

# Suggestion for Customized PROMIS Measurements of Sleep Disturbance and Fatigue for Ovarian Cancer Patients



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## BACKGROUND

- Sleep disturbance and fatigue are common among advanced stage ovarian cancer (OC) patients and associated with poor health-related quality of life<sup>1,2</sup>.
- PROMIS Short Forms (SFs) are frequently used to assess symptom burden in clinical and research settings in oncology patients<sup>3</sup>.
- This sequential mixed-methods study collected interview and survey data to assess OC patients' fatigue and sleep disturbance experiences across the treatment trajectory using a combination of custom PROMIS items and previously-validated SFs.

## DATA AND METHODS

- Qualitative analysis from 20 in-depth patient interviews informed the design of an original survey fielded with 200 Stage III and IV OC patients with diverse treatment trajectories with respect to treatment modalities, treatment timing, treatment response, and treatment status.
- Interview data illustrated four common facets of fatigue and sleep disturbance for OC patients that were not captured in widely-used SFs, namely emotional distress, cognitive impairment, social toxicity, and physical pain.
- A custom set of fatigue and sleep disturbance items from the PROMIS bank were selected and tested in a large-scale survey to assess OC patients' unique experiences across the treatment trajectory, along with previously-validated PROMIS SFs (8b & 8a), and sociodemographic and clinical covariates. Construct validity of the custom PROMIS items were evaluated using thematic prevalence from interview data, and Cronbach's Alpha coefficient was used to assess the scale reliability based on survey testing.

Participant Characteristics	Mean	SD	Participant Characteristics	n	%
Age, years (range 25-84)	56	13	<b>Employment Status</b>		
Sleep Disturbance Score (SF 8b)	56.9	5.4	Full- or part-time	74	37%
Fatigue Score (SF 8a)	60.9	9.1	Retired	58	29%
			Unemployed due to disability	44	10%
			<b>Treatment Status</b>		
<b>Race &amp; Ethnicity</b>			Currently getting treatment	67	42%
Non-Hispanic White	161	80%	Completed treatment	29	23%
Non-Hispanic Black	16	8%	Receiving maintenance therapy	88	26%
Hispanic	13	6.5%	Other	16	9%
Non-Hispanic other	9	4.5%	<b>Years Since Diagnosis (median=1)</b>		
Prefer not to share	1	1%	< 1 year	38	36%
<b>Annual Household Income</b>			1-2 years	68	34%
Less than \$40,000	34	17%	2-3 years	58	23%
\$40,000 to \$79,999	43	21.5%	3 years	36	41%
\$80,000 to \$119,999	46	23%	<b>Stage at Diagnosis</b>		
\$120,000 and above	53	26.5%	Stage III	142	71%
Prefer not to share	24	12%	Stage IV	56	28%
			Don't know	2	1%

