Author's response to reviews

Title: The SOSTA - net trial: a randomised, multi-centre controlled trial of the group-based social skills training SOSTA-FRA in children and adolescents with high functioning Autism Spectrum Disorder

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Submission of the revised article “The SOSTA – net trial: a randomised, multi-centre controlled trial of the group-based social skills training SOSTA-FRA in children and adolescents with high functioning Autism Spectrum Disorder” for publication in Trials

Dear editors,

Thank you very much for the positive comments on the above mentioned manuscript.

We have added the information which was requested by the editor:

1) As your research involves humans please include a statement of ethical approval in the Methods section of the manuscript, including the name if the body which gave approval, with a reference number where appropriate. Any experimental research on humans must be in compliance with the Helsinki Declaration.

This information was added under the header “Ethical Issues”.

2) Please include a section explaining your trial status. This should follow the “Discussion” section.

This section was added. The status of the trial at the time of manuscript submission also was added.

Answers to the comments of reviewer #1:

Major comments:

1. We do not agree with the reviewer’s suggestion to not allow individual therapy in addition to group based therapy and especially to eliminate individual therapy of the control group. Treatment as usual is allowed for (1) practical reasons: no parent would enrol a child into a study if she/he had to stop ongoing individual interventions for a case-control trial with a 50% risk of being randomised into the control group; (2) ethical reasons: children cannot be taken off their individual therapy and support at school for a trial with the risk of failing school because they are participating in the present study. The treatment and the control group are allowed to receive...
treatment as usual (TAU) with the exception of any kind of group based therapy throughout the study. The kind of and intensity of TAU is documented for each participant of the study and can be compared between groups. Due to the random allocation it is likely that both groups received the same average amount of TAU during the curse of the study, which in theory should eliminate group differences.

2. The unit of randomisation is not the group but the individual patient (who is allocated to one of the groups). Therefore, the random allocation procedure is not a cluster randomisation and hence there is no need to adjust the sample size accordingly.

3. It is the aim of the confirmatory analysis of our study to derive conclusions on the efficacy of SOSTA-FRA both at the end of therapy and three months after the end of therapy ('maintenance effect') while controlling the multiple type I error rate. This is accomplished by testing the related null hypotheses and applying the proposed multiple testing procedure. We included an explanation of the meaning of the two primary endpoints / null hypotheses to clarify the proposed procedure. Using a mixed effects model would provide no such differentiated results for these two specific time points of the longitudinal data but only global statements on differences in the time-course.

4. Group based therapy is not allowed during the 6 months prior to the trial. This is clearly stated as an exclusion criterion (table 2). It is highly unlikely, that any comparable kind of autism specific social skills training will have been offered the child prior to study, as there are hardly any options in Germany for such therapy.

5. This is an interesting comment, which we – unfortunately – cannot follow, as the study was planned differently and has started already in 2010. We will follow this comment in future trials.

Minor comments:

1. Information on the start of the study has been added in the last section.
2. SOSTA: social skills training in ASD; SOSTA-net: the trial; SOSTA-FRA: the manualised therapy program (this has been stated in the text).
3. See the reference given [5].
4. “skilled”: “minimum of 5 years of university studies plus >2 years of psychotherapy training”; this has been added in the text.
5. “mediating” has been changed to “moderating” – thank you for this detailed reading.
6. The part on the representativeness of the sample has been omitted from the text.
7. Several skills are thought within one group session, as e.g. introducing oneself to others, politeness, listening; and group rules are practices throughout the session, so the 18 skills fit well within the 12 sessions.
8. The respective sentence has been omitted from the text.

9. In Germany, students are visiting high school until the age of 19 years old. As no 20 y.o. has been included into the trial, this question has not arisen. In addition, University or Professional School teachers also can fill in the teacher report SRS.

All authors have read and approved the manuscript. None of the authors has any conflicts of interest to declare.

Yours sincerely,

Christine Freitag