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THE PLACEBO EFFECT----SOME VIEWS

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What is a placebo?

Placebo (Latin for “I shall please”) is a substance or procedure a patient accepts as medicine or therapy, but which has no specific therapeutic activity. Any therapeutic effect is thought to be based on the power of suggestion. It is a medication or treatment believed by the administrator of the treatment to be inert or innocuous. Even “fake” surgery and “fake” psychotherapy are considered placebos.

Originally, a placebo was a substance that a well-meaning doctor would give to a patient, telling him that it was a powerful drug (e.g., a painkiller), when in fact it was nothing more than a sugar pill. Thus, Hooper's medical dictionary of 1811 says placebo is "an epithet given to any medicine adapted more to please than benefit the patient." The subsequent reduction of the patient's symptoms was attributed to the patient's faith in his doctor and hence his belief in the drug.

Commonly used placebos

Placebos are things like sugar pills or starch pills or anti-bilious bitters, etc.

Placebo controlled trials

Placebos are used to create "blind" trials in which the participants do not know whether they are getting the active treatment or not, so that physical effects can be measured independently of the participants' expectations. Those trials where some participants take a placebo as a control and the others take the drug being investigated. There are various effects of expectations, and blind trials control all of these together by making whatever expectations there are equal for all cases. Here the placebo is an inactive substance designed to resemble the drug being tested. It is used as

a control to rule out any psychological effects which may show during testing. Most well-designed studies include a control group which is unwittingly taking a placebo. Researchers and medical doctors sometimes give placebos to patients. Anecdotal evidence for the placebo effect is garnered in this way. Those who believe there is scientific evidence for the placebo effect point to clinical studies, many of which use a control group treated with a placebo. Generally speaking, for a drug to be put on the market, it must be significantly more effective than its placebo counterpart.

Placebo effect

The placebo effect is the measurable, observable, or the felt improvement in health not attributable to treatment. This effect is believed by many people to be due to the placebo itself in some mysterious way**.** Why an inert substance, or a fake surgery or therapy, would be effective is not known. With the result there has been much debate of whether to use a placebo pill or conduct a sham procedure as a control.

Related to this is the widespread opinion that placebo effects exist, where belief in the presence of a promising treatment (even though it is in fact an inert placebo) creates a real result e.g. recovery from disease. Placebo as a technique for "blinding" will remain important even if there is no placebo effect, but obviously it is in itself interesting to discover whether placebo effects exist, how common they are, and how large they are.

Placebo simulators are a standard control component of most clinical trials which attempt to make some sort of quantitative assessment of the efficacy of new medicinal drugs; it is a view held by many "*that placebo-controlled studies often are designed in such a way that disadvantages the placebo condition*".

A placebo response can amplify, diminish, nullify, reverse, or even divert the action of an active drug, and the study of placebo responses is essentially the study of the psychosocial construct surrounding a patient. Because a placebo response is just as significant in the case of an active drug as it is in the case of an inert dummy drug, the more that can be discovered about the mechanisms that produce placebo responses, the more one can enhance their effectiveness and convert their potential efficacy into actual relief, healing and cure.

A study showed that the placebo effect was stronger if patients believed that the drug they were given was more expensive compared to a control group who received exactly the same placebo but were told that the drug was very cheap. Recent research strongly indicates that a placebo response is a complex psychobiological phenomenon that may be due to a wide range of neurobiological mechanisms, with the specific response mechanism differing from circumstance to circumstance. Researchers in a number of different areas have demonstrated the presence of biological substrates, unique brain processes, and neurological correlates for the placebo response. They conclude that there is a real placebo effect for pain and for some other continuously-valued subjectively-assessed effects. Yet there is continuing controversy over what

might or might not be an appropriate placebo for such therapeutic treatments. A recent experimental demonstration reported that the psychological cause (belief that the placebo treatment might be effective in reducing pain) causes opioid release in the brain, which then presumably operates in an analogous way to externally administered morphine.

