



Published in final edited form as:

J Med Ethics. 2011 September ; 37(9): 563–566. doi:10.1136/jme.2010.038943.

Two concepts of therapeutic optimism

Lynn A Jansen

Abstract

Researchers and ethicists have long been concerned about the expectations for direct medical benefit expressed by participants in early phase clinical trials. Early work on the issue considered the possibility that participants misunderstand the purpose of clinical research or that they are misinformed about the prospects for medical benefit from these trials. Recently, however, attention has turned to the possibility that research participants are simply expressing optimism or hope about their participation in these trials. The ethical significance of this therapeutic optimism remains unclear. This paper argues that there are two distinct phenomena that can be associated with the term ‘therapeutic optimism’—one is ethically benign and the other is potentially worrisome. Distinguishing these two phenomena is crucial for understanding the nature and ethical significance of therapeutic optimism. The failure to draw a distinction between these phenomena also helps to explain why different writers on the topic often speak past one another.

Recent discussions of therapeutic optimism in clinical research display ambivalence over the ethical significance of the phenomenon. Therapeutic optimism is present when a research participant expresses the view that he/she will benefit from participation in a trial that offers its participants little or no prospect for direct medical benefit, such as an early phase oncology trial. This kind of optimism is not—at least not necessarily—the product of ignorance or confusion. An optimistic research participant need not be under the ‘therapeutic misconception’.¹ Similarly, an optimistic research participant may not be optimistic because he/she has made an error in calculating the risks and benefits that the trial presents to its participants. But if therapeutic optimism can be present even in the absence of misunderstanding, is it nevertheless a problem for informed consent in human subject research? It is in response to this question that the ambivalence manifests itself. On the one hand, a number of writers have maintained that hope or optimism is never ethically problematic.¹² On this view, those who express optimism about the therapeutic benefits of their participation in an early phase oncology trial are making no rational mistake; they are simply hoping for the best.¹² On the other hand, a number of writers have worried that therapeutic optimism contributes to the exploitation of research participants. It is a weakness or vulnerability on which investigators play to advance their research agendas.³⁴

This paper argues that both of these views hold part of the truth. Therapeutic optimism is both ethically unproblematic and a potential threat to the informed consent of research participants. The reason for this is that there are two distinct phenomena that can be associated with the term ‘therapeutic optimism’; one is ethically benign and the other is potentially worrisome. Distinguishing these two phenomena is crucial for understanding the nature and ethical significance of therapeutic optimism. The failure to draw a distinction

Copyright Article author (or their employer) 2011. Produced by BMJ Publishing Group Ltd under licence.

Correspondence to: Lynn A Jansen, Associate Research Professor (Prov), Madeline Brill Nelson Chair in Ethics Education and Associate Director, Center for Ethics in Health Care, Oregon Health and Science University, 3181 SW, Sam Jackson Park, RD (UHN-86) Portland, OR 97239, USA; ljhomes@aol.com.

Competing interests: None.

Provenance and peer review: Not commissioned; externally peer reviewed.

between these phenomena also helps to explain why different writers on the topic often speak past one another.

DISPOSITIONAL AND SITUATIONAL OPTIMISM

Social psychologists have called attention to the difference between people who are optimistic, in the sense that they have a generally hopeful outlook on life, and those who are optimistic with respect to some specific event or activity. The former is generally referred to as ‘dispositional optimism’ and the latter as ‘situational’ or ‘comparative’ optimism.⁵ For example, a person might be inclined to always view the positive aspects of any situation. Such a person, we might say, accentuates the positive. In contrast, a person might have no such rosy outlook on life, but he/she might express optimism with respect to some particular event or activity. For example, he/she might express the view that they are much less likely than others to be in a car accident, even though he/she drives as much as the average person. With respect to this event, he/she would be situationally optimistic even though he/she was not dispositionally optimistic.

The distinction between these two types of optimism suggests that there are two ideas or concepts that one might associate with the term ‘therapeutic optimism’. The fact that a given person reports an optimistic outlook on his/her participation in a clinical trial could be either a function of the fact that he/she is generally optimistic about life or a function of the fact that he/she is situationally optimistic about this specific activity. The former would be an instance of dispositional optimism while the latter would be an instance of situational optimism. Interestingly, as explained more fully below, social psychological research on optimism has tended to suggest that dispositional and situational optimism are not strongly related. People who are dispositionally optimistic do not exhibit a greater than average propensity for situational optimism with respect to a wide range of events and activities. Thus, while studies would need to be done to corroborate this hypothesis in the context of clinical research, it is possible that the two types of therapeutic optimism are not significantly related. Research participants who exhibit one type of optimism may have no tendency to exhibit the other.

