Reviewer's report

Title: Shared Decision Making for Prostate Cancer Screening: The Results of a Combined Analysis of Two Practice-Based Randomized Controlled Trials

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Reviewer: Steven B Zeliadt

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This manuscript describes two small trials of a decision making video and coaching session about prostate cancer screening given to men prior to meeting with a physician. While improving how men and providers communicate about prostate cancer screening is important, the description of the interventions and outcomes could be improved so that readers can build on this work. There may be some interesting findings buried in these studies, however, as currently presented these trials are not high quality enough to make any strong conclusions, especially conclusions distinguishing between shared and informed decision making. The authors should reconsider what can appropriately be concluded.

Major Revisions

1. The exact intervention is unclear. What video–based decision was used? The authors describe some of the content in Table 1, but more detail would be helpful. Was this video something the authors developed or did they use a previously developed one? As all men in both control and intervention groups were seen by physicians who went through the education session, the intervention does not seem to be testing the effect of this education session. Perhaps do not describe it as part of the intervention since the control subjects received it. Also, this presents an important limitation that authors do not address, which is that all providers were volunteers and knew they were being evaluated with a likely Hawthorne effect. The providers were notified of the patient’s participation in the trial, which would encourage a Hawthorne effect.

2. The description of the coaching session with the citation by Kennedy is unclear. The authors should describe in more detail the content of this coaching session. This also presents an important issue in that both providers and patients were not blinded to the intervention. Is it the content of the coaching session or the knowledge that patients received the session that influenced the outcomes the authors observe? The authors note that the providers were notified of a patient’s participation but not group assignment, however, isn’t it likely a provider could detect in a few seconds of conversation whether the patient received the screening videos/coaching session vs highway traffic safety video?

3. The authors should better justify the outcome “it is okay to decide not to have a PSA test after learning the facts” and how this measure was developed. The
authors attempt to label this measure as “personal choice” but the leading nature of the item and the emphasis that facts should drive the decision rather than a man’s underlying preference for potentially reducing his risk of cancer vs incurring potential harm seems disconnected to the proposed goal of the intervention. I would like to see more description of this measure, and its properties. The authors indicate they did focus group testing, was this measure included in that work, and if any testing was done with patients, what did they think this question means?

4. The authors adapted 4 items from a multi-item survey about knowledge. The authors selected 4 items about treatment and diagnosis but nothing focusing specifically on screening. Why were these items about treatment selected? There seems to be critical pieces of knowledge information related to screening that need to be included, such as the small absolute benefit relative the harms of overdiagnosis. This is important because the authors attempt to conclude: “Our findings suggest the ability of SDM interventions to increase men’s knowledge and alter their preferences for prostate cancer screening”. This conclusion seems like a stretch based on these outcome measures.

5. Please more fully describe the analytic approach. The authors indicate “P6….we employed identical implementation and measurement strategies to allow combining of data if no differences were noted in the outcomes of the two trials.” Neither trial appears to be appropriately powered for the clustered design given a cluster size of 28 providers, it is unclear who “differences in the outcome of the two trials” would have been interpreted. The authors note the trials were not powered on hypothesis testing – however, I was not sure what this comment meant. It would be helpful to clarify, and potentially report measures such as the intra class correlation of providers.

6. The authors need to clarify their rationale for presenting unadjusted risk differences but not adjusted risk differences with something more than the statement: “absolute differences can only be inferred from predicted probabilities.” The side by side presentation of unadjusted risk differences and adjusted odds ratios was not helpful or clear. If adjustment did not change the findings, then why do it for a randomized trial? The authors should consult: Kleinman LC, Norton EC. What’s the Risk? A simple approach for estimating adjusted risk measures from nonlinear models including logistic regression. Health Serv Res. 2009 Feb;44(1):288-302. The authors appear to be presenting adjusted odds ratios from a logistic regression model, not risk ratios as described. The underlying probabilities are quite common, so risk ratios would be more appropriate. The authors should clarify whether their results are adjusted odds ratios mislabeled as risk ratios or how they calculated risk ratios from the logistic regression model. The authors described including random effects for provider and practice, but the results suggest this was done only as part of sensitivity analysis and not the main findings that presented: P14 “After adjustment for potential confounders and the random effects of physicians differences remained statistically significant.” Please clarify what model was used for the tables, and adjust the methods section appropriately.
7. The authors focus the discussion section and interpretation of their findings their intervention led to an “informed” decision but maybe not a “shared” decision. This interpretation seems a bit of a stretch, and the manuscript could be improved by discussing this more clearly. The attention to “informed” does not on its face seem to correlate with the 4 knowledge items the authors used, and the focus on a “shared” outcome based only on the Denger Control Preferences Scale is also a very limited interpretation of shared. The authors should connect this to the extensive literature on both informed and shared decision making outcomes.

Level of interest: An article of limited interest

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.