Author's response to reviews

Title: Short-term psychotherapeutic treatment in adolescents with non-suicidal self-injury - A randomized controlled trial

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Author's response to reviews: see over
Dear Professors Altman, Furberg, Grimshaw, and Rothwell,

Thank you very much for the opportunity to submit a revised version of our manuscript to Trials. We would also like to thank the reviewer Sæn Perrin for the very constructive and helpful comments and suggestions as they have certainly improved the quality of this manuscript. Below, we have responded to each comment separately and have amended the manuscript accordingly. All changes in the manuscript are highlighted in yellow. In addition, the manuscript has now undergone professional language editing.

With Kind Regards,

Michael Kaess

Reviewer:

1. Will the study design adequately test the hypothesis?
This is a well designed study that will more than adequately address the stated hypotheses.

Thank you very much for appreciating our study.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?

The following information is missing from the manuscript:

We apologize for missing some important details. We have now included the missing information in the manuscript.

The authors need to say how IQ<80 was assessed.

The IQ<80, which we have now reworded as intellectual disability, is clinically assessed by a psychologist, and only adolescents who are students of a regular school are allowed to take part in the study. Being in a regular school is a very good indicator of a normal range of intelligence in Germany. In the manuscript the following sentence has been added: "Impaired
intellectual functioning (according to clinical evaluation by a psychologist, whereby only adolescents who attend a regular school were assessed)*.

It is not clear if the authors attempted to match the first post-treatment assessment points between the two groups in terms of duration since baseline assessment. Thank you for addressing this issue: we do match the post-treatment and the follow-up assessment points between the two groups in terms of duration since baseline assessment. In both groups the post-treatment assessment is four months after baseline and the follow-up assessment six months after the post-treatment assessment, with no regard for group affiliation. To highlight this fact within the manuscript, the following rewording was made on page 8: "After completion of the CDP, the post-treatment assessment will be conducted immediately, which is approximately four months after baseline assessment. In order to match the assessment points between groups, TAU participants will be invited to their post-treatment assessment four months after the baseline*

It does not seem logical or clinically safe that the therapists should be blinded to the information collected from the initial (baseline) assessment. It would be of great importance to the therapist to be effective to know the scores from the measures, the history etc. This sentence/section needs further clarification/justification.

We appreciate the reviewer's comments with regards to the blinding of our therapists to the baseline assessment information, as this issue has been extensively and controversially discussed within our research group. After these discussions, we finally decided to blind all therapists to the baseline information in order to keep the therapy as close to reality as possible, and in order to prevent advantages for the CDP group. We hope that the editors and reviewers can agree with our following arguments for the blinding: Our baseline assessment is a very broad and detailed assessment of the adolescents' medical history and mental state. It includes the results of reliable and valid semi-structured interviews which in "real-life therapy" the therapist would probably not have in "real-life therapy", every therapist would need a certain amount of time to assess each client. Our proposed short-term treatment allows, and explicitly plans, to do so during the first sessions. In the TAU group, German therapists usually conduct probation sessions (up to five sessions) to assess the adolescent's medical history and mental state. Additionally, we could have made the results of our research assessments available only to study therapists at our clinic (research assessments are not allowed to be handed over to other mental health services or private practitioners). Thus, this information could potentially bias the study results as it could be regarded as an advantage for the therapists in the CDP group.
3. Is the planned statistical analysis appropriate?
The planned analyses are appropriate to the design and hypotheses.

Thank you very much for your appraisal.

4. Is the writing acceptable?
The writing is acceptable. Suggested changes are as follows:

We thank the reviewers for the suggestions on our writing.

King's College London is one phrase, not “Kings College, London” as currently appears in the text (page 5, para 2).

We changed the wording to King's College London as mentioned by the reviewer.

The final sentence on page 5 should read "but a few of them [include percentage in parentheses]..."

We changed the final sentence on page 5 as mentioned by the reviewer to "but a few of them (22.2%)".

On page 6 it should read, "The main outcome of the trial is a clinically significant reduction....."

The very next sentence should read, "Secondary outcome criteria are a reduction in symptoms of depression as measured by the Beck Depression Inventory (BDI-II) [23] and increases in self-reported well-being and self-esteem as measured by the KIDSCREEN [24] and Self-Esteem Scales (SES) [25] respectively."

Primary hypothesis should read, "Significantly more adolescents in the CDP group than the TAU group will experience a clinically significant reduction in the frequency of non-suicidal self-injurious behaviours."

On page 6, should read "The potential participants and their families..." and "Boys and girls aged between 12 and 17 years with at least 5 prior acts of cutting,...."

We changed the sentences on page 6 as mentioned by the reviewer.

Top of page 7, should read, "The last NSSI must have occurred within the last month at the time of screening for the study. All adolescents were required to provide written informed consent to participate in the study, and for those under 16 years of age, written consent also had to be provided by the parents/care-givers/legal substitute."

Bottom of page 7, the word "postline" should be changed to "post-treatment" wherever the former is used throughout the manuscript. Also remove the phrase “supposed to be” from the following the second to last sentence in the final paragraph.
We changed the sentences on page 7 as mentioned by the reviewer. We also modified the word postline into post-treatment in the whole paper.

"Data Assessment" should be in bold as the other headings.

On page 8, the term "socio-biographic anamnesis" needs to be replaced with "sociodemographic interview"

We replaced "socio-biographic anamnesis" with "sociodemographic interview" according to the reviewer’s suggestion.

Page 12, the correct phrasing is "intent to treat"

We corrected the phrasing on page 12 in "intent-to-treat".

Page 12, the sentence should read "Clinically significant improvement is defined as a reduction of 50% in the frequency of NSSI's." The remainder of the paragraph needs rewording for correct English usage.

We corrected the sentence on page 12 and reworded the paragraph ("A clinically significant improvement is defined as a reduction in the frequency of NSSI by 50%. In this process the TAU group and the CDP group will be compared with each other to determine any differences in primary and secondary outcomes by using a $\chi^2$-test. As a secondary measure, ANCOVA with group as factor and frequency of NSSI at baseline as covariate will be assessed. Explorative analysis will be executed to account for the influence of childhood trauma, psychiatric diagnosis and personality traits and other factors potentially influencing the patients (e.g., gender). Descriptive analysis will be used to characterize the study sample. For nominal data frequencies will be determined, and for continuous data means and standard deviations with confidence intervals will be calculated.").

Throughout the manuscript and particularly in the Discussion section, the authors need to have a native English speaker read and offer suggestions on correct usage.

We thank the reviewer for the suggestions to have a native English speaker to correct the manuscript. We followed the advice and, after revising the manuscript, the paper was sent for professional language editing to a native English speaker.