



Target Article

The Use of Deception in Public Health Behavioral Intervention Trials: A Case Study of Three Online Alcohol Trials

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Some public health behavioral intervention research studies involve deception. A methodological imperative to minimize bias can be in conflict with the ethical principle of informed consent. As a case study, we examine the specific forms of deception used in three online randomized controlled trials evaluating brief alcohol interventions. We elaborate our own decision making about the use of deception in these trials, and present our ongoing findings and uncertainties. We discuss the value of the approach of pragmatism for examining these kinds of ethical issues that can arise in research on public health interventions.

Keywords: public health, research ethics

The authors are public health researchers. This article describes our efforts over a period of some years to address a set of long-standing methodological and ethical issues in the field of brief alcohol intervention research. Brief interventions are simply conversations or other interactions that help people reflect on a particular issue, such as alcohol consumption and its consequences, and whether and how people might change (Heather 2010). We have deployed a number of novel designs for behavioral studies being conducted on the Internet to address methodological problems, employing deception in so doing. We use three ongoing randomized controlled trials as a case study in which we present our analysis of the ethical issues. Because the issues raised are relevant to health behavior research and public health more widely, we begin by presenting these broader contexts. We have linked our decision making in these trials to available guidance and literature and include our reflections on the approach of pragmatism and the related need for empirical data to inform ethical evaluations.

BACKGROUND

Deception in Research

Deception is a word in common use, defined as “a misleading falsehood” (<http://www.thefreedictionary.com/deception>). It may be practiced in ways that generate

harms—for example, obtaining money under false pretences may cause victims various forms of suffering. In the context of research, Wendler and Miller (2004) have suggested: “Deception occurs when investigators intentionally communicate in a way that produces false beliefs . . . investigators may deceive subjects by intentionally giving them false information . . . by intentionally with-holding information in order to produce false beliefs” (47). Giving misleading information may be more deceptive than withholding information and allowing participants to form false beliefs (Wendler and Miller 2004). Deception may also infringe on rights that are widely acknowledged; for example, deception is usually precluded in clinical research by the Helsinki Declaration requirement for informed consent to be given by all capable participants. Clause 24 states that “each potential subject must be adequately informed of the aims, methods . . . anticipated benefits and potential risks of the study” (World Medical Association 2008).

Deception has long been used in research. In the Tuskegee study and the Milgram experiments the use of deception was one of many issues in these studies that have attracted wide attention in the bioethics literature (Cave and Holm 2003). In a landmark study published in the journal *Science*, Rosenhan (1973) had pseudo-patients feign hearing voices in order to be admitted to psychiatric hospitals and thereafter behave normally. While providing

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valuable information about psychiatric diagnosis and treatment in asylums (Bulmer 1982) this study was fiercely criticized as unscientific (Spitzer 1975). Before the Rosenhan study, there had been long-standing discussions among social scientists about the ethics of covert observation, and these included studies in health care contexts (Bulmer 1982). Deception in research has often provoked controversy. The Tearoom Trade study by Laud Humphreys, for example, involved a researcher providing false information about the researcher's identity and purposes in order to find out about men having sex together in public rest rooms, generating considerable methodological and ethical debates (Lenza 2004). Mystery clients are still used in sexual health behavior research (Wong et al. 2012) and health care research (Kirschner et al. 2010) today.

Deception is widely practiced within experimental social psychology, particularly so in laboratory settings, most often with psychology students (Miller, Gluck, and Wendler 2008; Wendler and Miller 2004). Fisher and Fyrberg (1994) reviewed 30 years of this tradition of study, with approximately half of all social psychology studies conducted until the early 1980s involving deception. A partial replication of the Milgram experiment has been more recently undertaken (Burger 2009), and highly complex forms of deception have evolved to preserve experimental manipulations from bias (Laney et al. 2008).

Deception in the psychology laboratory with relatively small numbers of participants may pose ethical dilemmas very different from those that arise in the less constrained contexts of studies involving larger numbers of people in other settings. For example, concern has been articulated that the harms potentially caused by deception in clinical contexts may include impairment of trust that patients have in health care staff, potentially leading to poorer health outcomes (Wendler and Miller 2004). Similarly, attempts to influence behaviors under the autonomous control of research participants in their own lives are different in nature from experimental manipulations of the performance of behaviors in laboratory contexts.