A second distinction is necessary at this point. Unlike dispositional optimism, situational optimism can be either realistic or unrealistic. A person might believe that he/she is more likely than others to benefit from participating in a trial and might have good reasons for believing this to be the case. If so, his/her situational optimism would be realistic. But, as numerous studies on optimism in social psychology have demonstrated, situational optimism is often unrealistic.⁶⁻⁹ As such, it is the result of a bias which leads people to believe—with respect to a specific event or activity—that they are more likely to experience positive outcomes and/or less likely to experience negative outcomes than similar others. In a common example, smokers have been shown to be unrealistically optimistic with respect to their chances of developing lung cancer even when they are fully informed of the cancer-related risks of smoking. They believe that they are less likely to develop cancer from smoking than other smokers. The same bias may be present in research participants. If so, it would be an instance of unrealistic situational therapeutic optimism, or unrealistic therapeutic optimism for short.

In the next section, I will argue that these different types of therapeutic optimism vary in their ethical significance for informed consent in clinical research. That is why, for purposes of ethical assessment, it is crucial to separate them. Before turning to this issue, however, a brief summary is presented of some of the instruments that have been developed to study the different types of optimism.

Dispositional optimism is standardly measured by the Revised Life Orientation Test (LOT-R), an updated version of the original Life Orientation Test. In numerous studies the LOT-R has demonstrated ample validity and high internal consistency reliability.¹⁰ The LOT-R asks respondents to indicate the extent to which they agree to statements such as: 'In uncertain times I usually expect the best' or 'Overall, I expect more good things to happen to me than bad'. Positive responses to these statements reveal a generally hopeful orientation towards life. In contrast, situational optimism is standardly measured by asking respondents to compare themselves with others with respect to a specific event. The results can establish the presence of unrealistic optimism at the group level. The Comparative Risk/Benefit Assessment Questionnaire (CRBA) developed by Weinstein is one instrument that has been developed for this purpose. It has been widely used in the field of social psychology and has been adapted successfully to health psychology, particularly in the field of preventive medicine. Since the questionnaire has consistently detected unrealistic optimism in populations that would not be expected to demonstrate the bias, it also has shown discriminant validity.^{9,11} (Additional evidence of discriminant validity is the demonstration that unrealistic optimism can be distinguished from dispositional optimism. The relationship between the two kinds of optimism, as measured by the LOT-R and the CRBA, is discussed below).

The CRBA asks a group of people to make comparative risk assessments with respect to a range of specific health-related events. For example, if a majority of smokers report that they are less likely than average to develop lung cancer compared with other smokers, then one can infer that the group consists of persons with unrealistically optimistic assessments. Importantly, using the CRBA, one cannot infer that any particular member of the targeted group is unrealistically optimistic, since some members of the group may have a risk profile that makes it accurate for them to report a lower than average susceptibility to the risk. Thus, to assess either realistic or unrealistic situational optimism with respect to individuals, one must have information on their specific risk/benefit profiles.⁵ Unrealistic therapeutic optimism among a targeted group of research participants, however, can be measured using instruments such as the CRBA.

ETHICAL IMPLICATIONS

Dispositional optimism and situational optimism are different phenomena and are measured by different instruments. Writers who have discussed the ethical significance of therapeutic optimism for clinical research generally have failed to appreciate that there are different phenomena to consider. This matters since it is likely that the different phenomena have different consequences for behaviour.

Research has shown that dispositional optimism in general does not adversely affect behaviour. More to the point at hand, there is no good evidence for thinking that dispositionally optimistic people are unusually prone to make mistakes in processing, appreciating and applying information about the risks and possible benefits of specific health-related events. There is even some evidence to suggest that dispositionally optimistic people are healthier than others. Radcliffe and Klein provide a summary of the evidence.

