Author's response to reviews

Title: Internet-based cognitive-behavioural self-help for the premenstrual syndrome: study protocol for a randomized controlled trial

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Author's response to reviews: see over
Re-Submission of Study Protocol

Dear Prof. Altman, Dear Prof. Furberg, Dear Prof. Grimshaw,

Enclosed please find the revised version of our manuscript entitled “Internet-based cognitive-behavioural self-help for the premenstrual syndrome: study protocol for a randomized controlled trial” (MS: 2579731721340429). The revised manuscript is 27 pages long, including one table and one figure.

We wish to thank our reviewers for their valuable comments and their positive evaluation of the manuscript. We have incorporated the comments into the revised version for the resubmission. Please find attached our point-by-point reply to the reviewers' comments.

We hope that our manuscript is now suitable for publication in Trials and look forward to hearing from you.

Sincerely on behalf of all authors,
Johanna N. Kues

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Response to Reviewers

First of all, we would like to thank our reviewers for their valuable comments and their positive evaluation of the manuscript. We have incorporated the comments into the revised version for the resubmission. Below follows our point-by-point reply. All major changes are highlighted by underlinings in the text throughout the manuscript.

**Editorial requests:**
“Please include the date your study was registered with your trial registration number at the end of the Abstract.”
“Please include the reference number given with ethical approval with your ethics statement in the Methods section.”

**Response:**
We thank the Editors for the useful comments and have added the information.

**Reviewer 1:**
Reviewer 1 had no comments on the first version requesting a correction. We thank the reviewer for the positive evaluation of the manuscript.

**Reviewer 2:**
“The authors should discuss new developments in the diagnosis of PMS or PMDD within the DSM-5, as these are the most recent changes in the diagnosis (and treatment) the symptoms.”

**Response:**
We agree with the reviewer that we missed to explicitly discuss the new developments concerning the diagnosis within the DSM-5. We have now incorporated the new diagnostic criteria for the PMDD in comparison to the DSM-IV-TR and the proposed diagnostic criteria for the PMS (Section: Background, p. 4/5).

In the DSM-IV-TR, PMDD was only included in the appendix at a research criterion stage (American Psychiatric Association, 2000). Since DSM-5 (American Psychiatric Association, 2013) PMDD has been outlined as a distinct diagnostic category. To diagnose PMDD, at least five symptoms out of eleven (including at least one out of the first four affective symptoms) have to be confirmed by prospective daily self-ratings of PMS-symptoms in form of a diary over two consecutive menstrual cycles (American Psychiatric Association, 2013). These symptoms include (1) affective lability; (2) irritability or anger or increased interpersonal conflicts; (3) depressed mood; (4) anxiety or tension; (5) decreased interest; (6) difficulty in concentrating; (7) lethargy, fatigueability, or lack of energy; (8) change in appetite; (9) hypersomnia or insomnia; (10) a sense of being overwhelmed or out of control; and (11) other physical symptoms (e.g. breast tenderness, pain). The symptoms have to exist in the majority of cycles over the preceding twelve months and must cause significant distress or interference. Symptoms are not only an exacerbation of the symptoms of another mental disorder, however other mental disorders may co-occur. With the inclusion of PMDD in the DSM-5, some changes have been implemented (Epperson & Steiner, 2012), that is, “distress” in addition to interference, a more precise timing of the onset and the offset of the
premenstrual symptoms, possibility of co-occurrence of other mental disorders, possibility of a provisional diagnosis based on clinical history, and distinctiveness from substance use or another medical condition. In particular, the possibility of a provisional diagnosis is an important change as it allows an earlier diagnosis and thus earlier access to healthcare for suffering women (Cirillo, Passos, López, & Nardi, 2014). Also the extension of the interference criteria with the expression of distress is essential as it takes into account that women may maintain their function with a high level of distress without suffering from interference in functioning (Halbreich, 2004).