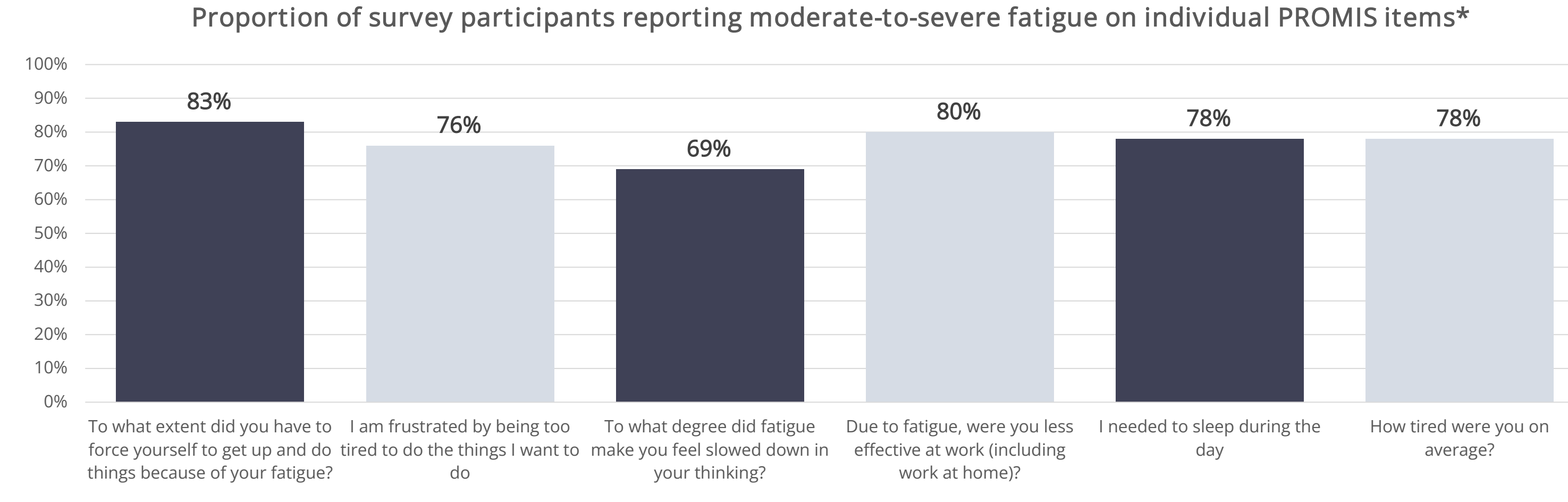
N=200 Surveyed

## RESULTS

Support for Construct Validity of Custom PROMIS Items for Fatigue		
PROMIS item stem ("When I was getting [treatment type]...")	Interview participants reporting issue	Exemplar quote
To what degree did you have to force yourself to get up and do things because of your fatigue?	14 / 20	"Coming home, even just making dinner, that takes a lot out of me. Before, I used to just make dinner and do the dishes and everything else and be fine. Now, especially if I'm making a big family meal, I have to stop and take a break because I do get tired and then by the time it's bedtime - I used to stay up until 3 in the morning, and now, by 8 o'clock, I'm done." - Participant 01
I am frustrated by being too tired to do the things I want to do.	15 / 20	"It's the fatigue that really bothers me... My body is just saying "no," and I don't have control over that. It pisses me off... Not being able to do whatever I want, whenever I want." - Participant 02
To what degree did your fatigue make you feel slowed down in your thinking?	7 / 20	"[Work] is a lot more challenging...I think things like fatigue and brain fog, specially make it hard to do, especially with the thought type of work I do...with the fatigue, everything is really slow... My response time is a lot slower in reaction to things or processing stuff..." - Participant 03
Due to fatigue, were you less effective at work (including work at home?)	15 / 20	"I was trying to do as much work as I could in between treatments, so that was pretty stressful to predict if I had the energy and brain power to do it or not. So, I ended up taking leave... I'm worried about getting back and remember everything because it's basically going to be six months since I've been out of office... I'm just not feeling very motivated" - Participant 04
I need to sleep during the day.	17 / 20	"The fatigue hits you hard... it's going to knock you out, it's going to sock you in the eye, punch you in the head...I typically book my [chemotherapy] treatment on Friday... so then, on Monday, I'm here [working from home], so I can lay down and take a nap for an hour." - Participant 05
How tired were you on average?	19 / 20	"I feel like I have no 'get up and go,'... I'm tired... I'll go down the stairs and just have to sit down because I'm so tired... I usually take a nap every day." - Participant 06

