

## ENDGAMES

## STATISTICAL QUESTION

## Cluster randomised controlled trials

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Researchers investigated whether a systematic approach to the treatment of pain reduced agitation in people with moderate to severe dementia living in nursing homes. A cluster randomised controlled trial study design was used. The intervention comprised a stepwise protocol for the treatment of pain for eight weeks, with additional follow-up lasting four weeks from the end of treatment. The control group received the usual treatment and care.<sup>1</sup>

A sample of 352 residents living in 60 nursing home units across five municipalities of western Norway was identified. Each nursing home unit was independent, with no crossover of staff, and defined as a natural cluster for the purpose of the trial. Residents were eligible if they were aged 65 or older and had moderate to severe dementia and clinically significant behavioural disturbances. In total, 175 residents living in 33 clusters were randomised to intervention, and 177 residents living in 27 clusters were randomised to control. The primary outcome was agitation as measured on the Cohen-Mansfield agitation inventory. The researchers reported that the systematic approach to pain management significantly reduced agitation in residents of nursing homes with moderate to severe dementia.

Which of the following statements, if any, are true?

- The nursing home units were randomised to treatment group.
- All residents within a nursing unit had an equal probability of being randomised to intervention or control.
- The cluster of residents—the independent nursing home unit—was the unit of observation.
- Cluster trials are prone to the ecological fallacy.

## Answers

Statements *a* and *b* are true, while *c* and *d* are false.

In a cluster randomised controlled trial, cluster random allocation rather than simple random allocation is used to allocate trial participants to treatment groups. In the above example the clusters—*independent nursing home units*—were randomised to intervention or control rather than the residents themselves. The clusters were natural groupings of people. All the residents in each nursing home unit then received the same

treatment—*intervention or control*—that their nursing home had been allocated (*a* is true). Although the clusters and not the residents themselves were randomised to treatment, at the point of randomisation all residents within a nursing home unit had an equal probability of being allocated to intervention or control (*b* is true).

The sample of 352 residents was obtained by cluster sampling. Natural clusters of residents (*independent nursing home units*) were identified across five municipalities of western Norway. Sixty clusters were identified, and all eligible residents within the nursing home units were invited to participate. Cluster sampling is done for convenience: it was easier to identify all clusters in western Norway, and then sample all residents within the selected nursing home, rather than to obtain a complete list of all residents eligible for the trial across western Norway and then to select a random sample of residents.

The main reason for using a cluster randomised trial design is that it overcomes practical and contamination problems that may arise when trial participants are randomised. For example, if the residents had been allocated by simple randomisation it might have proved problematic to implement the intervention within a nursing home for some but not other residents. Although care staff would have been trained in the assessment and treatment of pain for both treatment groups, it might have proved difficult to treat residents differently depending on the group to which they had been allocated. Furthermore, residents allocated to the intervention might have influenced the activity of those allocated to the control group, or vice versa.

In the above example, although clusters were randomised to treatment, the residents were the unit of observation, not the cluster (*c* is false). Outcome measures were collected for each resident. The cluster randomised controlled trial is a between-subject study design. Nursing home units were randomised to treatment, and all residents within a home received the same treatment. The treatment outcomes were compared between treatment groups and therefore between independent groups of residents—that is, between subjects.

Cluster randomised controlled trials are not prone to the ecological fallacy (*d* is false). The ecological fallacy, described in a previous question,<sup>2</sup> is a term used when data collected at a

group level are analysed and the results assumed to apply to relationships at the individual level. In the above example, data were collected for each resident and not for each cluster. Ecological studies are prone to the ecological fallacy, where the unit of observation is a community or group of individuals. An ecological study design, for example, could be used to explore the relation between socioeconomic deprivation and acute emergency admissions to hospital for cancer. Data could be collected for electoral wards, with rates of admissions obtained from hospital statistics and a measure of socioeconomic deprivation derived for each electoral ward. If those electoral wards with the highest socioeconomic scores had the highest rates of admission to hospital for cancer, it would be an erroneous belief to assume that members of the community with

the greatest socioeconomic deprivation were more likely to be admitted to hospital for cancer. The purpose of ecological studies is to make large scale comparisons between groups of people, allowing an initial examination of the health status and needs of communities.

Competing interests: None declared.

- 1 Husebo BS, Ballard C, Sandvik R, Nilsen OB, Aarsland D. Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial. *BMJ* 2011;343:d4065.
- 2 Sedgwick P. The ecological fallacy. *BMJ* 2011;343:d4670.

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