The 1979 Belmont Report and the consequent development of institutional review boards limited the widespread use of deception in health, psychological, and social research (Rosnow and Rosenthal 1997). Since then, whether a particular study should be allowed to use deception is a matter for institutional review boards and guidance is available on the circumstances in which informed consent may be waived (Office for Human Research Protections 1993), as well as in many professional ethical codes in different countries.

Public Health and Public Health Ethics

Public health is concerned with creating the conditions in which people can be healthy (Childress et al. 2002). It increasingly pays attention to lifestyle in relation to the causes, prevention, treatment, and management of health and disease (Nuffield Council on Bioethics 2007). There is particular interest in better understanding how people can be helped to protect and enhance their health and well-being by increasing health-promoting behaviors and reducing health-

compromising behaviors. There are many ethical issues attendant upon these efforts to influence behavior (Marteau, Oliver, and Ashcroft 2008). For instance, we obviously intervene more with some behaviors, such as drug use, and in some populations, for example, among the poor, in ways not obviously justified in health terms. The intervention itself may also raise ethical issues (Marteau, Ashcroft, and Oliver 2009); for instance, should we pay pregnant smokers to stop smoking? Although widely accepted as the ethical foundation of human health research, the Helsinki Declaration has also been criticized for providing an individualistic approach (Nuffield Council on Bioethics 2007; Buchanan and Miller 2006). It has evolved over time and since 2000 has included a specific responsibility for health research to deliver benefits to populations (Williams 2008). Dedicated frameworks for moral reasoning in public health ethics have also been developed (e.g., Kass 2001; Childress et al. 2002). These do not provide specific guidance on research ethics in the context of public health.

More rigorous research studies provide more accurate estimates of intervention effects for decision making, and are thus more ethical to the extent that this information will be used effectively and fairly to improve population health (Kass 2001). The Cochrane Collaboration (Higgins et al. 2011) recommends the use of blinding to prevent bias in randomized controlled trials on the basis of empirical evidence of bias in unblinded trials. According to Boutron and colleagues (2007): "Blinding refers to keeping key persons, such as participants, health care providers, and outcome assessors, unaware of the treatment administered or of the true hypothesis of the trial" (0371). In certain circumstances participants may be blinded to study participation itself, or to the purposes of the study, or to particular features of the study design, including details of interventions being evaluated, being randomized, or outcome data collection (Boutron et al. 2007). Deception may occur in blinding in certain circumstances (Carson et al. 2008), though study participants may also give consent to be blinded, as occurs, for example, in placebo-controlled drug trials.

Where blinding does involve deception, that is, research participants being given false information or led by omissions to hold false beliefs, the methodological imperative to constrain bias to produce socially useful research appears to be in conflict with the ethical imperative of informed consent, as enshrined in the Helsinki Declaration. This conflict brings together perhaps the two dominant perspectives in research ethics (Rachels 1999). On the one hand there are arguments based on a Kantian emphasis on respect for the autonomy of the individual research participant. Using research participants as means to an end should in all circumstances be avoided as a categorical imperative. On the other hand, various versions of utilitarianism promote the pursuit of the greatest good for society as a whole, thus taking account of wider interests beyond those directly pertaining to research participants themselves (Rachels 1999). This balancing of concern for individual rights with governmental responsibilities to protect and promote health has been described as the "central ethical dilemma" in public health (Krebs 2008).

CASE STUDY

Introduction to the Study Context and the Nature of the Research Problems Addressed

Alcohol is a drug whose use has been estimated to cause approximately 5.5% of the global burden of disease (Lim et al. 2012), as well as a range of social and economic harms (Rehm et al. 2009). Drinking more alcohol than is probably good for one's health is very common, and there is a global consensus that brief interventions should be offered opportunistically to people whose drinking is identified as risky, rather than simply targeting those who seek help (Room, Babor, and Rehm 2005). In brief intervention trials it has been found that there is much change over time among participants randomized to control conditions who are not seeking help and not receiving interventions (Jenkins, McAlaney, and McCambridge 2009; 2010). This may be a consequence of research participation itself, as well as being due to natural variability in the behavior over time and regression to the mean, as determination of eligibility usually requires selection. A systematic review of randomized comparisons within brief intervention trials indicates that simply answering questions about alcohol consumption can produce small effects on people's behavior, at least in some populations (McCambridge and Kypri 2011).

