

ENDGAMES

STATISTICAL QUESTION

Selection bias versus allocation bias

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The effectiveness of supported self management in reducing hospital readmissions and death in patients with chronic obstructive pulmonary disease was evaluated.¹ Researchers performed a randomised controlled trial. The intervention consisted of training patients to detect and treat exacerbations promptly, with ongoing support for 12 months. Patients in the control group continued to be managed by their general practitioner, hospital based specialists, or both.

Participants were patients admitted to one of six hospitals in the west of Scotland with an acute exacerbation of chronic obstructive pulmonary disease. In total, 464 patients were recruited and allocated to the treatment group using stratified randomisation based on demographic and disease severity factors. The main outcome measures included time until first hospital readmission or death owing to chronic obstructive pulmonary disease. The researchers reported that supported self management had no effect on time to first hospital readmission or death with chronic obstructive pulmonary disease.

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

- The method of patient recruitment meant there was the potential for selection bias
- Selection bias would result if patients were selected for treatment groups on the basis of a preference by one of the researchers
- The randomisation of patients to treatment group minimised allocation bias
- The randomisation of patients to treatment group minimised selection bias

Answers

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

The purpose of this randomised controlled trial was to evaluate the effectiveness of supported self management in reducing hospital readmissions and death in patients with chronic obstructive pulmonary disease. Patients were recruited using convenience sampling, which has been described in a previous question.² Stratified random allocation was used to allocate treatment.³

Selection bias would have occurred if there was a systematic difference between patients recruited to the trial and those who were not recruited, because this would mean that the sample was not representative of the patient population. Unfortunately, confusion often exists as to what is meant by the “population” in statistics, probably because it has a different meaning to its general everyday one, where it is used in a geographical sense. The above trial had well defined inclusion criteria that uniquely characterised the population. Statistically, the population would be regarded as an infinite group of people, but in reality there would be a finite number of patients with the same condition. Convenience sampling was used to recruit participants from patients admitted to one of six hospitals in the west of Scotland with an acute exacerbation of chronic obstructive pulmonary disease. However, the extent to which the sample was representative of the population was not clear and there was the potential for selection bias (*a* is true).

Allocation bias would have occurred if there was a systematic difference between participants in how they are allocated to treatment. Participants were allocated to treatment groups using stratified randomisation. Therefore, each participant had the same probability of being allocated to intervention or control and allocation bias would have been minimised (*c* is true). Stratified randomisation of participants was based on demographic and disease severity factors to control for key predictors of readmission. As a result, systematic differences in confounding factors between treatment groups at baseline were minimised, although not necessarily eliminated. Hence, any differences in outcome between treatment groups when the trial ended would have been due to differences in treatment and not to differences in characteristics at baseline.

Allocation bias would have occurred if, for example, the researchers had allocated those patients who they thought would show the greatest benefit from treatment to the intervention. The researchers might have done this, for example, because they favoured the intervention and wished to show that it was more effective than the control treatment.

Confusion frequently occurs in the interpretation of selection bias and allocation bias. As described, selection bias occurs if the selected sample is not representative of the patient

population. Sometimes selection bias is incorrectly thought to be the systematic difference in how patients are assigned to a treatment group—for example, if patients are selected for a treatment group on the basis of a preference by one of the researchers (*b* is false). If there is a systematic difference between participants in how they are assigned to treatment groups, then it is referred to as allocation bias. As described, allocation bias is minimised by the use of random allocation. The randomisation of patients to treatment groups will not affect selection bias (*d* is false).

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