PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Aversion to pragmatic randomized controlled trials: three survey experiments with clinicians and laypeople in the United States
AUTHORS	Vogt, Randi; Heck, Patrick; Mestechkin, Rebecca; Heydari, Pedram; Chabris, Christopher; Meyer, Michelle N.

VERSION 1 – REVIEW

REVIEWER	Raymond, Jean Univ Montreal
REVIEW RETURNED	06-Mar-2024

GENERAL COMMENTS	Well and clearly written Transparently planned

REVIEWER	Mirzaei , Alireza Ardabil University of Medical Sciences
REVIEW RETURNED	08-Mar-2024

GENERAL COMMENTS	General overview Overall, the paper requires Major revisions in terms of language, structure, and narrative. It is very difficult to read and understand. Abstract: 1. Provide a clear rationale for the selection of clinicians and laypeople as participants in the study. 2. Include a section discussing the practical implications of the study results for healthcare practice and policy. 3. Expand on the recommendations for future research directions based on the study findings. Introduction: 1. Provide more context on the setting of the study and its relevance to the broader healthcare landscape. 2. Include a comprehensive review of literature on experiment aversion in healthcare to contextualize the study within existing research. Methodology: 1. Provide a detailed overview of the survey design, including information on data collection methods and analysis techniques. 2. Address potential biases in the survey experiments and discuss strategies implemented to mitigate them. Results: 1. Conduct a deeper analysis of participant responses to identify underlying factors contributing to experiment aversion. 2. Discuss how the study results can contribute to improving the

	design and implementation of pragmatic randomized controlled trials in healthcare settings. Discussion: 1. Explore possible reasons for continued aversion to experimental comparisons among participants, considering factors such as risk perception and decision-making biases. 2. Discuss how addressing experiment aversion can enhance the adoption and implementation of evidence-based practices in healthcare settings. Conclusion: 1. Provide concrete recommendations for strategies to reduce experiment aversion among clinicians and laypeople. 2. Discuss potential benefits of overcoming experiment aversion in terms of promoting evidence-based decision-making and improving patient outcomes. Limitations: Propose strategies to address identified limitations in future research endeavors to enhance the validity and reliability of study results.

REVIEWER	de, Kazuki Osaka University
REVIEW RETURNED	16-Mar-2024

GENERAL COMMENTS	Thank you for giving me the opportunity to review the article. The authors conducted a study focusing on the aversion to pragmatic randomized controlled trials. I thought that the topic is socially important, but there are fundamental problems in the manuscript. Therefore, the authors should revise the manuscript before further considerations. I listed my comments below. COMMENTS: Title: 1. The authors should include the name of the country where the research was conducted in the title. Abstract: 2. The authors should add major characteristics/demographics of the participants in the abstract. Strengths and limitations of this study: 3. The authors should explain about the representativeness of healthcare professionals in more detail. Methods: 4. How did the authors prepare the vignettes? They should explain about the process. It is important to consider which specialists were involved in creating the vignettes. 5. The authors should explain about the allocation/randomization methods of this study. 6. The authors should add the statistical analysis section (including sample size calculation) in the main manuscript. 7. How did the authors recruit the clinicians? 8. It is also important to consider how the ratio of clinicians was determined/estimated before conducting the study. 9. The authors should clearly state the specific name of “a large health system” which they used in this study. They should write this kind of important information (also) in the main text. Results: 10. The authors should show the demographics of the participants in the main text. It is important information for the potential readers.

	11. Why are the authors using SE instead of SD? Discussion: 12. The authors should discuss about the limitations of this study in more detail. 13. In the “practice variation,1 but also anticipating”, “1” may be a typo.

