Version dated 31 August 2015

A systematic review of the use of deception as an intervention in clinical research

Introduction:

Deception of research subjects typically involves deliberately misleading communication by investigators about the purpose of the research and the nature of experimental procedures[1]. deception is an essential component of the behavioral scientist's research arsenal, emphasizing the theoretical or social advances one may anticipate from the research, and the avoidance of misleading findings that might result from a study had participants not been deceived[2]. Deception of research participants is used in various contexts such as pain, depression and Parkinson's disease by experimental manipulation of participants' expectations[3]. Expectation induction mechanisms of verbal suggestion and conditioning have been identified as central processes eliciting placebo and nocebo effects, by decreasing or increasing symptoms respectively, when administering an inert (placebo) treatment or agent[4]

However, deception violates the principle of respect for persons by failing to disclose relevant information that might affect an individual's decision to volunteer for a research study thereby causing distress and lack of trust in research when the deception is revealed[5]. An ethical alternative to the consent procedure in deceptive research is the concept of authorized deception. It alerts prospective participants to the fact that some or all participants will be deliberately deceived about the purpose of the research or the nature of research procedures without disclosing the exact nature of the deception[3]. Debriefing promotes transparency by explaining the deception and its rationale, provides an apology to subjects for infringing the principle of respect for persons, and offers subjects an opportunity to withdraw their data[6]

Hence we have planned this systematic review of the use of deception in clinical research with the objective of studying the trials involving deception in their methodology with respect to various parameters such as study design, type of deception, benefits, harms, use of authorized deception and whether debriefing was done.

Aims & Objectives:

1. To study trials using deception as an intervention with respect to study design, type of deception, type of participants, participants deceived, benefits & harms
2. To determine the extent of use of methods such as authorized deception & debriefing towards safeguarding patient autonomy.

Inclusion criteria:

1. English language publications from 1st January 1985 to 15 March 2015 pertaining to trials involving deception as an intervention in the methodology will be considered

Exclusion criteria:

1. Trials involving minimized deception
2. Trials involving therapeutic misconception
3. Trials involving deception of investigator by participants
4. Systematic reviews, narrative reviews or meta analyses
5. Guidelines on deception

Materials & Methods:

Experimental & observational studies involving the use of deception as a part of the methodology will be considered. Search engines such as Pubmed& Google will be screened for obtaining studies pertaining to deception using the key words "balanced placebo design", "expectancy manipulation", "nocebo", "placebo effect", "suggestion", "deception AND clinical trial". Published literature from 1st January 1985 to 15th March 2015 will be considered. Two reviewers will independently screen the studies that meet the inclusion criteria and any disagreement will be resolved by consensus. The outcomes of interest will be

1. Study design (parallel/cross-over/factorial/prospective single arm cohort). Also the extent of use of multiple study designs would be assessed
2. Nature of the participant (patients/healthy volunteers)
3. Randomized versus non-randomized studies

4. Controlled versus uncontrolled studies
5. Blinding (single blind/ double blind/open label)
6. Therapeutic areas in which deception is used
7. Expectancy manipulation (extent of use of multiple manipulations)
8. Ethical issues:

a) Potential risks
b) Benefits(direct/potential)
c) Use of ethical alternatives such as authorized deception & debriefing

Data Analysis:

The results will be entered in a pre-determined data extraction sheet. Individual percentages of all outcomes of interest will be calculated.

Discussion:

Through this review we propose to provide a concise overview of studies using deception for answering a research question. We would be able to enlist the various methods used for manipulation of response expectancies and thereby determine the commonest method used for the same. In addition we can understand the ethical problems involved in such studies and the attempts made by researchers to alleviate them.

References:

1. Miller FG, Kaptchuk TJ. Deception of Subjects in Neuroscience: An Ethical Analysis. The journal of neuroscience. 2008 May; 28(19):4841-4843
2. Kimmel AJ. Deception in psychological research - a necessary evil?. The Psychologist. 2011 Aug; 24(8): 580-585
3. Miller FG, Wendler D, Swartzman LC. Deception in Research on the Placebo Effect. PLoS Med. 2005 Sep; 2(9): 262
4. Bartels DJP, van Laarhoven AIM, Haverkamp EA, Wilder-Smith OH, Donders ART, van Middendorp H et al. Role of Conditioning and Verbal Suggestion in Placebo and Nocebo Effects on Itch. PLoS ONE. 2014 Mar; 9(3): e91727

5. Martin AL, Katz J. Inclusion of authorized deception in the informed consent process does not affect the magnitude of the placebo effect for experimentally induced pain. Pain. 2010 May; 149(2):208-215
6. Miller FG, Gluck JP Jr, Wendler D. Debriefing and accountability in deceptive research. Kennedy Inst Ethics J. 2008 Sep; 18(3):235-51