Study calls for drug trial patients to receive more information about effects of placebos

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Research carried out at the University of Southampton has concluded that participants in drug trials should be better informed about the potential significant benefits and possible side-effects of placebos.

Placebos are traditionally thought of as 'inert' pills, given in trials to act as a yardstick or constant by which to measure the effects of new 'active' drugs, known in clinical trials as the 'target treatment'. However, placebos themselves have been shown to create substantial health changes in patients.

"We believe the health changes associated with placebos should be better represented in the literature given to patients before they take part in a clinical trial. At the moment these effects are largely being ignored in the patient information leaflets," says lead researcher at Southampton and lecturer in psychology, Dr Felicity Bishop.

She continues, "There is an important issue of consent here – patients should be fully aware of possible health changes from all treatments in a trial before agreeing to take part."

The research team, led by the University of Southampton in collaboration with Harvard Medical School and Northern Arizona University, examined the wording of 45 participant information leaflets from clinical trials which used placebos and are listed on the UK Clinical Research Network Database.

Analysis of the participant leaflets led to these key observations:

- Emphasis was given to the target treatment being more desirable to receive than the placebo.
- Target treatments were widely described as 'real', 'genuine' and the focus of the study. Placebos were rarely described in their own right, rather they were mostly referred to in comparison to target treatments.
- Target treatments were often described in relation to a class of drug, thus implying a particular effect, for example, antibiotics (infection fighting) or statins (cholesterol lowering).
- Placebos were often described in negative terms, such as 'dummy' or 'fake'.
- The leaflets emphasised both the benefits and adverse effects that might be triggered by the target treatment, but largely ignored any potential effects of the placebo.

Crucially, the study showed the target treatments were prioritised over the placebo, from the words in the leaflet titles, to the description of the trial process, through to explaining what would happen at the end of the trial.

Professor of Health Research at the University of Southampton, George Lewith, comments, "The leaflets largely ignored the overwhelming evidence that placebos can actually have significant and sustained effects on people. This could affect the treatment beliefs and expectations of those volunteering for studies and in turn the results.

"Studies at Southampton have clearly shown placebos can help about half of the people we treat with chronic pain and can be effective for a long time afterwards. The placebo effect works by releasing our bodies' own natural painkillers into our nervous system."

The researchers argue that volunteers for clinical trials should be more fully informed about the health changes they might experience from a placebo, otherwise their informed consent, crucial to taking part, is in jeopardy. They believe different ways of describing placebos need to be developed and tested, both for participant information leaflets and for personal contact with those conducting research.

More information: To view the full paper, Informed Consent and Placebo Effects: A Content Analysis of Information Leaflets to Identify What Clinical Trial Participants Are Told About Placebos, visit: dx.plos.org/10.1371/journal.pone.0039661

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