The challenge for researchers in this area is to separate any effects of taking part in research studies from the effects of the interventions being evaluated, which are also small. Public health improvement increasingly involves attention to securing small changes in lifestyle as widely as possible. Both assessment effects and brief interventions probably influence behavior in similar ways, getting people to reflect on how much they are drinking and whether this is acceptable to them (Clifford and Maisto 2000). These methodological challenges stemming from research participation itself extend well beyond alcohol and have been recognized and studied in relation to a range of other behaviors, including diet and sexual health (see McCambridge et al. 2011; McCambridge, De Bruin, and Witton 2012).

Brief intervention trials have been undertaken for more than a quarter of a century using deception. The oldest, largest, and most influential studies internationally have done so, including, for example, Chick, Lloud, and Crombie (1985), Wallace, Cutler, and Haines (1988), WHO Brief Intervention Study Group (1996), and Fleming and colleagues (1997). Most commonly this has taken the form of using a formal consent procedure that does not disclose the study focus on alcohol consumption, leading participants to believe that the study is concerned with health or lifestyle more broadly. Preceding one of these studies, there was an evaluation of the effects of deception in a small sample of 54 participants (Fleming et al. 1989). This identified some evidence of discomfort and ambivalence, though at levels deemed acceptable for the subsequent conduct of the trial.

Brief alcohol interventions, as with health care itself (Barchard and Williams 2008; Sharkey et al. 2011; Whitehead 2007), are increasingly being delivered and evaluated using

the Internet (e.g., Linke et al. 2008). Deception in Internet-based research may be more easily implemented with computerized automation of procedures. As there is also a range of other distinct ethical issues raised in online research, dedicated guidance has been produced (Barchard and Williams 2008; British Psychological Society 2007). Justifications similar to those used in conventional research settings with regard to the use of deception are advanced. For example: "There must be a clear and convincing argument for the use of deception online, which is only condoned if the research question can be seen to justify it. . . . Strong justification is needed if the research involves deliberate misrepresentation by a researcher" (British Psychological Society 2007). Barchard and Williams (2008), applying the American Psychological Association ethics code to this area, disagree with those who suggest that deception should not be used online and additionally recommend that debriefing be used in all online studies.

Case Study Material

Case studies investigate phenomena within their own real life setting (Sarantakos 2005). Our case study sits somewhere close to the intersection of thinking about clinical and public health research ethics, as it involves evaluating interventions to alter individual behavior for the purpose of improving population health. For all three studies considered here, trial protocols have been published wherein more detailed information on study design is available: Study A (The Electronic Screening and Brief Intervention in New Zealand (e-SBINZ) trials; Kypri et al. 2010); Study B (The Alcohol e-Mail Assessment & feedback study: Dismantling Effectiveness for University Students (AMADEUS-1) trial; McCambridge, Bendtsen, et al. 2012); and Study C (a methodological study entitled "The Effects of Study Design and Allocation (ESDA) trial"; Kypri et al. 2011).

These studies have common features. They all involve thousands of university students receiving an e-mail, and study participation is triggered by responding to this e-mail. The burden of participation in time is small, taking not more than a few minutes at each contact, and much less than 1 hour in total. What is involved in each contact is answering some questions about personal alcohol consumption, and in some cases receiving brief feedback. Two studies (A and B) investigate the effects of feedback on subsequent drinking behavior (Kypri et al. 2010; McCambridge, Bendtsen, et al. 2012). Study B additionally examines the effects of answering questions alone in a three-arm trial. Study C is a methodological study designed to investigate the effects of study design, randomizing participants into three groups. One group is given to understand its members are participating in a cohort study. The other two groups are told that they are participating in a randomized controlled trial, having been allocated to either the intervention or control conditions, respectively (Kypri et al. 2011). However, all three groups receive the same alcohol information, which is not expected to promote behavior change.

The Content of the Deceptions and Reasons for Their Use

There are various forms of deception used in each of the studies. In some cases, the same deception is apparent in all three studies, whereas other deceptions happen in only one or two studies. Given next is an overview of the nature of the deceptions being used and the reasons for their use (issues relating to debriefing are addressed in a later section).

