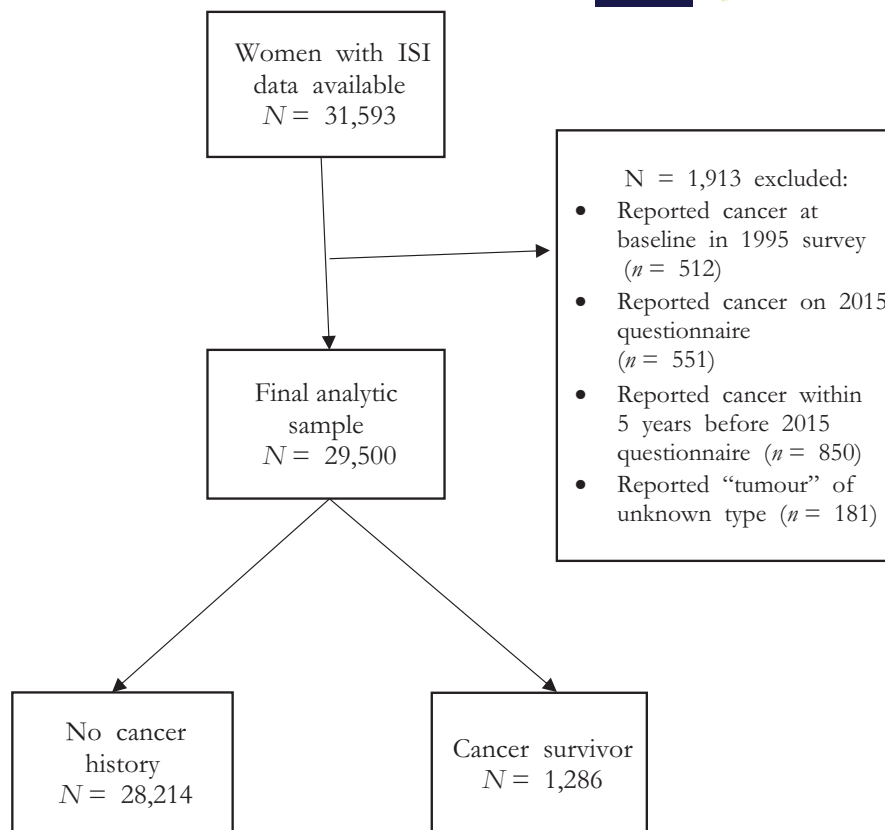
Item characteristics and internal consistency

Characteristics of the ISI items were described by reporting frequency, and mean, mode and corrected item-scale correlations for each ISI item. Internal consistency reliability of the ISI was examined using coefficient alpha (α), recalculated alpha (α) with each item deleted, coefficient omega (Ω) and recalculated omega (Ω) with each item deleted. Following published recommendations, we considered α and Ω of 0.70 to 0.79 as “acceptable”, 0.80 to 0.89 as “good”, and equal to or greater than 0.90 as “excellent” (Knapp, 1991). These descriptive statistics were calculated separately for the entire study cohort ($N = 29,500$), the cancer survivors ($n = 1,286$) and the non-cancer group ($n = 28,214$).

Exploratory factor analysis in cancer survivors

The cancer survivor sample was randomly divided into a derivation sample ($n = 643$) for exploratory factor analysis (EFA) and a replication sample ($n = 643$) for confirmatory factor analysis (CFA). Factor structure was examined using exploratory factor analysis with varimax rotation on item correlation matrices. The principal axis factoring extraction method was used, given that the ISI data were significantly not normally distributed (Kolmogorov-Smirnov test; $D(29,500) = 0.109$, $p < 0.001$) (Osborne et al., 2011). Eigen values (>1) and a scree test guided factor retention. Factor loadings >0.40 were reported and interpreted. Analyses were conducted using the Statistical Package for Social Sciences Version 26.0 (SPSS 26.0).

FIGURE 1 Flow diagram for inclusion of participants in analyses in the Black Women's Health Study (BWHS)



Omega (Ω) internal consistency reliability was calculated using jamovi version 1.2. Of note, although the factor structure of the ISI has been examined in multiple prior studies (see Table 1), there is currently no consensus regarding the factor structure of the ISI across samples and settings. Therefore, we conducted an EFA prior to a CFA in order to investigate the factor structure in this particular sample.