Generally, it is found that people high in dispositional optimism have better overall physical health, report being bothered by fewer symptoms of illness, adjust better to important life transitions, cope better with stress, recover faster from coronary artery bypass surgery, use more problem-focused coping strategies, handle illness more effectively, and are more likely to accept or resign in a situation that appears to be uncontrollable.⁵

Thus, if therapeutic optimism were just an expression of dispositional optimism, and if dispositional optimism indeed has no adverse effects on behaviour and some positive effects on well-being, then it should not occasion ethical concern. The presence of a hopeful state of mind poses no ethical problem for clinical research. Realistic situational optimism is also not problematic. If a person is optimistic about his participation in a clinical trial, and if his optimism is based on a realistic assessment of his circumstances, then this optimism should occasion no concern. The process of informed consent is modelled on the idea that people should make voluntary decisions based on an accurate understanding and appreciation of the relevant risks and potential benefits that clinical research presents to them. Realistic therapeutic optimism may just reflect the fact that the research participant is adequately informed and processes information rationally. It is mentioned in this paper for the sake of completeness. The important contrast with dispositional optimism is unrealistic therapeutic optimism.

Unrealistic optimism in the context of clinical research is potentially ethically problematic. At the very least, its prevalence among research participants should occasion concern. This is true for two main reasons. First, unrealistic optimism in a number of health-related contexts has been shown to have adverse consequences with respect to information processing and subsequent behaviour. In one study, college students who were unrealistically optimistic about the likelihood that they would experience negative events from alcohol consumption were more likely to experience problems related to drinking than others. The students who were unrealistically optimistic about the risks appeared to engage in riskier behaviours.¹² Other studies, including many health-related studies, have shown that unrealistic optimism is linked to lesser attentiveness to risk information and less worry about the consequences of risky behaviour.⁶¹³ In general, unrealistically optimistic people tend to affirm self-protective myths and form riskier intentions than similar others who are not optimistic in this way.⁵ While not impairing understanding, unrealistic optimism may interfere with the appreciation and processing of information related to risks and benefits. Second, unrealistic optimism may directly interfere with voluntary or autonomous decision-making. As a bias, it typically operates behind the back of those who are subject to it, thus potentially interfering with the voluntariness component of informed consent.³¹⁴ (Although the point is controversial in medical ethics, a voluntary decision not only can be compromised by external factors such as coercion and manipulation, but also by internal factors such as biases and neuroses.) Like other cognitive and affective distortions such as adaptive preference formation, wishful thinking and conformism, unrealistic optimism more closely resembles a hidden drive than a consciously adopted strategy for planning one's life.³ On a plausible view of autonomy, persons are autonomous when they are free from coercion and manipulation and are adequately informed, and also when their desires have not been shaped by non-conscious mechanisms that distort (or have the potential to distort) rational judgement.¹⁵ This second point complements the first one. In many contexts, people make decisions that neither expose them to significant risks nor affect their lives in significant ways. The decision to buy one type of automobile rather than another is a mundane example. In these contexts, it is not important to worry too much about whether a person's decision is autonomous or not but, in other contexts in which a person is exposed to risks or is making an important decision about his/her life, it becomes more understandable to worry about his/her autonomy. The decision to participate in experimental research is a decision of this latter kind, which is why nearly everyone agrees that securing informed consent is an ethical requirement for conducting a clinical trial. Informed consent serves both a protective and an expressive function in this context. It serves a protective function by acting as a safeguard that protects participants from exposure to unnecessary risks. It serves an expressive function by ensuring that participants will make a rational, informed and voluntary choice about the use of their body as an experimental object as well as the use of their time in the process of the trial. However, both of these functions of informed

consent—the protective and the expressive—are threatened by non-conscious biases that distort (or have the potential to distort) the rational judgement of research participants. This is why those who take informed consent seriously in the research context need to take the phenomenon of unrealistic optimism seriously.

RELATIONSHIP BETWEEN DISPOSITIONAL OPTIMISM AND UNREALISTIC OPTIMISM

I have been arguing that there are two main concepts of therapeutic optimism and that they have a different ethical significance. This naturally invites the question whether or not the two types of optimism are significantly related to each other. Here it will be helpful to distinguish three theses.

Thesis 1: There is no significant correlation between dispositional and unrealistic therapeutic optimism. Those who are dispositionally optimistic are no more or less likely than others to exhibit unrealistic optimism with respect to their participation in clinical research.