As already mentioned, PMS does not represent a distinct clinical entity and the distinction between PMS and PMDD remains unclear (Braverman, 2007). The American College of Obstetricians and Gynaecologists (ACOG) (American College of Obstetricians and Gynecologists, 2000) suggests some diagnostic criteria for PMS that require only one symptom out of a list of ten affective and somatic symptoms (American College of Obstetricians and Gynecologists, 2000). They seem to focus more on the impairment and distress than on a specified number of symptoms (Halbreich, Borenstein, Pearlstein, & Kahn, 2003; Halbreich, 2004). “\( a \): Wording of PMDD criteria in this text is simplified and abbreviated. For exact wording, please consult the DSM-5 manual (American Psychiatric Association, 2013).”

Furthermore, we added one sentence in the discussion (Section: Discussion, p. 17).

*The new criteria of the DSM-5 have not yet been proven in practice. Thus our study might help to test their practicability.*

“*Are there any internationally-validated instruments used to assess PMS symptoms in this study? The questionnaires presented here all seem to have been developed by the authors themselves.*”

**Response:**

We thank the reviewer for this very important comment. Whereas the two questionnaires assessing impairment caused by the premenstrual symptoms and coping with premenstrual symptoms are self-developed the questionnaire assessing PMS symptoms is not.

To our knowledge, there exist two questionnaires measuring impairment caused by the premenstrual symptoms and coping with premenstrual symptoms: the Premenstrual Symptoms Impact Survey (PMSIS; Wallenstein et al., 2008) and the Premenstrual Coping Measure (PMCM; Read, Perz, & Ussher, 2014). The latter had not been developed when our study started. However, both inventories are only available in English so far.

There are only two validated questionnaires in German which assess PMDS according to the DSM-IV-TR criteria: the Screening Instrument for Premenstrual Symptoms (SIPS; Bentz, Steiner, & Meinlschmidt, 2012 German version of the Premenstrual Symptoms Screening Tool (PSST)) and the German DSM-IV-TR-based Questionnaire for the Screening of Premenstrual Symptoms (Ditzen et al., 2011). We decided to use the latter one for the following reasons:

(1) The German DSM-IV-TR-based Questionnaire for the Screening of Premenstrual Symptoms measures premenstrual symptoms in a more detailed way by using 27 items instead of 14 items like the SIPS. This detailed assessment is particularly important in the context of an intervention study in order to be able to evaluate specific effects of our treatment.

(2) The SIPS possesses only one item asking for physical symptoms in general. Contrary, the German DSM-IV-TR-based Questionnaire for the Screening of Premenstrual Symptoms dif-
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ferentiates between the different physical symptoms. Many women report several different physical symptoms. Consequently, a questionnaire asking for different physical symptoms gives the women the feeling of being understood in their symptomatology and their illness perceptions. Furthermore, we would like to know which intervention may improve which physical symptom (e.g. sports, relaxation techniques).

(3) The authors of the German DSM-IV-TR-based Questionnaire for the Screening of Premenstrual Symptoms explicitly mention that this questionnaire can be used as a prospective diary. In our study we need a retrospective screening as well as a prospective diary to assess the diagnostic criteria.

We have summarized these reasons for the decision to use this questionnaire in the 'Assessments' section (p. 13):

> It measures the different dimensions of the premenstrual symptoms in a very detailed way.

“How does the study team monitor compliance with the study protocol?”

Response:

We are not sure if the reviewer was asking about information about compliance with the manual (treatment adherence), about compliance with the treatment (patients' compliance), or about compliance with the assessment. But we totally agree with the reviewer that all these information should be mentioned.

Consequently, we have incorporated three paragraphs which describe our procedure to monitor compliance (Section: Intervention and Section: Assessment, p. 12/13)

> To ensure therapist adherence to the manual they receive regular supervision by a licensed CBT therapist.

> To investigate patients' compliance with the treatment they are required to give a weekly e-mail feedback on the treatment material. If participants do not send their feedback they receive two e-mail-reminders. If they do not reply to these reminders they are called by their therapist.

> To ensure compliance with the assessment participants receive two reminders via email for every questionnaire they do not complete. If they do not reply the interviewer or the therapist calls the participant.

Again, we wish to thank our reviewers and the editors for the constructive comments on the manuscript and believe that it has been clearly improved.