Confirmatory factor analysis in cancer survivors

Confirmatory factor analyses were conducted using Stata 16.0 with the replication cancer subgroup ($n = 643$) to evaluate the degree to which the replication sample fitted the model created by the EFA. Model fit and factor loadings were evaluated. Maximum likelihood estimation methods were used for fit indices (comparative fit index [CFI], non-normed fit index [NNFI], standardized root mean squared residual [SRMR], and root mean-square error of approximation [RMSEA]) because item data were ordinal (Kline, 2011). The Satorra-Bentler chi-square was used (χ^2) (Satorra & Bentler, 1994) as it adjusts the maximum likelihood chi-square to account for non-normality (Yu, 2010). The CFI values of 0.90 and above indicate good fit (Hu & Bentler, 1999). RMSEA values <0.05 indicate good fit, although values from 0.05 to 0.08 suggest reasonable approximation error, and values >0.10 indicate poor fit (Browne & Cudeck, 1993). As prior ISI studies (Table 1) suggested that the ISI might have a two-factor structure, (Chung et al., 2011; Savard, Savard, Simard, et al., 2005; Yusuf et al., 2019) alternative two-factor structures were also evaluated using this same CFA approach.

Multigroup confirmatory factor analysis

Multigroup CFAs (i.e., measurement invariance testing) were used to evaluate the consistency of the ISI's factor structure in the cancer and non-cancer groups. This was accomplished by systematically comparing fit statistics between the two groups. Initially, participants with and without cancer were set to have different model parameters (i.e., independent group analyses). Next, constrained factor loadings and factor correlations were set to be common across the cancer and non-cancer groups (i.e., simultaneous group analysis). Finally, CFAs were conducted with the entire study cohort ($n = 29,500$) and non-cancer subgroup ($n = 28,214$).

3 | RESULTS

Of the 28,214 participants with no cancer history, ages ranged from 40 to 90 years (mean [M] = 57.5, standard deviation [SD] = 9.6); 61.5% had completed 16 or more years of education and 59.9% were postmenopausal. Among the 1,286 cancer survivors, ages ranged from 41 to 89 ($M = 63.2$, $SD = 9.6$); 59.4% had completed 16 or more years of education, 84.5% were postmenopausal and 57.9% had breast cancer ($n = 745$) (see Table 2). The cancer survivors were older ($M_{\text{age}} = 63.2$) than the women without a history of cancer ($M_{\text{age}} = 57.5$) ($\chi^2(2, N = 29,500) = 340.6$, $p < 0.001$). The difference between the cancer and non-cancer groups for menopausal status was also significant ($p < 0.001$).

TABLE 2 Demographic and clinical characteristics of black women in the Black Women's Health Study (BWHS) with and without a history of cancer

	Cancer (n = 1,286)	No cancer (n = 28,214)	Total (N = 29,500)
Mean age, years (SD)	63.2 (9.6)	57.5 (9.6)	57.8 (0.1)
Age*			
35–49	103 (8.0%)	6,591 (23.4%)	6,694 (22.7%)
50–64	620 (48.2%)	14,991 (53.1%)	15,611 (52.9%)
≥65	563 (43.8%)	6,632 (23.5%)	7,195 (24.4%)
Years of education			
≤12	166 (12.9%)	3,321 (11.8%)	3,487 (11.8%)
13–15	355 (27.6%)	7,518 (26.7%)	7,873 (26.7%)
16	303 (23.6%)	7,659 (27.2%)	7,962 (27.0%)
≥17	461 (35.9%)	9,695 (34.4%)	10,156 (34.4%)
Menopause status*			
Premenopausal	108 (8.4%)	8,035 (28.5%)	8,143 (27.6%)
Postmenopausal	1,091 (84.8%)	16,912 (59.9%)	18,003 (61.0%)
Unknown	87 (6.8%)	3,267 (11.6%)	3,354 (11.4%)
Cancer types			
Breast cancer	745 (57.9%)	–	–
Gynaecological	141 (11.0%)	–	–
Gastrointestinal	129 (10.0%)	–	–
Haematological	92 (7.2%)	–	–
Endocrinological	74 (5.8%)	–	–
Genitourinary	34 (2.6%)	–	–
Lung cancer	24 (1.9%)	–	–
Head and neck cancer	14 (1.1%)	–	–
Sarcoma	13 (1.0%)	–	–
Melanoma	9 (0.7%)	–	–
Other solid tumours	11 (0.9%)	–	–

* $p < 0.001$ between cancer and non-cancer groups. SD, standard deviation.

