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## **Incorrect Design and Analysis Renders Conclusion Unsubstantiated: Comment on ‘A digital movement in the world of inactive children: favourable outcomes of playing active video games in a pilot randomized trial’**

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Cluster randomized trials offer a design that allows researchers to randomize intact groups of subjects to treatment and to analyze groups of individuals where the effects of treatments are confounded with the groups. However, it is crucial that data are analyzed per the unit of randomization to draw valid conclusions.

We read with interest Coknaz et al.’s work [1], where they randomized four schools with three schools allocated to the active video game treatment and one school to the control group. In the data analysis, the authors justified not accounting for a clustered design by saying “There was no difference between the schools in terms of SES due to their public nature. Therefore, each student was assumed to act individually regardless of the attended school.”[1] This leads to two points of concern.

First and most importantly, the authors used only one cluster in the control arm. According to the CONSORT extension for cluster randomized trials, “Trials with one cluster per arm

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should be avoided as they cannot give a valid analysis, as the intervention effect is completely confounded with the cluster effect". [2]

The second concern is how the data were analyzed. The authors referenced the CONSORT extension for cluster randomized trials [2], but it contradicts their analytical decision to ignore clustering because it explicitly states "Even if cluster specific characteristics are balanced (that is, characteristics of the randomly allocated clusters), researchers have little control over the participants within each cluster (this is the case whether the number of clusters is large or small)." When clustering and nesting are not accounted for in the analyses, the type I error rate is likely markedly inflated.

Taken together, the data from this study should be re-evaluated and conclusions revised accordingly.

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