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Journal of Clinical Epidemiology ■ (2014) ■

Journal of Clinical Epidemiology

COMMENTARY

Research participation effects: a skeleton in the methodological cupboard☆

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Accepted 14 March 2014; Published online xxxx

Abstract

Objective: There have been concerns about impacts of various aspects of taking part in research studies for a century. The concerns have not, however, been sufficiently well conceptualized to form traditions of study capable of defining and elaborating the nature of these problems. In this article we present a new way of thinking about a set of issues attracting long-standing attention.

Study Design and Setting: We briefly review existing concepts and empirical work on well-known biases in surveys and cohort studies and propose that they are connected.

Results: We offer the construct of ''research participation effects'' (RPE) as a vehicle for advancing multi-disciplinary understanding of biases. Empirical studies are needed to identify conditions in which RPE may be sufficiently large to warrant modifications of study design, analytic methods, or interpretation. We consider the value of adopting a more participant-centred view of the research process as a way of thinking about these issues, which may also have benefits in relation to research methodology more broadly.

Conclusion: Researchers may too readily overlook the extent to which research studies are unusual contexts, and that people may react in unexpected ways to what we invite them to do, introducing a range of biases.

Keywords: Research participation; Bias; Research methods; Hawthorne effect; Research assessment; Mixed methods; Surveys; Cohort studies

The construct of ''research participation effects'' (RPE) has been proposed to better guide the empirical investigations of issues previously conceptualized as the Hawthorne effect [1]. We have also elaborated overlooked implications for behavioral intervention trials, identifying mechanisms by which bias may be introduced which randomization does not prevent [2]. This discussion considers the wider implications of RPE for thinking about bias, particularly addressing existing thinking about bias in surveys and cohort studies.

New ways of understanding biases provide platforms for important advances in research design and methods. For example, Solomon [3] identified that the discovery of ''pre-test sensitisation'', whereby measuring individual psychology or behavior at one point of time biased later measurement of the same characteristics, led to the introduction of control groups within behavioral sciences. Chalmers [4] identified allocation concealment to prevent selection bias as the primary motivation for the use of randomization in the original streptomycin trial. Chalmers [4] has suggested that addressing biases resulting from patient preferences may provide the next historical milestone in the development of trials methodology. Just as patients may prefer allocation to one arm of a clinical trial over another, people may react to whatever it is they are requested to do in the context of research. These reactions have the potential to affect study outcomes in ways that undermine the validity of inferences the research was designed to permit.

A few years after the Hawthorne effect made its debut in the scientific literature [5], the concept of ''demand characteristics'' was introduced to psychology [6]. This referred to the ways in which study participants responded to their perceptions of the implicit preferences of researchers, tailoring their responses so as to be good subjects. Like the Hawthorne effect, although being well known, this construct has contributed disappointingly little to the methodological literature [7]. The unintended effects of research assessments have received attention other than when conceptualized as the Hawthorne effect. Randomized evaluation studies often show small effects, though there are inconsistencies [8–12].

Conflict of interest: There are no competing interests to declare.

Funding: J.M. is supported by a Wellcome Trust Research Career Development fellowship in Basic Biomedical Science (WT086516MA) to investigate the issues addressed in this article.

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0895-4356/$ - see front matter
http://dx.doi.org/10.1016/j.jclinepi.2014.03.002

What is new?

- "Research participation effects" offer a new way of thinking about poorly understood sources of bias in surveys and cohort studies, and also in trials.
- Research studies are unusual contexts, and people may react in unexpected ways to what we invite them to do.
- Adopting the perspective of the participant suggests that existing well-known sources of bias may be connected to each other.
- Mixed methods participant-centred research may lead to better prevention of bias.

Change due to having been assessed, having views about the desirability of different possible research requirements, and deliberately or unwittingly trying to satisfy researchers, are all consequences of research participation. The interaction of the research participant with the research process is discernible as a common thread running through these examples. The consequences of research participation may vary in strength across study designs, participants, topic areas, and the contexts in which research is done, and according to more specific features of the studies themselves.

1. Well-established biases in surveys and cohort studies

Ensuring adequate response rates, that is securing participation itself, is widely established as a key issue in survey design [13]. Evidence has accumulated over decades on how to do this [14], and in a context of falling response rates there has been extensive research on the implications of nonresponse for the estimation of prevalence and other parameters of interest in general household surveys [13]. There has also been much study of reporting errors made by participants in surveys, which draws attention to the sensitivity of the particular behavior or issue being enquired about [15]. This literature also distinguishes between task-related errors that are technical products of survey design, and motivated responses, for example, in the form of self-deception and impression management [16]. Thus in surveys, biases associated with research participation apply both to the decision to take part and to the accuracy of information provided. These biases may be conceptualized in many ways and often are thought about differently across disciplines and over time [17].

In a prospective cohort or longitudinal study [18], repeated data collection permits consequences of research participation to manifest themselves in altered behavior, cognitions, or emotions [12]. As Solomon [3] described, it is possible for inferences about data collected at one time point to be biased simply because of earlier data collection. This complication is more likely to occur, and is more likely to be problematic, in certain circumstances (see below). Some outcomes cannot be influenced by reactivity to evaluation, for example, where data collection is unobtrusive [19].

Asking someone how often they ride a bicycle may increase cycling in some circumstances and not others. It can only do so if the causal pathway to this outcome involves behavior that can be modified by this procedure [20]. For example, if a study participant owns a bicycle and is asked about their cycling behavior or views about cycling in a cohort study of health and lifestyle, they might think further about cycling, and might cycle more frequently as a result. This would artificially inflate levels of cycling in the cohort. If the study participant does not have access to a bicycle, this is less likely to occur unless they first acquire the means to start cycling. Asking about cycling in a different context may also reduce the likelihood of this occurring. The psychological processes involved are not important here; the point is that the more such effects occur, the more they may undermine the objectives of the study by introducing bias.

This problem may not emanate only from the content of data collection. Participants may have read the consent form carefully and thought about their health and lifestyle before deciding whether or not to take part. A cohort study is thus vulnerable to both the possible reporting and participation problems previously described for cross-sectional surveys, at both study entry and at follow-up. Additionally, actual change in the behavior being investigated may have been induced. Change in the object of the evaluation influenced by any aspect of research participation entails bias, regardless of how it has been produced. This is so unless an assumption is made that such influences do not vary in time with repeated measurements, which is unlikely to be very often a safe assumption. Randomized controlled trials are cohort studies with randomization, and as such are vulnerable both to the previously described problems, and also to additional ones associated with randomization [2]. This implies problems in making valid inferences from research data that afflict all study designs. These problems are mostly, but not all, very well known. What is novel about this presentation is the suggestion that they are linked, and by extension that conceptualizing them in this way as RPE may lead to better understanding of methodological problems.

2. A research participant-centred perspective

Different types of studies make different requests of, and place different demands on, their participants. There is nonetheless a core sequence of early events involving both a recruitment and baseline assessment phase, as presented in Fig. 1 for a typical individually randomized trial. We have found this a useful vehicle for thinking through the potential for RPE. For those who continue to participate over time, our lack of attention to the possible impact of the research process might imply that it is inert [12] and perhaps also that participants are somehow passive in this