3.1 | Item characteristics and internal consistency

In participants without cancer ($n = 28,214$), the mean ISI score was 7.82 ($SD = 6.18$), reflecting no or minimal to subthreshold insomnia, and the modal response for all items was 0, reflecting either high satisfaction or low impairment, except for Item 4, which had a modal response of 3 ("dissatisfied") (Table 3). A total of 12.4% ($n = 3,501$) met criteria for moderate insomnia and 3.1% ($n = 887$) met criteria for severe insomnia. Mean item scores ranged from 0.68 (Item 5) to 1.86 (Item 4). Item-total correlations ranged from 0.58 (Item 3) to .81 (Item 6), internal consistency reliability (α) was .89, McDonald's omega (Ω) = 0.892, and internal consistency would not have been improved by eliminating any item.

For the cancer survivors ($n = 1,286$), mean item scores ranged from 0.62 (Item 5) to 1.82 (Item 4) and the mean ISI score was 7.88 ($SD = 6.18$). A total of 13% ($n = 167$) met criteria for moderate insomnia and 2.8% ($n = 36$) met criteria for severe insomnia. The modal response for all items was 0, reflecting either high satisfaction or

low impairment, except for Item 4, which had a modal response of 2 ("moderately satisfied"). Item-total correlations ranged from 0.58 (Item 3) to 0.83 (Item 6) and the internal consistency reliability (α) was 0.89; McDonald's omega (Ω) = 0.896. Results demonstrated that internal consistency would not have been improved by eliminating any items.

3.2 | Exploratory factor analysis in the cancer survivor subgroup

First, data from the 643 participants designated as the derivation sample were analysed using parallel analysis. Specifications for the parallel analysis included seven variables and 1,000 datasets and generated random data eigen values of 1.10 and 1.06. The largest eigen values in the true data (EFA) were 4.25 and 0.76, indicating that a one-factor solution was optimal (i.e., 2nd eigen value was larger in random data than real data). The scree plot supported a

TABLE 3 Item-total correlations and descriptive statistics of the Insomnia Severity Index in the Black Women's Health Study (BWHS)

ISI item	Modal response			Mean (SD)			Corrected item-total correlation			McDonald's omega if item deleted		
	All	No cancer	Cancer	All	No cancer	Cancer	All	No cancer	Cancer	All	No cancer	Cancer
	0	0	0	0	0.96 (1.07)	0.96 (1.07)	1.03 (1.08)	0.60	0.60	0.63	0.89	0.89
1. Problems falling asleep	0	0	0	1.27 (1.15)	1.27 (1.15)	1.27 (1.14)	0.72	0.72	0.74	0.87	0.87	0.88
2. Problems staying asleep	0	0	0	1.02 (1.09)	1.02 (1.09)	1.02 (1.07)	0.58	0.58	0.58	0.89	0.89	0.89
3. Early awakenings	3	3	2	1.86 (1.21)	1.86 (1.21)	1.82 (1.23)	0.73	0.73	0.75	0.87	0.87	0.88
4. Dissatisfaction	0	0	0	0.68 (1.02)	0.68 (1.02)	0.62 (0.98)	0.62	0.62	0.59	0.89	0.89	0.89
5. Noticeability	0	0	0	1.01 (1.21)	1.01 (1.21)	0.98 (1.21)	0.81	0.81	0.83	0.86	0.86	0.86
6. Distress	0	0	0	1.03 (1.17)	1.03 (1.17)	1.01 (1.16)	0.76	0.76	0.75	0.87	0.87	0.87
7. Functional impairment	0	0	0									

Note: Total N = 29,500; cancer n = 1,286; non-cancer n = 28,214.

one-factor solution, with the largest eigen value being 4.25, accounting for 61.4% of the total variance. EFA indicated that all items loaded on to Factor I, with item loadings ranging from 0.68 (Item 3) to 0.89 (Item 6) (see Figure 2).

3.3 | Confirmatory factor analysis in cancer survivors

To determine the reliability of the factor structure derived from the EFA, a CFA was applied to the data from the replication sample of cancer survivors ($n = 643$). We also used CFA to determine fit for the structures of two-factor models previously reported in three studies (see Table 1; Chung et al., 2011; Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005).