- In all three studies the true purpose of the research is withheld from participants (Studies A, B, and C).
- It is not clear to participants that their individual behavior is being tracked over time in Study B.
- Where participants are aware of being individually followed up, they are given false information about why this is happening in Study C.
- In Studies A and B, participants are unaware they are participating in a randomized controlled trial, as are those in one of the three groups in Study C.
- In Study A those randomized to intervention are not made aware that they are receiving of an intervention being evaluated for capacity to change their behavior (i.e., feedback), believing instead they are participating in a survey.
- In Study B participants are not aware they are involved in research at all when they access interventions.
- In Study C those randomized to intervention are led to believe that they are receiving a potentially effective intervention when they are not.

The core rationale for employing deception in these studies is the same in all three cases: Communicating the true nature of the study in advance would interfere with the achievement of study aims. Participation rates would be adversely affected in both intervention studies (A and B) (Kypri et al. 2010; McCambridge, Bendtsen, et al. 2012), and participation itself is an object of study. We want to find ways to reach as much of the population as possible without the research context obstructing their willingness to take up these offers. Failure to achieve high uptake has implications for the generalizability of the intervention effect estimates. Study B (McCambridge, Bendtsen, et al. 2012) was undertaken in Sweden, where sending an e-mail to university students was adopted as routine practice nationally before this study took place and we were particularly interested in which components (i.e., whether it was answering questions or the feedback) were responsible for any reported change (McCambridge, Bendtsen, et al. 2012). Study A, the New Zealand intervention study, has now led to the development of a similar national system for offering this service modeled on the intervention approach used in this study (Kypri et al. 2013). In study C, the effects of awareness of the nature of the study (i.e., the actual study design, whether cohort or trial) and participant role in the trial (i.e., intervention or control) are precisely what is being investigated in this methodological study. This allows consideration of whether the usual processes of informed consent and trial recruitment induce self-reported behavior change (Kypri

et al. 2011). We have sought to design the research process as far as possible in the intervention studies to minimize the risk that participants' behavior will be affected by the research process itself.

OUR APPROACH TO THE ETHICAL ISSUES

We could not find a framework dedicated to public health research ethics, never mind one that was concerned with our more specific interests in individual behavior change for public health benefit. As the importance of this type of research is increasingly recognized, it is anticipated that such guidance will be developed. According to Buchanan and Miller (2006), "Taking a public health perspective on research ethics is associated with broadening the conceptualisation of risk and benefits deemed ethically relevant in deliberations on health research. To ascertain its social value, a comprehensive analysis must take into account not only the risks and benefits to the research participants themselves but also the benefits and risks to the population as a whole" (730). Childress and colleagues (2002) identify five "justificatory conditions" (effectiveness, proportionality, necessity, least infringement, and public justification) useful for resolving conflicts between public health goals and other ethical principles.

Effectiveness

Childress and colleagues (2002) suggest that evidence of effectiveness is required to justify public health interventions where they infringe on other moral considerations. This implies that evidence in the form of publicly available data from rigorously conducted scientific studies has a moral value in its own right, though the justification is more obvious for effectiveness studies than for methodological research. These studies aim to provide data on the effectiveness of interventions and to improve methods for the identification of biases that undermine the value of effectiveness data. The use of deception permits the identification of these biases. There is a moral argument for effectiveness research (Kass 2001), and by extension for methodological research that aims to enhance the validity of effectiveness data by eliminating or controlling biases. This is because developments in intervention research methods, including those obtained by using deception, offer potential to provide more reliable and socially useful data, which may in turn be more widely used. This contribution of enhanced methodological rigor obviously needs to be considered carefully in relation to the ethical risks inherent in using deception.

Proportionality

In relation to proportionality, both the risks and the benefits to the individual may be fairly trivial. The study population is judged relatively safe for doing this type of work, being less likely to contain significant proportions of vulnerable people who may be discomforted, distressed, or otherwise harmed by deception. There is some potential for distress with the subject of alcohol being raised for some

participants, as may occur outside the research context. Extensive and detailed pilot work has been done in a range of earlier studies to refine the methods used, being vigilant for adverse reactions (Hallett et al. 2009). We have focused on the ethical concerns involved in infringing rights rather than causing harm to participants, partly due to the lack of obvious potential to engender significant harm and the absence of such data in feedback.

Fisher and Fyrberg (1994) reported a study of 90 introductory psychology students who read reports incorporating a range of forms of deception in research. Their analyses of responses indicated that approximately 70% of students adopted a basically utilitarian attitude to what they had read, and of the 30% who had what might be characterized as a Kantian approach, approximately 10% objected in principle to the use of deception.