REVIEWER	YANG, Li Peking University School of Public Health
REVIEW RETURNED	25-Mar-2024

GENERAL COMMENTS	The idea of comparing the aversion to pRCT within and without COVID-19, and the interventions including COVID-19 interventions and non-COVID-19 interventions is meaningful. However, this paper is not well structured or presented. The authors should revise the wording to make it more straightforward and more precise. The Introduction part is lengthy, the Methods part has no clear description of the statistical methods used, and the Discussion part does not present a conclusive trend of the aversion. 1. Page 4 summary box, what “decision-science approach” is used in this study? This term is not in the main body of manuscript. 2. Page 4 summary box, the authors mention 8 pRCT in layperson and 4 pRCT in clinician; however, this information is inconsistent with Table S1. In the manuscript, survey was done during the COVID-19 pandemic. 3. Page 4 summary box, authors mentioned tye questionaires were collected before and during COVID-19; however, the information in Result part 4. Page 7 line 37, what do these acronyms mean? 5. Page 8 line 28, how do you define “significantly less”? The wording in this manuscript should be more precise. 6. The Introduction part is lengthy (3.5 pages). Some of the information should be merged into the Methods part. 7. Some descriptions, especially in the Introduction part are confusing. 8. The method part should contain your sampling method, study population, and statistical analysis method. However, the methods part did not include the information and was not well structured. 9. Page 10, line 43, why 700 participants can be “broadly representative”? 10. Page 13-14, the description of participants and scenarios should be listed in Tables. 11. Page 19 line 28, wrong citation. 12. Could the author try to summarize under what circumstances the lay people/ health workers can be less aversion to pRCT?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Jean Raymond, Univ Montreal
Comments to the Author:
Well and clearly written.
Transparently planned.
Response: Thank you for your positive feedback.

Reviewer: 2
Dr. Alireza Mirzaei , Ardabil University of Medical Sciences
Comments to the Author:
General overview
Overall, the paper requires Major revisions in terms of language, structure, and narrative. It is very difficult to read and understand.
Response: This is a difficult comment to address, as it is not very specific and we—perhaps naturally—believe that the manuscript is overall clear. We have attempted to address all the reviewer's specific comments on the different parts of the paper, and we hope that our detailed responses to those comments will also address the general concern of the reviewer as well.

Abstract:
1. Provide a clear rationale for the selection of clinicians and laypeople as participants in the study.
Response: Thank you for this suggestion. In the Abstract, we now note that we chose clinicians because they are "the types of people who conduct or make decisions about conducting pRCTs" and laypeople because they are "the types of people who are included in pRCTs as patients." Understanding the extent to which these stakeholders are experiment averse is important.

2. Include a section discussing the practical implications of the study results for healthcare practice and policy.
Response: Given the structured format of abstracts in BMJ Open, we do not have room to add a practical implications section. However, in the Discussion section, we outline some practical implications of our results. For example, we note that "explaining critical concepts like clinical equipoise or unwarranted variation in medical and NPI practice might diminish experiment aversion" (page 22).

3. Expand on the recommendations for future research directions based on the study findings.
Response: Similarly, due to the structured nature of the abstract, we do not have room to add future research directions to the abstract. However, in the discussion, we note that "the solution [to the widespread experiment aversion that we document in this manuscript] is not to abandon randomized evaluation, but to incorporate it into routine clinical care and healthcare delivery via pRCTs" (page 24).

Introduction:
1. Provide more context on the setting of the study and its relevance to the broader healthcare landscape.
Response: In this revision, we have significantly restructured the Methods section to include a "Study setting" section and a "Patient and public involvement" section. In the "Study setting" section, we clarify that lay participants were recruited using an online crowdworking platform and that clinicians of various levels were recruited via email at Geisinger, a network of hospitals and clinics in central and northeastern Pennsylvania, US (page 8). In the "Patient and public involvement" section, we have added a note about the broader relevance of our choice of participants: "Decisions about whether to participate in or conduct pRCTs are made against the backdrop of individuals' personal views and/or anticipation of potential backlash or other public reactions; therefore, how patients and clinicians feel about experiments is relevant to whether and how advancements in healthcare are made" (page 14).

2. Include a comprehensive review of literature on experiment aversion in healthcare to contextualize the study within existing research.
Response: We were the first to observe the "A/B Effect" both within healthcare and in other contexts (Meyer et al., 2019, PNAS). Following this first paper, there was an exchange of letters in PNAS (which we have now cited in our introduction) and a brief report in PNAS where we first demonstrate "experiment aversion" as it is operationalized in the current paper. More recently, there was another paper published in PNAS (Mazar et al., 2023) that calls into question the generalizability of experiment aversion because of its tendency to be reduced when decisions to carry out pRCTs are framed in substantially different ways. We (Vogt et al., in press) and another team of researchers (Bas et al., 2023) exchanged letters with those authors in which we argue that experiment aversion may differ across social contexts and can be affected by debiasing efforts, but that does not mean that it is not an important phenomenon that may affect stakeholder decisions about participating in, conducting, or objecting to pRCTs. We discuss this paper in our "Limitations" section in the Discussion. Although we are aware of other research teams around the world working on experiment

aversion, besides these papers (included in either the Introduction or Discussion, as appropriate), there is no other published empirical literature to include. However, we do include in the Introduction some literature which demonstrates that people have debated the merits of experiments including in ways that suggest experiment aversion may be involved.

