

## Answers

The child (answer *a*) was the unit of analysis.

The purpose of this cluster randomised controlled trial was to assess the effectiveness of the multicomponent physical activity programme on the physical and psychological health of young schoolchildren. For each child the change between baseline and follow-up in body fat, aerobic fitness, physical activity, and quality of life was recorded. The intervention and control groups were then compared in the outcome measures for the children who received each of the treatments. Therefore, the unit of analysis was the child (answer *a*). When comparing treatments in clinical trials, the outcomes for participants who received each of the treatments are almost always compared.

The unit of analysis is defined statistically as the “who” or “what” for which information is analysed. In the example above, the child was the unit of analysis and descriptive statistics were obtained for those children who received each of the treatments in order to compare the intervention and control groups. Because children were the unit of analysis, the conclusions related to them.

The example above used a cluster randomised controlled trial study design, which has been described in a previous question.<sup>(2)</sup> Cluster random allocation rather than simple random allocation was used to allocate children to treatment groups. This involved the random allocation of schools, and all classes recruited in those schools, to intervention or control, rather than the children themselves. The clusters—the classes—were natural groupings of children. All children in each class then received the treatment—intervention or control—that their school had been allocated.

The main reason for using cluster randomisation is that it overcame practical and contamination problems that may have arisen if trial participants had been randomised. For example, if the children had been allocated by simple randomisation it might have been difficult to implement the intervention for some children within a class but not for others. All classes within a school were allocated to intervention or control for similar reasons: to avoid practical and contamination problems if classes within a school had been allocated different treatments.

A distinction is made between the unit of analysis and the unit of observation. As described, the unit of analysis is defined statistically as the “who” or “what” for which information is analysed and conclusions are made. The unit of observation is defined statistically as the “who” or “what” for which data are collected. In the example above, the unit of observation and unit of analysis were the same, although they need not always be.

They typically differ, for example, in an ecological study. Ecological studies were described in a previous question,<sup>(3)</sup> where the example used investigated the association between injury resulting in hospital admission and socioeconomic deprivation in children.<sup>(4)</sup> Data were collected for children and aggregated across electoral wards in the Trent region of northern England. The purpose of the study was to compare electoral wards in their health status and needs. Therefore, the unit of observation was the child, whereas the unit of analysis was the electoral ward.

The conclusions of the ecological study were that those electoral wards with the greatest socioeconomic deprivation had the highest hospital admission rates for children with injuries. The ecological study did not allow the child to be examined and was therefore prone to the bias in interpretation known as the ecological fallacy. The ecological fallacy is a term used to describe when data are analysed at the group level but the results are assumed to apply to the person. It was reported that those electoral wards with the greatest socioeconomic deprivation had the highest hospital admission rates for children with injuries. However, it would be incorrect to assume that children who came from the most socioeconomically deprived families were most likely to be admitted to hospital with an injury.

Competing interests: None declared.

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- 2 Sedgwick P. Cluster randomised controlled trials. *BMJ* 2012;345:e4654.
- 3 Sedgwick P. The ecological fallacy. *BMJ* 2011;343:d4670.
- 4 Hippisley-Cox J, Groom L, Kendrick D, Coupland C, Webber E, Savelyich B. Cross sectional survey of socioeconomic variations in severity and mechanism of childhood injuries in Trent 1992-7. *BMJ* 2002;324:1132.

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