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Editorial

Ethical issues surrounding the study of nocebo effects: Recommendations for deceptive research

Background

The nocebo effect has been described as the flip side to the placebo effect, whereby an adverse reaction is experienced by someone who receives an inert exposure (Kennedy, 1961). An inert exposure in this context is a substance or procedure that has no active medicinal or physiological properties able to directly influence the symptom experience in the receiver. Nocebo effects seem to primarily occur due to negative expectations (Webster, Weinman, & Rubin, 2016) and are commonly encountered in clinical practice (Colloca & Miller, 2011).

Experimental nocebo research commonly involves some element of deception by misleading participants about the nature of the experimental stimulus. Such procedures are often essential – informing participants that the stimulus is inert may dramatically change their expectations of side effects and hence their subsequent symptom experience. This reliance on deception raises a number of ethical concerns, not least in terms of informed consent. Due to concerns about these potential negative effects, deception is not always received favourably by institutional ethics review boards, making nocebo effects notoriously difficult to study. However, whilst the adverse ethical implications of deceptive studies are a concern, the costs of not conducting deceptive research should also be considered. Nocebo effects are one of the underlying mechanisms for the development of non-specific side effects to medications (Barsky, Saintfort, Rogers, & Borus, 2002). In their recent overview, Benedetti and Shaibani (2018) note the importance of understanding nocebo effects as something different from placebo effects, explaining that more research is needed to understand these nocebo-induced side effects which may prove crucial in controlling treatment adherence and therefore patient outcomes.

In addition, many nocebo researchers still claim that their participants provide informed consent for their studies, when logically this cannot be the case if they are deceived as to the nature of the exposure. For example, in a systematic review conducted by our team, the majority of studies incorrectly explained that participants gave informed consent (Webster, Weinman, & Rubin, 2016). Therefore, further discussion around these issues is clearly warranted.

This editorial provides an overview of what deception is, the current guidelines for using deception, and its effects. We include recommendations for deceptive research and

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draw upon an example of a recent study conducted by our team. Although these suggestions will not resolve all ethical issues relating to nocebo research, they may help researchers navigate some of the key issues involved in this field.

What counts as deception?

There is no one agreed definition of deception. Hey (1998) explains there is a difference between withholding information from participants and telling them the wrong thing; it is the latter which counts as deception. However, more recently, others have taken a broader view and include violations of participants' default assumptions in their definition of deception. For example, according to Pierce (2008), withholding information can result in participants forming false beliefs about a study. Therefore, perhaps a more appropriate definition of deception in research is that which intentionally allows participants to have, or maintain, a belief that the investigator knows is not true.

Current guidelines for using deception

Although discouraged, deception is not 'banned' in social science research. The British Psychological Society (BPS) allows withholding information from participants in exceptional circumstances to preserve the research integrity (BPS, 2009). This is not a carte blanche for researchers, however. Additional requirements stipulate deception should only be used if: (1) There are no other effective procedures to obtain the desired results; (2) the research has a strong scientific merit; (3) there is an appropriate risk management and harm alleviation strategy; and (4) when deception is revealed, it is unlikely to lead to discomfort, anger, or objections from participants (BPS, 2014). The code also requires that participants can withdraw at any time and are debriefed as soon and as sensitively as possible after the study. In addition, deceptive studies should be designed to protect the dignity and autonomy of the participants, and withholding of information should be clearly specified in the protocol that is subjected to ethical review (BPS, 2014).

The effects of deception

Although allowed by the ethical guidelines, there is a contested trade-off between the need for deception and the consequences this could have on participants. Evidence, however, on its effects is mixed. In a review of studies assessing participants' reactions to being involved in deception experiments, Christensen (1988) concluded that participants do not perceive that they have been harmed as a result and do not mind having been misled. Instead, participants enjoyed the experience more and felt they received more educational benefit than those who participated in non-deceptive experiments (Christensen, 1988). Kimmel (1998) also concludes that deception has minimal negative effects on participants and that they do not become resentful about being deceived. However, a more recent review by Hertwig and Ortmann (2008) noted that this is not always the case. For example, participants who have been deceived have been annoyed (Allen, 1983), and confederates have noted the angry reactions from participants once they find out they have been deceived (Oliansky, 1991).

There are also broader effects of deception to consider. Deception has been suggested to affect the reputation of research teams and the discipline of psychology as a whole (Lawson, 2001). Indeed, studies have shown that deceived participants tend to be more

suspicious of the truthfulness of experimenters, although this does not seem to affect their beliefs about psychologists' trustworthiness in general (Cook *et al.*, 1970). Similarly, no negative effects have been found on deceived participants' attitudes towards psychological research (Kimmel, 1996; Sharpe, Adair, & Roese, 1992).

The main reason why the evidence is so mixed is because the type of deception varies between studies (Hertwig & Ortmann, 2008). Unless a direct replication, no two studies deceive their participants in the same way. It seems logical that different types and degrees of deception will have different effects. For example, the BPS notes there is more likely to be a problem if the deception implies a more benign topic of study than is actually being carried out. However, in reality, it is hard to predict the effect any type of deception will have on participants as many studies fail to report how the deception was received by participants.

Recommendations for deceptive research

Deceptive research, however, is still not risk-free, and researchers should be wary of any potential deleterious effects. There are various approaches that researchers can take as precautions. Although widely discussed in the context of reducing nocebo effects in clinical practice, authorized concealment (Wells & Kaptchuk, 2012), which would involve deciding what to tell research participants based on their characteristics and previous experiences, may not be a viable way to inform them about a study. Instead, some of our suggested approaches originate from placebo research, but can still be applied in the context of nocebo research as the element of deception is still the same – participants cannot be informed of the true nature of the exposure (i.e., that it is inert).

