



# Fiction and Fantasy in Medical Research: The Large Scale Randomised Trial

*James Penston*

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## **Fiction and Fantasy in Medical Research: The Large Scale Randomised Trial** James Penston

Fiction and Fantasy in Medical Research: The Large-Scale Randomised Trial Every day, millions of patients around the world take medication based on the results of large-scale randomised trials. This method of testing the efficacy of new drugs is widely accepted as the gold standard of medical research. But is this accolade deserved? Fiction and Fantasy in Medical Research subjects the large-scale randomised trial to scrutiny and finds it to be seriously flawed. The best that may be said for these studies is that they merely demonstrate a trivial benefit to patients. But, given the lack of any sound foundation for the methodology, even such modest claims have to be questioned. On the basis of the results of these studies, more than 95% of patients receiving long-term treatment with lipid lowering drugs obtain no benefit whatsoever; of every ?1 million pounds spent on these drugs, more than ?950,000 is wasted. If, as is argued, the methodology is flawed, then these estimates exaggerate the possible benefits of treatment. Yet, the drugs continue to be widely prescribed, exposing patients over long periods of time to the risk of side-effects. This critical appraisal of the large-scale randomised trial raises fundamental issues. How is it that a flawed methodology is so readily embraced by all involved in the delivery of health care? To what extent are those with a vested interest able to influence the outcome of these studies? And what are the ethical implications of treating patients on the basis of such dubious data? The answers to these and many other questions make uncomfortable reading for the advocates of the large-scale randomised trial currently involved in clinical research.

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