

Comments to the Authors:



Manuscript

SBSM Position/Guidelines Paper Review Form

Your responses are confidential upon submission of this form.

Instructions

Rate the quality of the paper on a number scale from 1-100. 70

Include major gaps and any issues with methodology, results or conclusions

The reviewed study attempts to address important questions to the field of BSM by reviewing relevant literature and qualitatively comparing these studies. I agree with the authors conclusions that medication tapering and associated support should be the result of a shared decision process between the patient and clinician in most cases.

However, I have concerns surrounding whether the samples of the 53 included studies accurately reflect the patient population in typical clinical practice. The exclusion of participants with comorbid psychiatric and contributing medical concerns is particularly concerning given the high prevalence of these factors in clinical practice. If the populations are highly controlled, I would recommend revising the primary study conclusions to explicitly state BSM support is appropriate but not medically necessary for adults who do not have comorbid psychiatric / contributing medical concerns (for example).

Including a list of the 53 studies - perhaps as a supplemental - would be of great benefit.

I would also encourage minor revisions to the results section to improve clarity surrounding the included study methods. For example, it's

Comments to the Organization:

Describe any concerns with the paper as well as implications for the field.

The reviewed study attempts to address important questions to the field of BSM by reviewing relevant literature and qualitatively comparing these studies. I agree with the authors conclusions that medication tapering and associated support should be the result of a shared decision process between the patient and clinician in most cases. However, I have significant concerns as to whether the study accurately reflects the realities of medication tapering support in typical clinical practice and whether the primary

study conclusions should inform a position paper. Secondly, I question whether the use of the RAM method in this study is the best means of informing a position paper concerning such an important topic.

Major Concerns

1. Transparency of included studies

Authors should provide a list of the 53 studies included in the analyses. Readers should have the ability to review the included studies to determine whether their specific patient population was included in the analyses / to what extent.

2. Representativeness of the study populations

From a clinician's standpoint, I have significant concerns about how well the study populations reflect the actual patient population in typical practice and the value of the conclusions given this uncertainty. More specifically, based on the in-text citations, it appears the eight papers listed below were included among the 53 total studies reviewed. In these studies, exclusion criteria included use of other psychotropic/psychiatric medication (n=3); concurrent psychiatric conditions (n=4); concurrent OSA, RLS or other chronic health conditions (n=4); and "poor candidates for CBT-I" (n=1).

I fully understand the rationale for a well-controlled clinical study and the tradeoff between internal and external validity. However, these study populations do not accurately reflect the patient population in typical clinical practice. Frankly, my FTE has been >80% clinical BSM over the last several years – and I don't think a single patient I have supported during a medication taper would have been included in these studies.

The full list of studies may be a better representation of typical patient populations. But if not, I feel the studies primary conclusion would be better presented as: "BSM approaches, in most cases, are appropriate but not medically necessary to integrate into sleep medication reduction efforts in adults who do not have any concurrent psychiatric comorbidities, psychiatric medication use, and/or chronic medical conditions including RLS or OSA."

I'm unsure of the value of such a statement considering the limited scope of its application. Secondly I think it's worth considering how such a narrow statement would contribute to the ongoing efforts to increase awareness of BSM and the value of our expertise.

To be clear, I don't think it's appropriate to state that BSM support is *medically necessary* for patients with comorbid psychiatric disorders (e.g., GAD, ADHD, MDD, Bipolar disorder), concurrent psychiatric medication use, and/or contributing medical concerns (e.g., RLS, OSA, chronic pain). However, I think the value of BSM tapering support for patients with these factors may differ from the benefits of BSM tapering support for patients without these factors. Secondly, I think it's important to consider how well position papers apply to typical clinical practice.

Studies referenced above

Ayabe et al., 2018

Fung et al., 2019

Garland et al., 2019

Giblin & Clift, 1983

Gilbert et al., 1993

Lichstein et al., 1999

Riedel et al., 1998

Taylor et al., 2010

Additional Concerns

Methods

I interpret the section below (under BSM interventions; pg. 6) to indicate 34 studies utilized CBT-I, and 6 utilized single components of CBT-I as stand-alone interventions. What intervention did the remaining 13 studies use? I may have missed something here but clarifying the number of reviewed studies and methods used is important given the purpose.

"Thirty-four studies (64%) used a multi-component CBT-I, the most common intervention, that consisted of

combinations of stimulus control (n=33; 62%), sleep restriction (n=26; 49%), cognitive therapy (n=28; 53%), relaxation (n=23; 43%), sleep hygiene (n=29; 55%), sleep education (n=17; 32%), and medication education (n=14; 26%). Six studies used a single intervention: stimulus control (n=3; 6%), sleep hygiene (n=2; 4%), relaxation (n=2; 4%), and medication education (n=1; 2%)."

Similar to the above concern, the description of treatment modality and content needs revised for clarity. 43 of the included studies utilized individual, group or hybrid format. What format did the other 10 studies use?

"Individual interventions were the most common (n=24), followed by group format (n=17); two studies used an individual/group hybrid format."

My understanding is that the function of position papers is to indicate the consensus amongst experts and guide the provision of BSM in clinical practice. With those functions in mind, I feel the application of statistical methods (e.g., meta analyses, systematic reviews) would be a more appropriate means of answering the study questions. I'm not strongly opposed to the RAM method from an empirical standpoint, but I do question whether a consensus among 6 panel members – two of whom (experimental psychologist & health sciences librarian) I would assume don't have experience in the clinical provision of BSM or tapering support – is the best way to achieve the functions of a position paper.

Overall, I feel the paper is adequate from an empirical standpoint and would be published if the authors were to pursue this outcome. However, I feel unable to positively endorse the questions below. The uncertainty surrounding the 53 studies included, representativeness of the study samples, and absence of statistical analyses/results derived from analytical comparison render me unable to determine whether the original studies support the papers conclusions or accurately reflect the benefits of BSM medication tapering support in typical clinical practice. As a result, I feel the paper is not appropriate for SBSM to endorse at this time.

Does the data support the conclusions of the paper?

No

Are the findings or recommendations a valid reflection of the current field?

No

Is this paper appropriate for the SBSM to endorse?

No

Form Completed By (Please provide your initials below) CJW