Thesis 2: There is a significant negative correlation between dispositional and unrealistic therapeutic optimism. Those who are dispositionally optimistic are less likely than others to exhibit unrealistic optimism with respect to their participation in clinical research.

Thesis 3: There is a significant positive correlation between dispositional and unrealistic therapeutic optimism. Those who are dispositionally optimistic are more likely than others to exhibit unrealistic optimism with respect to their participation in clinical research.

Empirical investigation is necessary to determine which of these theses is correct. At present, no research has been done on this topic. However, in other contexts, several studies have attempted to ascertain whether dispositional optimism is related to unrealistic optimism. In one study Davidson and Prkachin found a small but statistically significant relation between dispositional and unrealistic optimism with regard to two events (exercise behaviour and coronary heart disease). They also found a small interaction effect between the two types of optimism with regard to exercise behaviour.¹⁶ However, as mentioned earlier, most studies have not found a significant correlation between the two types of optimism.⁵

The safe conclusion is that dispositional and unrealistic optimism have not been shown consistently to be significantly related in the contexts in which they have been studied. This may provide a presumptive reason for thinking that thesis 1 is correct, but more research is necessary before any judgement on this can be held with confidence. Still, if thesis 1 were proved to be correct, then a welcome consequence might follow. Efforts to counteract unrealistic therapeutic optimism might not dampen the potentially beneficial effects associated with dispositional optimism.

TALKING PAST ONE ANOTHER

Research ethicists have begun to consider the significance and implications of therapeutic optimism, but the failure to recognise that there are different phenomena to consider has led to a situation in which the participants in this discussion often do not address one another's concerns. When it is claimed, for example, that therapeutic optimism is ethically 'always tolerable because hope does not compromise the autonomy of a decision to participate in research'¹ or 'an optimistic outlook likely makes a positive contribution to the healing process',¹ these claims are best construed as claims about dispositional optimism.

Understood as claims about unrealistic optimism, they look to be unwarranted. In contrast, when it is claimed that ‘hope for an unlikely cure can reduce participants’ autonomy even if they do not suffer from the therapeutic misconception’ or hope ‘opens us up to harm and exploitation in a range of ways’,⁴ these claims are best construed as claims about unrealistic optimism. Understood as claims about dispositional optimism, they look to be unwarranted. In this way, the debate over the ethical significance of therapeutic optimism can look like a debate in which the participants largely talk past one another.

This same problem is present even in discussions of therapeutic optimism that neither encourage it nor worry about it. For example, in a recent careful and balanced discussion of the prospect for direct medical benefit from participation in phase 1 oncology trials, Miller and Joffe point to a number of uncertainties that affect judgements on this matter. They argue that:

Because well-informed individuals can disagree, there can be no ‘objective’ third-party judgement about the reasonableness of this prospect. Instead, whether or not the prospect of direct benefit is reasonable is entirely a subjective judgement on the part of the potential participant who is adequately informed about the relevant uncertainties.¹⁷

From this, they go on to conclude that ‘patients who maintain “therapeutic optimism” in the face of accurate information disclosure do not thereby fail to provide valid consent’.¹⁷

Miller and Joffe’s statement is true, as far as it goes. If the therapeutic optimism in question is dispositional optimism, then there is no reason to be especially concerned about the validity of informed consent to these trials. But if the therapeutic optimism alluded to is unrealistic optimism, then the issue is considerably more complicated. As Miller and Joffe correctly observe, ‘informed consent may be compromised to the extent that participants fail to understand or appreciate the scientific design of this research (and how it differs from personalised medical care), or that they overestimate the likelihood or magnitude of the medical benefit that they may receive’.¹⁷ So, even if ‘objective’ third-party judgements about the likelihood and magnitude of direct medical benefits from participation in these trials is not available, it remains important to ensure that the subjective judgements of participants on this issue are well-informed and, I would add, not subject to biases or other factors that can distort their rational judgement.

The key point for present purposes is that, while it is true that therapeutic optimism in early phase oncology trials does not imply any defect in informed consent, it is also important not to overstate this claim. From the fact that rational individuals can hope for the best from these trials without displaying any defect in informed consent it does not follow that therapeutic optimism should never be viewed as a potential threat to the informed consent of participants in these trials. The failure to draw the distinction between the two types of optimism encourages this mistaken inference.