The principal health and social value of research of this type lies in the benefits to be realized in populations if interventions are found to be effective and widely delivered, as well as to the extent that they contribute to our broader understanding of drinking behavior and how it may be influenced. Future epidemics of alcohol-related problems are entirely foreseeable, and thus preventable, in Sub-Saharan Africa and in low- and middle-income countries elsewhere. Intervention effectiveness research of this kind, to the extent that it is successful in identifying effective interventions, assists moral arguments for taking action. The extent to which this type of rationale for the use of deception is justified depends upon what exactly is being done.

Necessity

Whether we should not go beyond what is necessary in infringing moral considerations in research depends in part upon the value of the information obtained in so doing. If current information on brief alcohol interventions were widely accepted as being sufficiently rigorous on which to base decisions about what we as a society should do, then the work that we are doing would probably be unnecessary. The implementation of brief interventions has been slow in large measure because existing evidence and claims of potential public health benefit have not been found to be sufficiently compelling (Heather 2012). We thus believe this work is necessary.

Least Infringement

According to the Nuffield Council Report on Public Health Ethics (2007), "Individual consent is not always relevant or appropriate when considering public health measures. For example, individual consent might be unnecessary if the measure is not very intrusive or if it prevents significant harm to others . . . in particular where there is only a limited degree of interference with individuals' liberty and no substantial health risks" (3). The degree of intrusiveness is an example of least infringement, identified by Childress and colleagues (2002) as requiring justification.

If deception really is essential, could we reduce its extent, as participants may be expected to object more to be-

ing actively misled with false information than to having information withheld? It is hypothetically possible that deception could have been used differently in these studies in order to minimize the infringement of rights. Two possible alternatives have been suggested for this purpose, both of which involve some permission being given for deception to be used: (1) make the participants aware that they are going to be misled or not fully informed in advance (authorized deception; O'Neil and Miller 2009; Wendler and Miller 2004); or (2) have someone provide informed consent on their behalf (consent by proxy; Bortolotti and Mameli 2006). Both possibilities are problematic to the extent that they lack face validity for studies of this type. The former would specifically draw attention to the conduct of the research that the study is otherwise designed to deflect attention away from (Fisher and Fyrberg 1994). This would probably evoke wariness among participants, interfering with their engagement in the study. In this respect, our studies resemble social psychology experiments, whose designs are informed by consideration of psychological responses, moving the setting from the laboratory to the internet. A key advantage of working in this way is that behavior is not constrained by the artificial laboratory setting and the research process can be unobtrusive, important considerations for social and behavioral sciences. The latter possibility (proxy consent) would be so impractical on an individual level that it could not be considered for implementation. Although developmental work over the years has paid careful attention to any issues raised, consulting with student bodies might be useful to consider further as a form of proxy consent at a population level.

Public Justification

In publishing this article we invite consideration of the ethical issues raised by our own decisions, as well as about any implied possibility of more widespread use of deception in research. The final condition requiring justification identified by Childress and colleagues (2002) is public justification. This article offers a first step in a two-step process where public justification within the research community is a precursor to justification with the public. We have not yet developed our thinking about how this might best be done.

FURTHER JUSTIFICATIONS FOR OUR APPROACH

The fully informed right to decide whether or not to participate has been denied in the three trials comprising this case study, involving an apparent diminution of respect for persons (O'Neil and Miller 2009). Research participants are also members of society and thus may gain from the societal value of the research being done, however small and indirect this gain may be to them. The widely accepted, and perhaps the only possible, justification for these infringements of rights and lack of respect lies in the social value of the deceptive research and thus the possible consequences of the research not being done, or not being done as well, without deception (Brendel and Miller 2008; Wendler and Miller 2004). It could be argued that giving too much weight

to the views of research participants can itself be unethical if it disadvantages the community as a whole by depriving it of the most valid investigations of important issues. What respect is shown to those people who suffer because of their own or other people's drinking if we forgo opportunities to learn how to better prevent and deal with alcohol or other public health problems? Such a concern is fundamental to public health ethics. It is not of course being suggested that this justifies *any* use of deception, but rather that it is possible to justify the particular forms of deception employed here in this way. We suggest that it is unlikely in these studies that participants will be harmed beyond the lack of respect shown to them.