N=20 interview participants

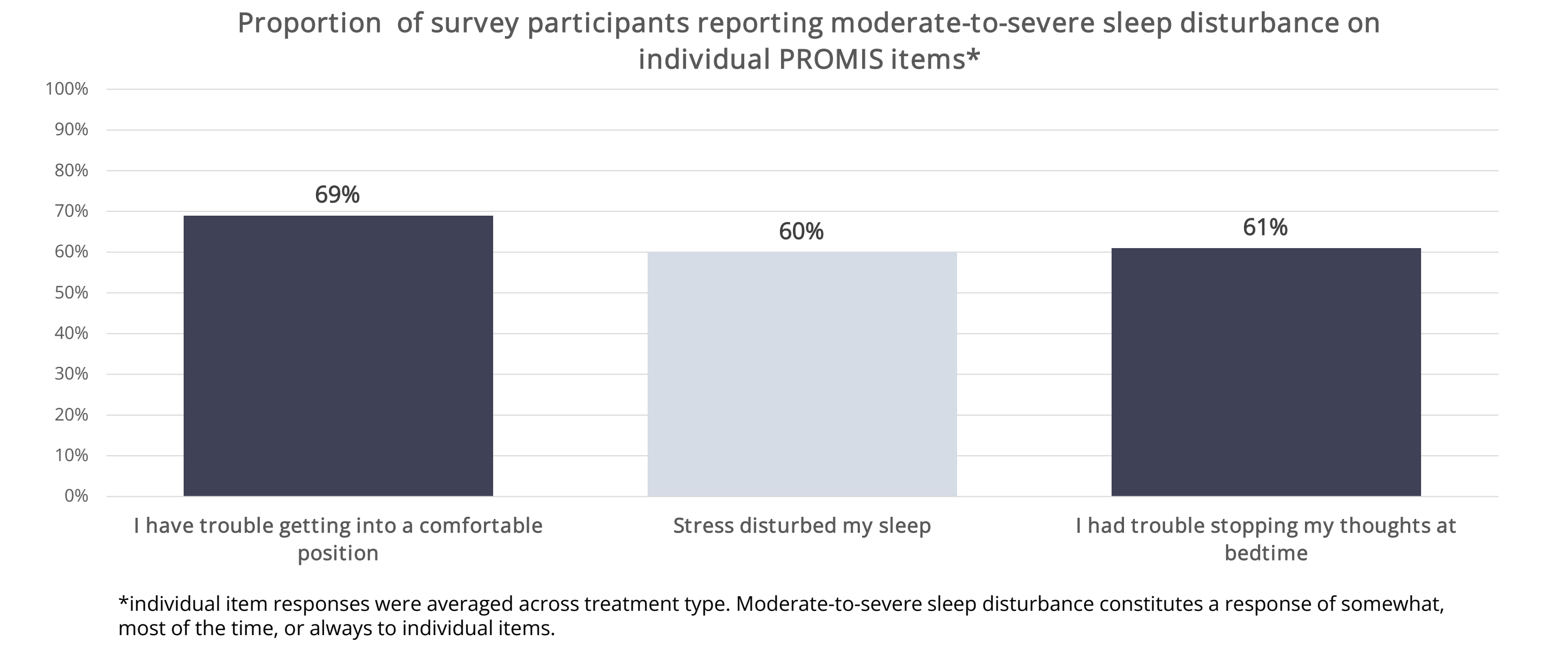
The prevalence of themes identified during interviews around emotional distress, cognitive impairment, and social toxicity were used to assess construct validity of custom PROMIS items in measuring OC patients' fatigue levels. Survey testing of custom items showed that they were reliable measures of fatigue (α=.939-.985).



Support for Construct Validity PROMIS Items for Sleep Disturbance		
PROMIS Item stem ("When I was getting [treatment type]...")	Interview participants reporting issue	Exemplar quote
I had trouble getting into a comfortable position	11 / 20	"I'm restless all night. I'm always tossing and turning. This hurts or that hurts... My knees hurt, and then my hips hurt.. It all snowballs." - Participant 08
Stress disturbed my sleep at night.	13 / 20	"When I was getting chemotherapy, my sleep was a lot worse...psychologically, that affects sleep... Because you're stressing and you're anxious about your diagnosis and what's going to happen." - Participant 09
I had trouble stopping my thoughts during bedtime	12 / 20	"I don't know if it's insomnia, but... My mind never shuts off, I don't know if it's cancer or the fear of dying... sleep hasn't been good ever since I was diagnosed." - Participant 10

N=20 interview participants

The prevalence of themes identified during interviews around stress, stopping thoughts at bedtime, and difficulty getting comfortable were used to assess construct validity of custom PROMIS items in measuring OC patients' sleep disturbance levels. Survey testing of these custom items showed that they were also reliable measures of sleep disturbance (α=.898-.946).



## CONCLUSIONS

Customizing the menu of PROMIS measures used to assess symptom burden among OC patients may improve identification of sleep disturbance and fatigue issues for this patient population. This study demonstrates that widely-used SFs do not capture the extent and complexity of psychosocial distress associated with sleep disturbance and fatigue for OC patients. These results may not be generalizable to all OC patients. Further research could help identify the best fitting set of questions for a clinical setting when screening advanced OC patients, as well as other patient groups with long term sleep and fatigue issues.

### References:

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