Methodology:
1. Provide a detailed overview of the survey design, including information on data collection methods and analysis techniques.
Response: We have significantly restructured the Methods section to include additional information about the study setting, participants, study design, and data analysis.

2. Address potential biases in the survey experiments and discuss strategies implemented to mitigate them.
Response: Thank you for this suggestion. We have expanded the limitations paragraphs of our Discussion section to further discuss the potential biases in our sample, including the specificity of our clinician sample and setting.

Results:
1. Conduct a deeper analysis of participant responses to identify underlying factors contributing to experiment aversion.
Response: In the Supplemental Materials, we include extensive analyses on individual difference predictors (including educational attainment, number of years in practice, familiarity with research methods) of experiment aversion (SM pages 29-35). At the end of the Results section, we include a "Heterogeneity in Experiment Aversion" section which briefly notes that none of the individual differences that we collected explain more than 1.5% of the variance in experiment aversion.

2. Discuss how the study results can contribute to improving the design and implementation of pragmatic randomized controlled trials in healthcare settings.
Response: The data presented in this paper allow us to identify the scope of the problem (i.e., that significant proportions of laypeople and clinicians are averse to experiments across a number of different vignettes) and bring awareness of the problem to the medical community. However, they can not speak directly to how we can improve the design and implementation of pRCTs. Thus, in this paper, we are simply describing the baseline level of experiment aversion—a baseline that, we found, persisted during the pandemic when pRCTs plausibly might have been more appreciated—not yet investigating the solution.

Nevertheless, in the Discussion, we suggest that more patient and clinician education regarding the value of pRCTs and the reality of the illusion of knowledge bias may help reduce some experiment aversion.

In addition, we are currently developing new studies that probe whether experiment aversion is reduced when ethics oversight and prior notice to participants are explicitly included in the description of the pRCT, especially when consent is not possible, as is often the case for pRCTs. We look forward to publishing these results in the future.

Discussion:
1. Explore possible reasons for continued aversion to experimental comparisons among participants, considering factors such as risk perception and decision-making biases.
Response: In the Discussion, we note that the aversion we report could be explained by differences in the length and perceived severity of the pRCT as well as the illusion of knowledge, i.e., "the belief that either the participant herself or some expert already does or should know the right thing to do and should simply do it" (page 21). We also now mention that "Participants may have been averse to the uncertainty that the decision to conduct an experiment conveys. They may have perceived the experiment as more risky than implementing either of the policies it contains. Or they may have experienced hindsight bias, believing that the experiment was unfair to whomever received the least effective policy, neglecting the fact that the results were not known in advance" (page 20).

2. Discuss how addressing experiment aversion can enhance the adoption and implementation of evidence-based practices in healthcare settings.
Response: In our "Conclusion" section, we briefly mention a Norwegian school reopening trial that

was abandoned due to a lack of support for experiments. By addressing experiment aversion, we hope that future policy makers can avoid this missed opportunity.

Conclusion:
1. Provide concrete recommendations for strategies to reduce experiment aversion among clinicians and laypeople.
Response: Though not in our "Conclusion" section, we note that "explaining critical concepts like clinical equipoise or unwarranted variation in medical and NPI practice might diminish experiment aversion" (page 22) at the end of the first part of the Discussion. We have also added a few sentences about how teaching patients and clinicians about the illusion of knowledge may help them overcome that bias in making decisions about experiments: "One possible solution is to teach patients that clinicians typically have many options for treating a condition, that often no one knows which option is best, and that a pRCT is the optimal way to figure that out. Similarly, highlighting unwarranted variation in practice during medical training may help reduce clinicians' negative sentiments towards experiments" (pages 21-22). In the "Conclusion" section, we recommend that randomized evaluation should be "incorporate[d] ... into routine clinical care and healthcare delivery via pRCTs" (page 24).