Appropriate use of a placebo in a clinical trial often requires a double-blind study design, which means that neither the experimenters nor the subjects know which subjects are in the "test group" and which are in the "control group". Because a belief that one has received the active drug can produce a markedly heightened placebo effect, it is often necessary to use a psychoactive placebo in clinical trials; i.e., a drug that produces enough physical effects to encourage the belief in the control and experimental groups that they have received the active drug. The quantification of the two therapeutic components, as can be accomplished by a placebo-controlled drug trial, has revealed that the overall outcome of therapy for various important indications of this kind is attributable predominantly to the psychodynamic component. It may reasonably be assumed that the contribution made by the pharmacodynamic effects to the overall therapeutic response will amount to only about 20-50%.

Some views

The Psychological Theory: It's All In Your Mind

Some believe the placebo effect is psychological, due to a belief in the treatment or to a subjective feeling of improvement; the effectiveness of Prozac and similar drugs may be attributed almost entirely to the placebo effect. Several clinical trials of anti-depressants were analyzed and it was concluded that the expectation of improvement, not adjustments in brain chemistry, accounted for 75 per cent of the drugs' effectiveness. In an earlier study of depressed patients treated with drugs, psychotherapy, or a combination of both, it was found that 50 per cent of the drug effect is due to the placebo response. A person's beliefs and hopes about a treatment, combined with their suggestibility, may have a significant biochemical effect including that of the hormonal and immune systems. Thus, it is consistent with current knowledge that a person's hopeful attitude and beliefs may be very important to their physical well-being and recovery from injury or illness.

However, it may be that much of the placebo effect is not a matter of mind over molecules, but of mind over behaviour. In short, there is a certain amount of role-playing by ill or hurt people which is not the same as faking. The behaviour of sick or injured persons is socially and culturally based, to some extent. The placebo effect may be a measurement of changed behaviour affected by a belief in the treatment. The changed behavior includes a change in attitude, in what one says about how one feels, and how one acts. It may also affect one's body chemistry. The psychological explanation seems to be the one most commonly believed.
Perhaps this is why many people are dismayed when they are told that the effective drug they are taking is a placebo. This makes them think that their problem is "all in their mind" and that there is really nothing wrong with them. Yet, there are too many studies which have found objective

improvements in health from placebos to support the notion that the placebo effect is entirely psychological.

Ethical challenges and concerns

Bioethicists have raised diverse concerns on the use of placebos in modern medicine and research. These have been largely incorporated into modern rules for the use of placebos in research but some issues remain subject to debate. The ethics of prescribing placebos in medical practice is highly debated. Some practitioners argue that the use of placebos is sometimes justified because it will do no harm and may do some good.

Is it unethical for a doctor to knowingly prescribe a placebo without informing the patient?

A doctor may prescribe a placebo only with the consent of the participants**.** Disclosure Rules that govern modern clinical trials insist on full disclosure to subjects who take part in the trials. In addition to the requirement for informed consent from all drug-trial participants, it is also standard practice to inform all test subjects that they may receive the drug being tested or that they may receive the placebo.

In 2002, World Medical Association reaffirmed its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, if its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or if a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebos will not be subject to any additional risk of serious or irreversible harm. In addition, because a belief that one has received the active drug can produce a markedly heightened placebo effect, it is often necessary to use a psychoactive placebo in clinical trials. Besides, some studies have shown superior efficacy of St John's wort (*Hypericum perforatum*) extract WS 5570 compared to placebo in patients with major depression: a randomized, double-blind, placebo-controlled, multi-center trial with St John's wort extract WS 5570 at doses of 600 mg/day (once daily) and 1200 mg/day (600 mg twice daily) were found to be safe and more effective than placebo, with comparable efficacy of the WS 5570 groups for the treatment of mild to moderate major depression. Yet, other studies showed inconsistent results

Ethicists have also raised concerns on the use of placebos in those circumstances in which a standard treatment exists unless there are genuine doubts of the effectiveness of such standard treatment.

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