Author’s response to reviews

**Title:** Impact of the intervention program “JolinchenKids – Fit and Healthy in Daycare” on energy balance related-behaviors: Results of a cluster controlled trial

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Author’s response to reviews:

Russell Pate (Reviewer 2):

“This revised manuscript is substantially improved over the original submission, but there is still a lack of clarity regarding the relationship between the adherence information that is based on process data and the outcomes of the interventions. This manuscript does a better job of presenting the fact that the process and (apparently) the outcome is based on the specific intervention modules selected by the centers.”

We thank the reviewer for his comments and addressed the points that were raised by him in order to make our findings for the reader clear and meaningful.

“However, the adherence categories are not clearly connected to the outcome analyses. For example, on 419 it is reported that 17 centers selected the physical activity module, and in Table 2 the distribution of children (but not centers, unfortunately) across adherence categories is presented. “

In order to gain insights into the intervention dose that individual children were exposed to, process evaluation data were obtained at the DF group level and not at the DF level. In total, our sample of children was taken care of at 64 different DF groups. Table 2 gives an overview of the self-reported intervention dose that was collected from kindergarten teachers working in the individual DF groups and the number of children who received this intervention dose. We agree with the reviewer that the information that was given in Table 2 was not sufficient to the reader. We corrected the last column name “Intervention DF” which was misleading. This column reports data on individual DF groups whereas in the body of the manuscript, we described module choices at the DF level. In the results
section, we now clarify that we provide data gathered from the use of paper-and-pencil calendars used to track intervention dose in individual DF groups which will be considered in additional analyses and we now report module choices, accordingly (Results section, line 395-401, page 17).

“However, the findings of the outcome analyses for the centers opting for the physical activity module as presented on lines 444 to 464 and in Table 5 do not link to the adherence categories and it is not clear that intervention versus control comparisons are between children in centers opting for the PA intervention versus children in the wait-list centers. In order for the findings to be clear and meaningful, these relationships must be presented in a much clearer manner.”

There might be a misunderstanding with regard to this comment. It was not our intention to provide information on the adherence categories in Table 5. Rather, our main analyses examined intervention effects on different outcomes across all intervention DFs as defined at baseline. The aim was to assess the extent to which such an intervention which allows for a flexible implementation of the various modules leads to changes in associated outcomes, regardless of the group-level implementation. In a second step, we wanted to investigate in an additional, more in-depth analysis how many of the participating intervention DFs partially or fully implemented modules and whether this had an impact on the intervention effect on associated outcomes. Due to the amount of results, we only provided results based on these analyses in the supplement. We have added information to the statistical analysis section in order to specify that in a first step, analyses were carried out across all intervention DFs, and in a second step, analyses were carried out taking adherence to specific intervention modules into account (Statistical analysis section, l. 350-351, p. 14 and l. 364-366, p. 15).

Joanna Myszkowska-Ryciak, Associate Professor (Reviewer 3):
“Dear Authors, My questions were answered and the suggestions mostly included, which in my opinion contributed to strengthen the manuscript.”

Thank you!

Anna Harton, Ph.D., Assistant professor (Reviewer 4):
“Thank you very much to the Authors for the extensive explanation and inclusion the most of my suggestions in the revised article. Below other suggestions that Authors should consider at work. I wish the Authors success in next research and all scientific work.”

Thank you very much!

"AH Ad.1. Thank you for including this information in the limitations section. However, information about the lack of general representativeness for the country of the examined DFs (not children attending daycare in Germany) should be included in the methodology (section: Study design and participants)."

The majority of children between the ages of three and five years attend daycare in Germany (93%, Federal Statistical Office. Day care for children. https://www.destatis.de/EN/Themes/Society-Environment/Social-Statistics/Day-Care-Children/_node.html. Accessed 23 April 2019). However, we now include further information about the general representativeness of our sample in our manuscript: “For example, the percentage of children with migration background in our study was 20% compared to 28% reported for children attending daycare in Germany in 2017 (51). The overall proportion of children with a migration background in that age group, including children who do and do not attend
daycare, is, however; higher (40%, 2018) (52). " (Discussion section, l. 578-581, p. 26)

"AH. Ad.13. Thank you for clarifying this issue. Information about the lack of validation of the research tool (FFQ) used should be added to the limitations section because such a tool can be a source of bias that limits the conclusions."

We agree with the reviewer and added this point to the limitations section (Discussion section, l. 567-568, p. 25). We also added more information about our self-developed food frequency questionnaire (FFQ) in the methods section in order to clarify that it adapted based on a validated FFQ that was previously used in a longitudinal cohort study examining health of children and adolescents in Germany (methods section, l. 281-283, p. 11).