

LETTER TO THE EDITOR

The reply to Sharpe et al.: Hawthorne effect in the YourCall trial suggested by participants qualitative responses

Reductions in self-reported drinking in control groups in alcohol trials have been consistently reported for more than 40 years [1,2]. The qualitative data reported here by Sharpe et al [3] from approximately half the trial participants identify interesting sources of such reductions. Their observations provide new evidence for previously suggested explanations [4], and add to a qualitative literature on research participation effects which is in its infancy [5,6]. Sharpe et al discuss various causes of change, although omit here the effects of social desirability considerations on reporting on one's own behavior [7]. Such bias would likely afflict both the trial outcome data and the free text responses, although it is noteworthy that these data were volunteered rather than requested, and thus may be less likely to be biased in this way than the trial outcome data. We thus concur with Sharpe et al that study participation itself is a likely source of change [8], and that attention to study context and how it shapes participant behavior can develop our understanding of important but neglected issues [9–11]. The qualitative data reported here are thus valuable. We have two additional points to make.

Although the Hawthorne effect concept is well known, it nevertheless provides an unsatisfactory basis for advancing further study of the phenomena lurking beneath this umbrella term [12]. In addition to the uncertainties about whether the effect is on reduced drinking or on reporting behavior, the limitations of the construct can be illustrated by attention to the implications of the issues being considered within the specific context of trials. Relatedly, we take issue with the concluding statement that: “the phenomenon is likely to have underestimated the intervention effect in our study.” [3] In the parent trial report, it is stated that “we do not expect the level of underreporting [of alcohol consumption] to be different in the two groups, we do not expect this to threaten the validity of the intervention effect” [13]. We agree with the parent trial statement and suggest that the qualitative data analysis demonstrates that other research participation effects are also similar in both groups. In trials, where there is under-reporting or any other form of reactivity to study conditions, bias largely arises from the interaction

of these artifacts with randomized allocation (there may also be ceiling effects and other mechanisms of bias) [14]. In other words, that one randomized group reacts differently to another, to features of the study conditions [14]. Further qualitative analyses designed to examine subtle differences between arms would be needed to give substance to concerns about the validity of the effect estimate. Presumably the extent of any possible bias in this trial will be small.

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DOI of original article: <https://doi.org/10.1016/j.jclinepi.2019.05.035>.

Conflict of interest: The authors have no conflict of interest.

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<https://doi.org/10.1016/j.jclinepi.2019.05.034>