1. *Patient and public involvement***.** Action can be taken at the planning and designing phase of any deceptive study using patient and public involvement (PPI). PPI is promoted by the National Institute of Health Research and allows researchers to see through the public's eyes when designing studies by carrying out research with the public rather than about them (Involve, 2015). PPI can help make sure the right research is done, that it is conducted properly, and improve research quality. Using PPI researchers can talk to the public about their opinions on the use of deception in an upcoming study. This collaboration could help develop innovative ways to reduce the degree of deception required and to discuss strategies to help limit any potential negative effects both during and after the study. In this way, researchers can carry out their study with the backing of a separate group of the public that have been involved in the planning and the design.
2. *Authorized deception***.** Whilst recruiting participants, authorized deception can be used by informing them that some information will be withheld, inaccurate, or misleading; deception is necessary for research integrity; the study has been ethically approved; and they will receive full study details after participation (Wendler & Miller, 2004). This falls short of full informed consent, but does promote autonomy by allowing potential participants to decide if they are willing to participate in a study that involves deception (Miller & Kaptchuk, 2008). Therefore, participants maintain control over their participation as their initial consent is conditional on their renewal at the debrief, where they have the option to withdraw their data (Bortolotti & Mameli, 2006).

There are concerns that informing participants about deception may compromise the study's validity almost as much as revealing its true nature and may also hinder recruitment. However, Martin and Katz (2010) have found that authorized deception does

not affect the magnitude of placebo effects, recruitment, or retention of participants compared to non-authorized deception and is preferred to not alerting participants to the presence of deception. This suggests that the authorized deception is a viable and ethically preferable alternative consent process for deceptive studies.

In addition, it is worth noting that authorized deception is the process that is currently used in double-blind clinical trials, often branded as the gold standard research design. Here, participants are told that they will either get the experimental drug or the placebo; however, they are openly informed that the information about which drug they are receiving will be withheld until the end of the trial.

3. *Nominated informed consent*. A variant on authorized deception is for participants to nominate a person they trust to receive all the study information (Clarke, 1999). They can then judge whether it is acceptable and give consent on the participant's behalf. It is possible, however, the nominee may have different values and needs from the participant and thus may give consent when the participant themselves would not (Patry, 2001). To address this, Patry (2001) suggests that participants should also be told: (1) Their participation is voluntary and they can withdraw any time without consequence; (2) they can get more information (providing it is not necessary to withhold); (3) they could get false or incomplete information; (4) they will be completely informed at the study's conclusion; (5) the duration of the study; (6) what the study involves; and (7) information about expected risks. This combined with nominated informed consent provides additional protection to the participant.
4. *Debriefing participants*. When using deception, most ethics boards require researchers to debrief their participants. According to BPS guidelines, the debrief should explain that the need for deception was an essential feature of the study design and explain the conduct of the experiment. It should be made clear that deception is only used when no risk of significant harm is present to participants and when important results are at stake. Participants must be debriefed as early as is feasible, but no later than at the conclusion of the data collection. After debriefing participants should be allowed to withdraw their data to restore a degree of autonomy, allowing them not to contribute to research which they would have declined to participate had they known the true nature of the study (Miller & Kaptchuk, 2008).
5. *Assessing and reporting the impact*. It is also important for researchers to assess their use of deception and the strategies they used to limit any negative effects as well as to report the impact their deception had on participants. Miller and Kaptchuk (2008) suggest that scientific journals can help this by requiring researchers to be more explicit about their use of deception, and what methods they used to negate any potential deleterious effects. More than this, however, it could be argued that researchers using deception have a moral obligation to check they have not caused harm, if for no other reason than to reassure themselves and their ethics board. The required debriefing offers an opportunity to obtain feedback from participants and should be utilized. Making sure researchers assess the impact of deception will help to improve the transparency of deceptive research and the ethical design of future studies.

Our approach

In a recent study by our team, we used authorized deception whilst making sure that information given to participants was as truthful as possible (Webster, Weinman, & Rubin,

2018). Our study involved a randomized controlled trial altering patient information leaflets (PILs) to reduce symptom attribution to a sham medicine (an inert tablet). We openly informed participants that information would be withheld from them. For example, they were told we could not reveal the type of tablet to avoid biasing their views about it and that the difference between the PILs included slight changes to the wording, to see whether this influenced their thoughts about the tablet, but that we could not reveal what the changes were. In addition, we correctly described the tablet as 'a well-known tablet available without prescription', and the leaflet was truthful for an inert tablet. For example, sections about taking too many tablets explained that this can cause more severe side effects as noted by Webster, Weinman, & Rubin (2016), whilst all potential side effects listed the common non-specific side effects reported during a nocebo response (Wells & Kaptchuk, 2012).

Planning of the study was discussed with a PPI panel, to get their input on whether our approach was appropriate and how to minimize any ethical issues still further. In addition, all participants were debriefed at the end of data collection by informing them of the purpose of the study and what the tablet was. Participants had the opportunity to withdraw at this point, upholding their participant autonomy, and any feedback received from participants following the debrief was collated. No negative effects were found.

Conclusions

Current guidelines include withholding information as deception and allow deception in psychological research under a strict set of conditions. Evidence from the literature suggests that criticisms of the potential negative effects of deception are often unfounded. Nonetheless, maintaining high ethical standards in such a controversial area is important. We propose a strategy that includes deception by omission whilst still being truthful where possible, authorized deception and debriefing, together with input from a PPI panel.

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Conflict of interests

All authors declare no conflict of interest.

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