Reviewer's report

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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Reviewer: Toshiaki Furukawa

Reviewer's report:

The paper presents the background and protocol (apparently abridged) of the trial of group-based social skills training program for children and adolescents with high functioning autism spectrum disorder. Overall the paper seems acceptable but there are several major criticisms and also a number of minor but essential comments that I hope will contribute to improving the paper.

MAJOR COMMENTS

1. The authors allow “individual language, psychomotor or behaviour therapy” in the waiting list control. Or they also state “any individual, e.g. cognitive-behavioural therapy, school-based intervention, occupational, language, psychomotor therapy) as well as family-based intervention is also allowed.” This grossly undermines the ceteris paribus nature of the comparison. If the trial is not yet started, I would strongly advise that they exclude these interventions from the control group.

2. The description of the random allocation procedure sounds like a cluster randomisation to me (the unit of randomisation is the group). The authors therefore need to adjust the sample size accordingly. Please consult a statistician.

3. The authors aim to examine the 12-week outcomes and the 3-month outcomes as if separately. Why don’t they use mixed effects model to the repeated measurements? Such seems the most natural, and the most informative way to analyse this longitudinal data.

4. The authors need to adjust for prior treatment. It appears from the authors’ descriptions of the TAU that the kind of social skills training contained in the experimental condition may be taught elsewhere. If the majority of the children have already received such training, the additive effect of group SST will evidently be smaller. This should be taken account of.

5. In order to assure the quality control of the therapies delivered, it is not enough to record only 1 session out of 12. It is advisable to record all the sessions and then check a random subset of them for adherence (if the investigators do not have enough time and manpower to check them all.)

MINOR COMMENTS
1. First of all, has this trial already been started? The readers would very definitely want to know. So, if yes, perhaps it is good to give some information about it in the paper itself.

2. What do SOSTA and SOSTA-net and SOSTA-FRA stand for? They should be spelled out upon its first appearance. And are they the same or different?

3. Page 3 “SST has been advocated as the most efficient treatment option.” Please cite a reference. And indeed if there is a scarcity of RCT for this approach, how can it be advocated and on what ground?

4. Page 6, skilled behavioural therapists. Please define “skilled.”

5. Page 7, variables possibly mediating. Is this not “moderating”?

6. Page 8, representative of individuals with high-functioning autism. From the description of the sampling method given, I cannot find any reason why the authors can claim that they are representative.

7. The program teaches 18 skills over the course of twelve 90-minute group sessions. This seems to be a bit too much to an adult CBT therapist like me.

6. Page 17, “Individuals in the treatment group are definitely expected to benefit from the study.” Will this sentence be compatible with equipoise of this trial?

7. The age of the participants is 8-20. What teachers evaluate those aged 18, 19 or 20?

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

TAF has received honoraria for speaking at CME meetings sponsored by Asahi Kasei, Eli Lilly, GlaxoSmithKline, Mochida, MSD, Otsuka, Pfizer, Shionogi and Tanabe-Mitsubishi. He is diplomate of the Academy of Cognitive Therapy. He has received royalties from Igaku-Shoin, Seiwa-Shoten and Nihon Bunka Kagaku-sha. He is on advisory board for Sekisui Chemicals and Takeda Science Foundation. The Japanese Ministry of Education, Science, and Technology, the Japanese Ministry of Health, Labor and Welfare, and the Japan Foundation for Neuroscience and Mental Health have funded his research projects.