This should not, however, obscure that the use of deception unavoidably involves moral costs. Consider a world in which there was much more deception than there is now and ask whether this world is likely to be a better place. Although it may be justified in certain circumstances, and may produce moral benefits as well as moral costs, deception in research infringes on what are widely accepted as rights that research participants should have (Brendel and Miller 2008; Miller et al. 2008; O'Neil and Miller 2009). We see deception in research as involving a trust violation by those in a relatively powerful position (we researchers), in relation to the people we want to study. This entails the infringement of rights, and suggests the possibility that other harms may emanate from deception. Although there may be moral benefits consequent on the wider use of deception in research imaginable, there would also be moral costs.

Bortolotti and Mameli (2006) identify both moral benefits and costs in the use of deception, arising from an examination of the nature of autonomy. They describe examples in relation to prejudices and other forms of personal biases where the use of deception promotes the revelation of insidious ways of thinking and the accrual of self-knowledge, which serve to increase rather than decrease individual autonomy. Being given opportunities to reflect upon one's attitude or behavior may lead, they argue, to more autonomous behavior. Their conception of autonomy is one where it is "not only about offering people the opportunity to make their own independent decisions, but also about ensuring that those who have this opportunity are aware of the relevant factors that might affect their decisions" (Bortolotti and Mameli 2006, 270). They recognize that such learning or self-discovery may be distressing, and that one should attend carefully to the extent of any such distress, though they point out that we as a society value education as a moral good. If our studies encourage people to think a little bit more about their behavior because they answer some questions about it when taking part, this moral benefit needs to be considered, as well as the moral cost involved in getting them to do this thinking without seeking their permission for it. Our participants have given us data in the form of free text feedback comments that could be useful in this regard.

Studies of university student participants generally suggest that they do not mind taking part in deceptive studies and that there are not any obvious harms to so doing (Fisher and Fyrberg 1994; Miller et al. 2008; Wendler

and Miller 2004). It is unknown, however, what may be the nature and extent of harms to participants as a result of the use of deception in other research settings or in other populations because this has not been well studied. As well as direct harms to participants, there is also concern about the possible corruption of researchers where the use of deception in a given study may cause less ethical practice among researchers in other studies (Wendler and Miller 2004). Such harms would be difficult or impossible to quantify.

This leaves us in the position of preferring to use deception, for the reasons and in the ways we have described, in a context and on a scale that we believe has not been previously subjected to ethical scrutiny in the literature. We have consulted formal guidance where it is available in carefully developing the research methods over time, paying attention to feedback in our earlier studies that has not revealed any issues of concern not covered here (Hallett et al. 2009; Kypri et al. 2009; McCambridge and Day 2008). We are struck by the limited coverage of these issues in the various forms of existing guidance we have consulted. We have gained ethical approval for the conduct of these studies and worked through these issues in teaching sessions on public health research ethics and in more informal ways.

"PRAGMATISM" IN PUBLIC HEALTH ETHICS

Our public health ethics approach to these issues shares strong similarities with the approach of "pragmatism" in clinical research ethics, "best understood not as a unique method of ethical analysis or a systematic source of validated ethical principles, but instead as a spirit of open enquiry and practically focussed reasoning about ethical dilemmas" (Brendel and Miller 2008, 25). We discovered this approach in the literature when looking for helpful ways of thinking about the difficult moral issues arising from using deception in research. It had obvious appeal for us, as it both resembled a more coherent and well-articulated example of how we had ourselves made sense of these issues, and provided a guide to further thinking. Pragmatism strives explicitly to balance the moral value of socially useful research with moral responsibilities to research participants. The protection of research participants during the conduct of socially valuable research is framed as a practical problem, ultimately requiring judgments about which reasonable people may disagree. It is essentially a problem-solving case-study method, which applies ethical principles as potentially useful instruments rather than as fixed rules (Brendel and Miller 2008). It is certainly not implied that our treatment of these issues represents the only possible application of pragmatism.

This orientation to the likely consequences of acting or not acting in a given way calls attention to the value of empirical data in decision making, and experimental data in particular (Brendel and Miller 2008). Miller and Wendler (2006) suggest that empirical data are no substitute for ethical reflection, though they undoubtedly can be an aid to it. There are scant data on attitudes to deception in research in

general, as well as in relation to specific study contexts such as are considered here. Similarly, whether or not there exist harms consequent on deception remains largely unknown because of the lack of a tradition of empirical study. We see much potential benefit in bringing together methodological and ethical thinking, considering the ethical implications of the findings of methodological studies and likewise considering the methodological implications of empirical studies of ethical issues such as those already described. Surveys of views on ethical issues among prospective participants in research, for example, should not be difficult to undertake.

