

ENDGAMES

STATISTICAL QUESTION

Allocation concealment

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Researchers assessed the effects of a multimodal group exercise programme, as an adjunct to conventional care, on fatigue, physical capacity, general wellbeing, physical activity, and quality of life in patients with cancer undergoing chemotherapy. The intervention consisted of supervised exercise comprising high intensity cardiovascular and resistance training, relaxation, and body awareness training, together with massage, for nine hours a week for six weeks in addition to conventional care. A randomised controlled trial study design was used. The control treatment was conventional medical care.¹

The sequence in which participants were allocated to treatment was generated randomly by computer. Participants were recruited by a clinical research unit that was not involved in treatment delivery or data collection. To ensure allocation concealment, the patients and the research unit were unaware of the allocation sequence before recruitment. Treatment allocation was revealed only after patients had been allocated.

The primary outcome was self reported fatigue. The secondary outcome measures were collected by self report and from medical records, as well as by the physiotherapists and trained nurse specialists who carried out the intervention. The researchers reported that the multimodal exercise intervention was feasible, could be safely delivered, and reduced fatigue.

Which of the following types of bias, if any, did allocation concealment minimise?

- a) Allocation bias
- b) Ascertainment bias
- c) Detection bias
- d) Selection bias

Answers

Allocation and selection bias (answers *a* and *d*) were minimised by allocation concealment, whereas ascertainment and detection bias (answers *b* and *c*) were not.

The random allocation of participants to treatment was essential to achieve comparability between groups in baseline characteristics. If treatment groups differed at baseline, confounding may have resulted. Confounding factors are those that affect treatment and outcome measures and include

demographic characteristics, prognostic factors, and other characteristics that influence someone to participate in or withdraw from a trial. Therefore, differences between treatment groups in outcome may have been due not to differences in treatment received but to differences at baseline. Randomisation is crucial in clinical trials to be able to infer causation between treatment and outcome.

The success of randomisation in the trial depended on allocation concealment, without which it may have been possible to subvert the recruitment of participants and their allocation to treatment. The allocation sequence was constructed by someone not involved in recruitment or treatment allocation. Treatment allocation was revealed only after patients had been allocated. Allocation concealment therefore minimised selection bias (answer *d*). If the nurses and physicians recruiting the patients knew the allocation sequence, they may have selected, unconsciously or otherwise, which patients were recruited or the order in which this was done. They may have believed that some patients would not have accepted or been suitable for the next treatment in the sequence. Patients were also unaware of the allocation sequence, thereby ensuring they were not able to dictate their participation or “self selection” on the basis of knowledge of the subsequent treatment in the sequence. Allocation concealment also therefore minimised allocation bias (answer *a*): by not knowing the allocation sequence, the patients and the recruiting nurses and physicians were unable to influence who received the next treatment.

Allocation concealment should not be confused with blinding. Allocation concealment, which can be achieved in all trials, necessitates the patients and recruiting personnel not knowing the allocation sequence. Allocation concealment safeguards the allocation sequence before and until the participants have been allocated, thereby limiting confounding by minimising selection and allocation bias. Blinding, however, safeguards the allocation sequence after randomisation and cannot always be achieved. It was not possible to blind the participants or outcome assessors in the trial. If it had been possible to do so, ascertainment bias would have been minimised. Ascertainment bias (answer *b*), sometimes referred to as detection bias (answer *c*), is the systematic distortion of assessment of outcomes, unconsciously

or otherwise, by the investigators or participants because they know the treatment allocation. Allocation concealment does not therefore ensure that ascertainment bias is minimised. Ascertainment bias on behalf of the assessors, sometimes called assessor bias, can be the result of assessors favouring one treatment over the other. Ascertainment bias on behalf of the participants, sometimes called reporting or response bias, can occur as a result of patients giving responses that they believe the assessors wish to hear.

Competing interests: None declared.

- 1 Adamsen L, Quist M, Andersen C, Møller T, Herrstedt J, Kronborg D, et al. Effect of a multimodal high intensity exercise intervention in cancer patients undergoing chemotherapy: randomised controlled trial. *BMJ* 2009;339:b3410.

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