

the quality of patient information and making the study more relevant to patients' needs.^{7,8}

During the informed consent procedure patients are told that they may receive a placebo; this is usually described as a harmless inactive substance or an inactive dummy drug. We found that the most common method of informing patients in the placebo arm was to simply tell them that they were in this arm, without giving possible explanations for this effect. Just as knowing that patients have a 50% chance of being randomised to a placebo has been shown to influence health outcomes, it is possible that the placebo response may be disrupted when the treatment is unmasked to patients who have responded.⁹ Unmasking the allocation of placebo may be a source of confusion and disappointment to patients and may even damage clinical relationships and have negative effects on patients' health, particularly in placebo surgery. For this reason, feedback should be handled sensitively. A recent trial evaluating the effects of antidepressants found that when placebo responders were told that they were receiving a placebo their mood deteriorated.¹⁰ Within a month 70% of the patients needed antidepressants.¹¹ In another study, 50 patients with depression who responded to placebos over a 10 day single blind trial were randomised in a double blind way to either continue taking placebos for six weeks or to stop treatment. Half in each group relapsed at six weeks.¹² Therefore unmasking had no effect.

To avoid negative thoughts, misconceptions, or mistrust in health professionals, patients must be well informed. They could be told about the various debates on the therapeutic effectiveness of placebos, but that there is growing evidence for the healing effects of psychological and social factors, such as positive expectations and good patient-doctor relationships.^{13,14}

Practical and research implications

A major gap is apparent in the literature examining patient understanding of placebos and their effect. Research should examine whether and how treatment should be disclosed to patients and the risks that disclosure may have on measured outcomes. Assessing context effects such as treatment preferences and the level of enthusiasm for trial participation may encourage a participant partnership approach in trials. It may also decrease the likelihood of disrupting placebo responses. Such research would therefore aid the development of effective and sensitive ways to communicate trial and treatment information to participants.

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What is already known on this topic

Information is poor on the nature, extent, and effect of informing participants of placebo controlled randomised trials about their treatment allocation at trial closure

Less than 50% of participants receiving placebo are informed about their treatment allocation

What this study adds

No standard procedure is available for informing patients of their treatment arm or of study results at trial closure

Effective and sensitive ways of communicating treatment allocation to participants are required, as is information on the effects on placebo responders

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Corrections and clarifications

Minerva

Our electronic processing system allowed an author's name to "drop off" the authorship details accompanying a Minerva photograph (19 October p 912). B J Burgess is a specialist registrar in accident and emergency medicine at Southend Hospital, Westcliff-on-Sea, Essex SS0 0RY.

The SCOFF questionnaire and clinical interview for eating disorders in general practice: comparative study
In the graph of a receiver operating curve in this article by Amy J Luck and colleagues (5 October, pp 755-6), the label for the x axis should have read "1 - specificity" [not "specificity"].

Whooping cough—a continuing problem

In this editorial by N S Crowcroft and Joseph Britto (2002;324:1537-8), we inadvertently failed to include Dr Crowcroft's statement of his competing interests. The following statement should have appeared with the article: "NSC has participated in epidemiological studies jointly funded by the Public Health Laboratory Service and Aventis Pasteur and GlaxoSmithKline, which manufacture various pertussis vaccines and which may gain or lose from the conclusions of this editorial."