The EFA-derived model (i.e., one-factor) had the highest CFI (0.93) (Hu & Bentler, 1999). However, its RMSEA (0.15) indicated unacceptably high approximation error (Browne & Cudeck, 1993). The two-factor solutions suggested in prior studies (Phipps et al., 2016; Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005) revealed poor fit, with a CFI of 0.77 and RMSEA of 0.26. An alternative two-factor solution (Chung et al., 2011) revealed poor fit, with a CFI of 0.77 and RMSEA of 0.26. Finally, the two-factor solution suggested by our previous study of cancer survivors (Yusufov et al., 2019) had poor fit in the present investigation, with a CFI of 0.30 and RMSEA of 0.34. In sum, none of the four models tested indicated adequate fit statistics, and the one-factor solution generated by the EFA analysis had superior fit compared to the other models tested (CFI = 0.93, RMSEA = 0.15). Fit statistics for the models are reported in Table 4.

3.4 | Comparisons of cancer and non-cancer groups

To examine the consistency of the ISI factor structure in the cancer and non-cancer groups, we conducted a multigroup CFA. The goal was to conduct a systematic assessment of measurement invariance across the two groups. However, the independent group analysis with cancer survivors and non-cancer participants set to have different model parameters failed to estimate after the 66th iteration, resulting in non-convergence (Boomsma, 1985). Similarly, the simultaneous group analysis with parameters set to be common across the cancer and non-cancer groups, failed to estimate after the 89th iteration (Boomsma, 1985).

Because of the non-convergence of these factor analytic models, we were unable to use multigroup CFA to quantify differences in fit between the cancer and non-cancer groups and to assess measurement invariance across the two groups. However, in examining factor loadings descriptively, we found that responses of the cancer and non-cancer groups were remarkably similar. Specifically, factor loadings ranged from 0.58 to 0.90 for the cancer subgroup and from

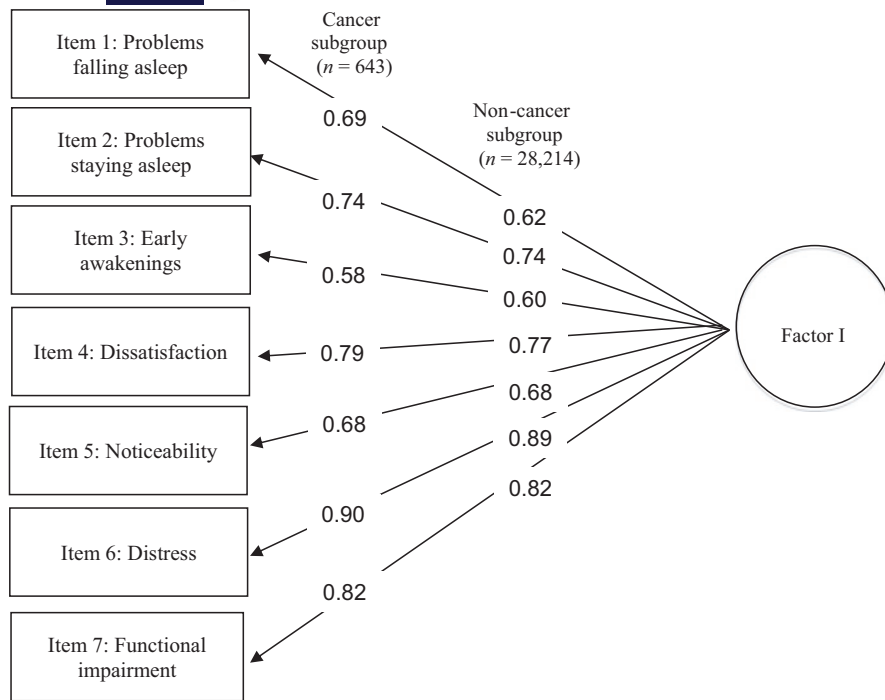


FIGURE 2 Factor structure of the Insomnia Severity Index in black women with and without a history of cancer in the Black Women's Health Study (BWHS). Factor loadings for the total study cohort ($N = 29,500$) are as follows: 0.73 (Item 1), 0.81 (Item 2), 0.68 (Item 3), 0.82 (Item 4), 0.70 (Item 5), 0.89 (Item 6), 0.83 (Item 7)

TABLE 4 Fit indices for confirmatory models for the cancer subsample ($n = 643$) in the Black Women's Health Study