2. Discuss potential benefits of overcoming experiment aversion in terms of promoting evidence-based decision-making and improving patient outcomes.
Response: In our "Conclusion" section, we now mention these benefits like promoting evidence-based decision-making and improving patient outcomes could result from identifying experiment aversion and then discovering strategies to mitigate it. "Better understanding experiment aversion and then discovering strategies to mitigate it will help grow the evidence base necessary for evidence-based decision-making and, ultimately, improved patient outcomes" (page 25).

Limitations:
Propose strategies to address identified limitations in future research endeavors to enhance the validity and reliability of study results.
Response: Thank you for this suggestion. In addition to the limitations included in the previous version of this manuscript, we now include a discussion about the limitations of the clinician sample that we used (pages 22-23).

Reviewer: 3
Dr. Kazuki Ide, Osaka University
Comments to the Author:
Thank you for giving me the opportunity to review the article. The authors conducted a study focusing on the aversion to pragmatic randomized controlled trials. I thought that the topic is socially important, but there are fundamental problems in the manuscript. Therefore, the authors should revise the manuscript before further considerations. I listed my comments below.

COMMENTS:
Title:
1. The authors should include the name of the country where the research was conducted in the title.
Response: Thank you for this suggestion. We have added "United States" to our title. It now reads "Aversion to pragmatic randomized controlled trials: Three survey experiments with clinicians and laypeople in the United States."

Abstract:
2. The authors should add major characteristics/demographics of the participants in the abstract.
Response: We now include in the abstract demographic details about our samples including age, race, and gender for the layperson sample, and gender, position, and number of years of experience for the clinician sample. "The layperson sample ranges in age from 18 to 88 years old (mean = 38.4, SD = 12.8) and the majority were White (74.6%) and female (55.9%). The clinician sample was primarily female (80.8%), comprised doctors (14.9%), physician assistants (8.5%), registered nurses (53.6%), and other medical professionals, including other nurses, genetic counselors, and medical students (23%), and the majority of clinicians had more than 10 years of experience (62.3%)" (page 2).

Strengths and limitations of this study:
3. The authors should explain about the representativeness of healthcare professionals in more detail.
Response: Thank you for this suggestion. We have added a short explanation to this point in the strengths and limitations summary box by noting that our samples "are convenience samples of clinicians at a specific teaching hospital system in the United States and laypeople on a specific online crowdworking platform." In addition, we added details about the limitations of the clinician sample where we had more room in the Discussion section.

Methods:
4. How did the authors prepare the vignettes? They should explain about the process. It is important to consider which specialists were involved in creating the vignettes.
Response: The authors (and our previous collaborators in this line of research), who are experts in bioethics, philosophy, sociology, decision sciences, cognitive psychology, and social psychology, created the vignettes. On page 11, we have added "To develop the vignettes, we consulted the literature and our knowledge, as experts in bioethics and psychological science, of pRCTs that have historically proved controversial (see Table S3 in the SM for motivations for all vignettes)."

5. The authors should explain about the allocation/randomization methods of this study.
Response: Thank you for this feedback. We have clarified that participants were randomized to vignettes "using the Qualtrics survey software, such that aside from participants who dropped prior to completing the survey, the same number of participants are allocated to each vignette" (page 10).

6. The authors should add the statistical analysis section (including sample size calculation) in the main manuscript.
Response: Thank you for this suggestion. We have reorganized the methods section and included additional details. Power analyses/sample size calculations can now be found in the "Participants" section (pages 8-10) and statistical analyses can now be found in the "Data analysis" section (page 14).

7. How did the authors recruit the clinicians?
Response: We have now clarified that "Clinicians of various levels in healthcare were recruited by email (following a procedure successfully used in several previous studies including [18]) from Geisinger, a network of hospitals and clinics in central and northeastern Pennsylvania, U.S. with a medical school and a research institute" (page 8).

8. It is also important to consider how the ratio of clinicians was determined/estimated before conducting the study.
Response: We conducted a power analysis regarding how many participants (laypeople and clinicians) we should recruit per vignette. However, we did not aim to collect data from a certain percentage of doctors, nurses, etc. within the clinician sample (and it would not have been practically feasible, given the constraints on data collection and recruitment, to ensure specific percentages). