BMJ

BMJ 2011;342:d3427 doi: 10.1136/bmj.d3427

ENDGAMES

STATISTICAL QUESTION

Open label trials

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Researchers assessed the effectiveness of a supervised exercise programme for the treatment of patellofemoral pain syndrome. An open label randomised controlled trial was performed. Participants with a new episode of patellofemoral pain syndrome were recruited by general practitioners or sport physicians. The intervention group received a six week standardised exercise programme tailored to individual performance and supervised by a physical therapist; people in this group were instructed to practise the personalised exercises at home for three months. The control group received usual care, comprising a "wait and see" approach of rest during periods of pain and avoidance of pain provoking activities.[1]

The primary outcome measures were self reported recovery, pain at rest, pain on activity, and function at three months and 12 months of follow-up. When compared with usual care, supervised exercise therapy resulted in significantly less pain and better function, although no difference in recovery was seen.

Which one of the following statements best describes an open label trial?

a) The investigators and participants are both blind to treatment allocation

b) Only the investigators are blind to treatment allocation

c) Only the participants are blind to treatment allocation

d) The participants and investigators are both aware of treatment allocation

Answers

Answer *d* is the best description. In an open label trial, the participants, investigators, and all peripheral staff know which participants are allocated to which treatment. Because the treatments differed greatly in nature and participant involvement, it was not possible to blind the participants and investigators to treatment allocation. The necessity for informed consent before trial recruitment meant that participants were informed about the treatment options. Participants were then randomised to the treatment groups, either the standardised exercise programme or control treatment consisting of the "wait and see" approach.

This awareness of treatment allocation may have led to methodological problems. Participants who received the standardised exercise programme may have felt that they were receiving special attention, and this could have biased them to respond more favourably in the self reported outcome measures. Similarly, those allocated the control treatment may have believed there was an apparent lack of care and been biased in their response for an unfavourable outcome. Furthermore, if participants were not allocated their preferred treatment they may have been less likely to comply with the treatment regimen and may even have left the trial. This would have led to reduced apparent effectiveness of treatments. Because the outcome measures were self reported by participants, there would have been little opportunity for investigators to have introduced bias. However, the physical therapists supervising the standardised exercise programmes would no doubt have favoured this treatment, and they might have encouraged participants to report more favourable outcomes.

Competing interests: None declared.

1 Van Linschoten R, van Middelkoop M, Berger MY, Heintjes EM, Verhaar JAN, Willemsen SP, et al. Supervised exercise therapy versus usual care for patellofemoral pain syndrome: an open label randomised controlled trial. *BMJ* 2009;339:b4074.

Cite this as: *BMJ* 2011;342:d3427

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