The Importance of Empirical Studies Investigating Issues of Ethical Significance: Debriefing as an Example

Debriefing, making participants aware of deception after the event, is usually strongly recommended in all relevant ethical guidance of which we are aware. In some cases recommendations on debriefing are qualified with “as appropriate” (O’Neil and Miller 2009) or in similar terms, and the question of whether or not debriefing is beneficial requires consideration in specific study contexts. One main argument in favor of debriefing pertains to the rights and respect deficit. While debriefing is not any form of retrospective informed consent, we agree with Miller and colleagues (2008) that it serves a moral accountability function. Another argument is that it provides an opportunity for research participants to make known their reactions (British Psychological Society 2007). One counterargument is that debriefing itself may cause distress, and for this reason information given is recommended to be constructed with care to minimize this possibility (British Psychological Society 2007). Another counterargument is that informing large numbers of people that deception has been used may have deleterious impacts on future participation in research, thus diminishing the methodological rigor and hence the social value of future research. We see no direct harms to our participants consequent upon not debriefing and thus allowing them to possess uncorrected beliefs about the nature of the studies in which they took part, while in other studies this may not be the case (O’Neil and Miller 2009).

We wished to explore how to actually implement debriefing in practice in large online trials and thus randomized all participants in the ESDA methodological Study C (Kypri et al. 2011) to be debriefed in two different ways: (1) with the debriefing information in the body of the e-mail and additional information on study methods and results available by clicking on links; and (2) making all this information available only by clicking on links. We measured the proportions who clicked on the links and how long the pages remained open. We found that the latter method approximately doubled the rates of clicking on the links to study protocol and results respectively, though overall only one quarter of this group clicked on any links (McCambridge, Kypri, and Wilson 2012). These data provide a platform for further investigations of implementing debriefing online and inform ethical evaluation of this practice.

We invited participants in Study B, the AMADEUS-1 trial (McCambridge, Bendtsen, et al. 2012), to take part in two focus-group interviews. In each we explored in-depth reactions to being debriefed in person in the presence of other participants, discussed the ethical issues addressed here, and sought views on whether and how debriefing of the remainder of the study population might take place. We subsequently decided to debrief all trial participants, and reserved the possibility that data could be withdrawn if e-mail correspondence revealed concerns that were not satisfactorily resolved. Interestingly, the participants thought that this option should not be made too easily available. The other main finding concerned heightened distrust of research invitations, and although this was interwoven with confidentiality and privacy concerns about Internet use in general, it suggested a paradoxical harm arising from, or accentuated by, debriefing itself. There are obvious moral costs to any actions inhibiting future participation in research. We intend to think further about whether we should undertake debriefing in future studies involving deception and are considering not doing so. We anticipate not making any such decision without further empirical studies.

CONCLUDING COMMENTS

The existing consensus is that deception may be used as a last resort when there is no alternative to not using it in order to obtain required data of a methodologically rigorous standard. Rather than being a last resort, some degree of deception appears more an essential prerequisite to doing methodological research of the type presented here and also to be useful in evaluations of behavioral interventions that exert small effects and are vulnerable to biases associated with research participation. These small effects on behaviors are, nonetheless, important to know about as we try to find better ways to deal with alcohol and other health compromising behaviors. Using the Internet to do research on large numbers of people in this way means the potential for deception is likely to grow. This public health context changes the ways in which the moral costs and benefits of deception are weighed up but does not remove the moral costs.

The use of deception in public health intervention research and elsewhere, in our view, thus should be treated with skepticism on ethical grounds. It should not, however, be rejected out of hand. Its possible use should be considered carefully by ethical committees, paying close attention to study context. If it is judged useful or necessary to produce more valid inferences, the moral costs involved in obtaining such data need to be considered in relation to the moral benefits that the data may produce, which are in turn contingent upon the scientific and social value of the research. Evaluation of the costs and benefits will be enhanced by empirical data. We recognize that one possible consequence of our own openness to deception, and any favorable attention to the issues raised here, is that there may be more of it. We thus see it as raising obligations, which we are happy to accept, that the use of deception in research

should be accompanied by empirical studies to inform ethical decision making and that there should be both scientific debate and public justification. ■

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