Reviewer's report

Title: Cognitive Behaviour Therapy in Medication-Treated Adults with ADHD and Persistent Symptoms: A randomized controlled trial.

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Reviewer: Ylva Ginsberg

Reviewer's report:

The authors present the findings from an RCT evaluating the effectiveness of a CBT programme, as compared to treatment as usual, in pharmacologically treated adults with ADHD. This structured and manualised programme integrates 15 group sessions with individual coaching between sessions. It comprises five different modules, aiming to improve residual ADHD core symptoms, social, problem solving and organizational skills. The authors report that treatment with CBT in addition to medication had better outcomes than medication alone, in treating ADHD symptoms and common comorbid problems of anxiety, depression, antisocial behaviour and social functioning. Core ADHD symptoms improved significantly with a large effect size at the end of trial, and had further improved at 3-months follow-up. Improvements in comorbid symptoms were not significant at the end of trial, but evident at follow-up, suggesting that participants continued to use the acquired strategies, transferring them into daily life.

The manuscript is overall well-structured, well-written and of great interest and importance in the field.

However, I have some remarks calling for minor essential revisions, or discretionary revisions as follows:

1. Methods, Participants: The authors could preferably change “Ritalin, Ritalin Uno and Concerta” to generic names and also specify the different formulas, such as immediate-release methylphenidate and extended-release methylphenidate. Were there other stimulants provided except from methylphenidate? If so, please specify (minor essential revision).

2. Methods, Participants: The authors could preferably change stimulants to methylphenidate, or specify if other stimulants also were provided, such as amphetamine-salts (minor essential revision).

3. Methods: It should be easier to grasp the entire procedure if the authors provide a study flow chart (CONSORT) (discretionary revision).

4. Methods, Measures: Is there anything to report on psychometric properties for the modified K-SADS-PL ADHD section and CGI-ADHD (discretionary revision)?

5. Methods, Participants and Procedure: Regarding treatment with stimulants: It would be interesting to know the ranges and mean dosages of stimulants used by participants in both groups, before and after the trial, and if they were told to try to keep dosages unchanged during the study period, if possible (discretionary
6. Methods, the Intervention: The authors revised the R&R2 programme to fit ADHD. R&R2 ADHD comprises five treatment modules, according to the paper: 1) Neurocognitive, e.g. learning strategies to improve attentional control, memory, impulse control and planning, 2) Problem solving, e.g. developing skilled thinking, problem identification, consequential thinking, managing conflict and making choices, 3) Emotional control, e.g. managing feelings of anger and anxiety, 4) Pro-social skills, e.g. recognition of the thoughts and feelings of others, empathy, negotiation skills and conflict resolution, and 5) Critical reasoning, e.g. evaluating options and effective behavioural skills. In what way was the original R&R2 revised, except from decreasing the number of sessions from 35 to 15? Were the ingredients the same as in the original R&R2 programme, newly developed or modified in some way? What decisions were made during this process on what to keep and what to exclude in the programme to fit ADHD (discretionary revision)?

7. Methods, Procedure: Did the authors collect any Adverse Events during the trial? The authors could preferably comment on that and explain why AEs were not collected, or if they were collected, report them (discretionary revision).

8. Methods, Procedure: The authors could preferably expand a little bit about the control condition of TAU/MED. Were participants asked not to engage in other interventions than medication during the study period? Did other interventions take place? If so, what interventions? It is essential to know more about the comparator in relation to the experimental treatment condition (minor essential revision).

9. Methods, Procedure: Were the participants of the CBT/MED condition asked not to engage in other interventions during the trial besides the CBT programme and medication? If so, did the authors ask them afterwards to what degree they adhered to this recommendation (discretionary revision)?

10. Methods, Statistical analysis, and Results section: An intention to treat protocol was followed (analysed as randomized), but how did the authors handle missing values (drop-outs)? Did the authors calculate results both per protocol (completers only) and by including results from drop-outs, using an imputation method? It would be most appropriate to report results both ways, and discuss any differences in the Discussion section (minor essential revision).

11. Methods, Statistical analysis: The authors measured effect size by using partial eta squared. Most readers are probably more familiar with effect sizes measured by using Cohen’s d. To make results more interpretable, and to facilitate comparison with results from other trials, the authors preferably should report effect sizes by using Cohen’s d, in addition to, or instead of partial eta squared (minor essential revision).

12. Discussion, Limitations: Two limitations are discussed in the Discussion section. However, preferably the authors should include a third limitation. This study compared the experimental treatment condition of CBT/MED with a control condition of TAU/MED. Possibly (see remark nr 8) the control condition comprised medication only, or at the least, not group sessions in combination
with individual coaching. Therefore, it would be difficult to disentangle the nonspecific effects from meeting with a group, as well as with an individual coach, from the specific effects of the CBT ingredients, which is to be considered as a limitation. The way this study was performed, the effect size might have been exaggerated if participants of the TAU/MED group experienced less nocebo effect (minor essential revision).

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

Ylva Ginsberg has served as a principal investigator for Janssen-Cilag, and as a consultant and speaker for Janssen-Cilag and Novartis.