Placebo comparator group selection and use in surgical trials: the ASPIRE project including expert workshop

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Plain English summary

The ASPIRE study including expert workshop

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Plain English summary

What was the research about?

One of the best ways to prove that a new medicine really works is to use a scientific test called a 'placebo-controlled trial'. In this type of test, half of the participants are given a new pill and the other half are given a 'placebo', which is a dummy pill (usually a sugar pill) that is made to taste and look the same as the active pill, but has no active ingredients. The results are then compared.

Just like medicines, new surgical procedures need to be tested to show that they are safe and benefit patients. Ideally, they would also be tested using the 'placebo-controlled trial' approach, but asking patients to have 'dummy' surgery is not the same as asking people to take a dummy pill. Placebo surgery raises lots of ethics questions and is controversial. As it is controversial, guidelines are needed to recommend when placebo surgery studies can be used (if at all) and what special considerations need to be taken into account. Our research team was commissioned to develop these guidelines.

What did we do?

We summarised, to the best of our knowledge, all previous research that had used placebo surgery and reviewed all the ethics literature on this topic. We also looked at the latest scientific understanding of how placebos work.

We then held a workshop to discuss and summarise the existing knowledge and to develop the new guidelines. This involved an international team of patients, surgeons, researchers, ethicists, psychologists, physiologists and funders.

We published the guidelines [i.e. the ASPIRE (Applying Surgical Placebo in Randomised Evaluations) guidelines] in an influential medical journal and also wrote several other publications. This report provides a slightly more detailed version of our findings and recommendations.

Who will this help?

The guidelines will help researchers and doctors know when, and how, to best design placebo surgery studies in the future.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

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This report

This issue of the Health Technology Assessment journal series contains a project commissioned by the MRC–NIHR Methodology Research Programme (MRP). MRP aims to improve efficiency, quality and impact across the entire spectrum of biomedical and health-related research. In addition to the MRC and NIHR funding partners, MRP takes into account the needs of other stakeholders including the devolved administrations, industry R&D, and regulatory/advisory agencies and other public bodies. MRP supports investigator-led methodology research from across the UK that maximises benefits for researchers, patients and the general population – improving the methods available to ensure health research, decisions and policy are built on the best possible evidence.

To improve availability and uptake of methodological innovation, MRC and NIHR jointly supported a series of workshops to develop guidance in specified areas of methodological controversy or uncertainty (Methodology State-of-the-Art Workshop Programme). Workshops were commissioned by open calls for applications led by UK-based researchers. Workshop outputs are incorporated into this report, and MRC and NIHR endorse the methodological recommendations as state-of-the-art guidance at time of publication.

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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