CONCLUSION

Researchers and ethicists have long been concerned about the expectations for direct medical benefit expressed by participants in early phase clinical trials. Early work on the issue considered the possibility that participants misunderstand the purpose of clinical research or that they are misinformed about the prospects for medical benefit from these trials. Recently, however, attention has turned to the possibility that research participants may be expressing or displaying optimism about their participation in these trials. Confident pronouncements about the ethical significance of this optimism for informed consent to clinical research are premature until we learn a good deal more about the nature of the

optimism exhibited by research participants. A necessary first step in this direction is to distinguish clearly between the two concepts of therapeutic optimism reviewed here.

Acknowledgments

Funding: Work on this paper was supported by an NIH-NCI grant # R21CA131601-01A1, Understanding Optimism in Clinical Research.

References

1. Horng S, Grady C. Misunderstanding in clinical research: distinguishing therapeutic misconception, therapeutic misestimation, and therapeutic optimism. *IRB*. 2003; 25:11–16. [PubMed: 12833900]
2. Weinfurt KP, Seils DM, Tzeng JP. Expectations of benefit in early-phase clinical trials: implications for assessing adequacy of informed consent. *Med Decis Making*. 2008; 28:575–81. [PubMed: 18378940]
3. Jansen LA. The problem with optimism in clinical trials. *IRB*. 2006; 28:13–19. [PubMed: 17036434]
4. Martin A. Hope and exploitation. *The Hastings Center Report*. 2008; 38:49–55. [PubMed: 18947141]
5. Radcliff NM, Klein WMP. Dispositional, unrealistic, and comparative optimism: differential relations with knowledge and processing of risk information and beliefs about personal risk. *J Pers Soc Psychol*. 2002; 28:836–46.
6. Gold RS, Aucote HM. 'I'm less at risk than most guys': gay men's unrealistic optimism about becoming infected with HIV. *Int J STD AIDS*. 2003; 14:18–23. [PubMed: 12590787]
7. Prentice KJ, Gold JM, Carpenter WT. Optimistic bias in the perception of personal risk: patterns in schizophrenia. *Am J Psychiatry*. 2005; 162:507–12. [PubMed: 15741467]
8. Weinstein N. Unrealistic optimism about future life events. *J Pers Soc Psychol*. 1980; 39:806–20.
9. Weinstein N. Unrealistic optimism about susceptibility to health problems. *J Behav Med*. 1982; 5:441–60. [PubMed: 7154065]
10. Scheier MF, Carver CS, Bridges MW. Distinguishing optimism from neuroticism (and trait anxiety, self-mastery, and self-esteem): a reevaluation of the Life Orientation Test. *J Pers Soc Psychol*. 1994; 67:1063–78. [PubMed: 7815302]
11. Weinstein ND. Optimistic biases about personal risks. *Science*. 1989; 246:1232–3. [PubMed: 2686031]
12. Dillard AJ, Midboe AM, Klein WM. The dark side of optimism: unrealistic optimism about problems with alcohol predicts subsequent negative event experiences. *Pers Soc Psychol Bull*. 2009; 35:1540–50. [PubMed: 19721102]
13. Barnoy S, Bar-Tel Y, Treister L. Effect of unrealistic optimism, perceived control over disease, and experience with female cancer on behavioral intentions of Israeli women to undergo screening tests. *Cancer Nurs*. 2003; 26:363–9. [PubMed: 14710797]
14. Elster, J. *Sour Grapes: Studies in the Subversion of Rationality*. New York: Cambridge University Press; 1991. p. 25
15. Dworkin, G. *The Concept of Autonomy*. In: Christman, J., editor. *The Inner Citadel: Essays on Individual Autonomy*. New York: Oxford University Press; 1989.
16. Davidson K, Prkachin K. Optimism and unrealistic optimism have an interacting impact on health-promoting behavior and knowledge changes. *Pers Soc Psychol Bull*. 1997; 23:617–25.
17. Miller FG, Joffe S. Benefit in phase 1 oncology trials: therapeutic misconception or reasonable treatment option? *Clin Trials*. 2008; 5:617–23. [PubMed: 19029210]