Model source		$\chi^2_{SB^2}$ (df)	CFI	NNFI	SRMR	RMSEA (90% CI)
One-factor solution						
Present study EFA		203.6 (14)**	0.928	0.89	0.051	0.15 (0.13, 0.16)
Two-factor solutions						
Factor I: Items 1–4; factor II: Items 5–7	Savard, Simard, Hervouet, et al., 2005; Sadeghniaat-Haghighi et al., 2014; Yu, 2010	616.8 (14)**	0.763	0.653	0.348	0.26 (0.24, 0.28)
Factor I: Items 4–7; Factor II: Items 1–3	Chung et al., 2011	1302.9 (14)**	0.740	0.623	0.344	0.27 (0.26, 0.28)
Factor I: Items 2, 4, 5–7; Factor II: Items 1, 3	Yusufov et al., 2019	542.5 (14)**	0.302	0.103	0.247	0.34 (0.32, 0.37)

Abbreviations: CFI, comparative fit index; CI, confidence interval; *df*, degrees of freedom; EFA, exploratory factor analysis; NNFI, non-normed fit index; RMSEA, root-mean-square error of approximation; SRMR, standardized root-mean-square residual; $\chi^2_{SB^2}$, Satorra-Bentler scaled chi square.

* $p < 0.001$; ** $p < 0.01$

0.60 to 0.89 for the non-cancer subgroup. Across the cancer and non-cancer subgroups, loadings were identical for three of the items (Items 2, 5 and 7), nearly identical for three items (Item 3, 4, and 6) and had a 0.07 difference for Item 1 (see Figure 2).

4 | DISCUSSION

In a sizable sample of an under-represented population in sleep research, black women, we assessed the psychometric properties of the ISI among those with and without a history of cancer. The present study is the largest investigation of the factor structure of the ISI in any group. Regarding reliability, the internal consistency for

both the non-cancer subgroup ($\alpha = 0.89$; $\Omega = 0.892$) and cancer subgroup ($\alpha = 0.90$; $\Omega = 0.896$) is within the range observed in other clinical samples ($\alpha = 0.61$ to 0.92) (Yusufov et al., 2019). The internal consistency reliability results support the use of the ISI in black women, both with and without a cancer history. However, given inadequate fit statistics for the one-factor model, as well as lack of indices of validity, results of the factor analyses do not provide additional support or interpretive guidance for those using the ISI in black women.

Among the previous studies that did not include cancer patients, two found a one-factor structure (Kaufmann et al., 2019; Sierra et al., 2008), five found a two-factor structure (Albougami & Manzar, 2019; Chung et al., 2011; Yu, 2010) and four found a three-factor structure (Fernandez-Mendoza et al., 2012). The two previous

studies of cancer patients (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005; Yusufov et al., 2019) reported a two-factor structure for the ISI, but the nature of the factor structure differed substantially with items loading differently across the two factors. In a prior study of 1,670 survivors and patients on active treatment (48.6% female), the following four items represented the first factor: problems falling asleep, problems staying asleep, early awakenings and dissatisfaction with sleep. The following three items represented the second factor: noticeability of sleep problems, distress and functional impairment (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005). In our previous study of 100 cancer survivors, factor I captured five items: problems staying asleep, dissatisfaction, noticeability of sleep impairment, distress and functional impairment. Factor II captured two items: problems falling asleep and early awakenings (Yusufov et al., 2019).

As described above, the factor structures identified in previous studies have differed appreciably, varying from one to three factors. The present findings suggest that all seven ISI items are best viewed as making up a single factor. Two small prior studies, both of individuals without cancer, have supported a one-factor structure (Kaufmann et al., 2019; Sierra et al., 2008). There are several explanations for why our results may differ from those reported by some prior investigations. First, unlike prior studies that examined participants with higher ISI scores, (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005) most of the present cohort, whether affected by cancer or not, reported minimal insomnia symptoms. In addition, almost all prior studies of the ISI have included men (Cho et al., 2014; Kaufmann et al., 2019; Morin et al., 2011; Yusufov et al., 2019). Women may be affected by insomnia factors that are different to those in men, such as anxiety and depression, and reproductive factors (Soares, 2005) and menopausal symptoms (Baker et al., 2015) also could contribute to differential responding on the ISI. Previous investigations did not examine factor analytic differences across gender. Differences in our results from those of previous studies may also reflect racial and ethnic differences in insomnia symptoms (Giardin Jean-Louis et al., 2008; Girardin Jean-Louis et al., 2009). For example, black women tend to under-report insomnia symptoms (Foley et al., 1999), and prior research suggests that white female breast cancer survivors worried that breast cancer was associated with insomnia symptoms more than black female breast cancer survivors (Jean-Louis et al., 2009). Thus, black women reporting lower rates of insomnia could impact the factor structure of the ISI. Specifically, in the present study, mean ISI scores were low and most items had modal responses of zero, contradicting the broader literature on women and cancer survivors (Soares, 2005). Of note, our mean ISI score of 7.8 (indicating subthreshold insomnia) is similar to the median score of between 7 and 8 observed in women with breast cancer aged 56–65 years in a prior study (Savard, Simard, Hervouet, et al., 2005; Savard, Simard, Ivers, et al., 2005; Savard, Savard, Simard, et al., 2005). Finally, most previous studies were small and differences between studies might reflect sampling variation.

