Title: Using the theory of planned behaviour as a process evaluation tool in randomised trials of knowledge translation strategies: a case study from UK general practice

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Reviewer: Jeffrey Smith

Reviewer's report:

General Comments:
The stated purpose of the manuscript is to “illustrate the applicability of causal methods in randomised trials by undertaking a theory-based process evaluation study to explore whether the cognitions of general practitioners predicted their test requesting behaviours and secondly, whether the trial results were mediated by the theoretical constructs.” Although I agree with the authors’ premise that theory-based process evaluation can offer useful information on causal mechanisms of intervention effects and can enhance interpretation of study data, the approach utilized in this case raises concerns about the description of this work as a ‘process evaluation’ (see below).

Major Compulsory Revisions:
Process evaluation (PE) conducted alongside a randomized trial can offer useful information on fidelity of intervention implementation (ie, whether the intervention was implemented as planned), possible mechanisms/mediators of intervention effects, and (for future studies) potential refinements or modifications to consider in intervention design/implementation to enhance its impact on targeted clinical behaviors. PE is typically conducted either concurrent with intervention implementation (so information on the above can be assessed while the intervention is ongoing) or immediately following implementation… typically involving a combination of qualitative and quantitative methods. Concerns for this study are:

The quantitative survey for this study was administered 12 months after the interventions had been initiated, and the data collected in the surveys were based on ‘fixed’ scenarios that may or may not have been representative of ‘real’ patients seen by providers during the course of the trial. Data apparently were not collected while the interventions were ongoing, and it is possible that the scenarios included in the survey may not adequately represent patients presenting to providers with potentially more complex clinical issues.

No pre-intervention survey was administered, so it is not possible to assess with any confidence whether the intervention had an effect on TBP constructs (ie, we can not calculate pre-/post- change in survey scores). Although there are differences in the post-intervention survey scores between trial groups, we have no way of knowing whether these differences may have existed prior to the
intervention. Presumably, randomization of providers to trial groups should have limited the potential for such pre-intervention differences, but there are no pre-intervention survey data available to confirm (or refute) that presumption.

The use of practice rather than individual provider test requesting behavior as the dependent variable (DV) is a major study limitation (which the authors acknowledge), but particularly in this case since my understanding of the Theory of Planned Behavior is that it focuses on individual (rather than group) behavior. Data on individual provider test requesting behavior would have been more appropriate (the authors do note that such data were not available). Further, the authors point out another problem with the dependent variable in that it may not match the context of the scenarios included in the survey (ie, DV does not distinguish between initial and repeat tests).

The above concerns lead me to conclude that ‘process evaluation’ is not an appropriate description of this work; or if it is appropriate, represents process evaluation in its most limited form.

Minor Essential Revisions:

More information is needed on the rationale for selecting the 3 tests (ferritin, FSH, HPS) that were focused on in this study. Specifically, why were these 3 tests selected out of the 9 tests that were targeted in the randomized trial? What were the other 6 tests and why were they excluded?

Although completed surveys were returned from 42 of the 43 practices participating in the trial, the authors should moderate assertions of robust study results given that only 57% of the 50% of providers receiving the survey actually completed it (equating to only 28.5% of providers participating in the trial). Related to this issue, do the authors have any data on survey non-responders that could be compared to responders to assess whether they differ from one another on potentially important characteristics?

Figure 1 was not included in the version of the manuscript I downloaded from the website for the review, though it apparently was only an illustration of the TPB, with which I am familiar.

In the discussion section, it is too strong to state that the meditational analysis “suggested” that intentions to request an FSH or ferritin test was part of the causal pathway in the trial. Because the survey was not administered to providers before the trial began, we cannot be confident that the interventions had an effect on the TPB constructs (ie, no pre-/post- assessment is available).

The following sentence from the discussion section should be rewritten…

“In this example, the changes in constructs between intervention and control practices were large and provided compelling evidence of differences.”

The survey was administered only once (post-intervention), so although the results reflect some differences between interview and control groups, they do not represent any change in scores from an earlier assessment.

Discretionary Revisions:
It would be helpful if the authors could discuss concordance/discordance of their study findings to results from the systematic review conducted by Godin et al (citation #9 in the Reference list).

**Level of interest:** Reject as not of sufficient priority to merit publishing in this journal

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.