Although the use of an exclusively black female group is a major strength and contribution of this study, our findings may not be generalizable to males or to non-black groups. Further, given that this analysis assessed cancer survivors whose cancer had occurred at least 5 years previously, findings may not be generalizable to individuals on active cancer treatment, who have been shown to have high rates of insomnia or insomnia symptoms (Savard et al., 2001) and to report that cancer either caused or worsened insomnia. We note that we assessed cancer patients who were no longer in active treatment, so our results may not be applicable to black women receiving cancer therapy.

The results also may not generalize to groups with higher levels of insomnia symptoms or groups who meet criteria for an insomnia disorder. In addition, although we reported a strong similarity in responses between the cancer and non-cancer groups, we were unable to quantify differences between groups because of non-convergence in several models we tested. The fact that ISI item responses were highly correlated (Table 3) and highly skewed is likely to be a contributor. Validity studies may inform the extent to which the ISI is an adequate measure of insomnia in black women, and determine the best cut-off score for this population.

Inconsistencies across studies may reflect qualities of the ISI items themselves. Although many of the ISI items are consistent with the idea that they are “reflective” of insomnia (i.e., indicate core symptoms and consequences of insomnia), the first three ISI items, which inquire about specific insomnia symptoms, are better understood as being “indicators” or “formative” variables that measure *components* of insomnia that jointly define the condition. Specifically, Items 1–3 ask about insomnia symptoms at different points during sleep, corresponding to “early,” “middle” and “terminal” insomnia. In different populations, the prevalence of these different “types” of insomnia may well vary (Perlis & Gehrman, 2013; Yusufov et al., 2019) and individuals with one type of insomnia may not have symptoms of the other types. In that way, these variables are *not* consistent with the assumptions of internal consistency reliability and the factor analytic methods that have been used to examine the ISI in this and prior studies. Although including both “formative” and “reflective” variables in a single measure is not necessarily a limitation, especially in a measure of clinical symptomatology, it does mean that using analyses intended for reflective items alone can be problematic. Specifically, it can be expected that these analyses would result in the variability of internal consistency reliability and factor structures across samples that we have noted and the problem of model non-convergence (Boomsma, 1985) that we report in this study.

Finally, to the extent that internal consistency reliability and factor analytic approaches may not consistently capture measurement properties of the ISI, evaluating test–retest reliability and criterion validity could be useful alternatives. Future research evaluating validity of the ISI against accepted criterion measures in cancer survivors will be particularly important to insure it accurately identifies those in need of insomnia treatment. Recent studies have examined the validity of the ISI against structured diagnostic interviews

assessing DSM-5 diagnosis of insomnia disorder (Filosa et al., 2021), including a study of young adult cancer survivors (Michaud et al., 2021), but validation studies in larger and more diverse populations are needed. Clinicians and researchers using the ISI in black women and in cancer survivors would benefit from validation of specific ISI cut-off scores in these groups, and because the validity of a measure is limited by its internal consistency reliability (Price et al., 2015), results supporting the ISI's validity would also support its reliability, given that a measure cannot be valid unless it is also reliable.

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CONFLICT OF INTEREST

Miryam Yusufov serves as a paid consultant to Blue Note Therapeutics. The other authors have no interests to disclose.

AUTHOR CONTRIBUTIONS

All authors contributed to the study conception and design. Data analysis was performed by MY and CR. The first draft of the manuscript was written by MY and CR and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the senior author upon reasonable request.

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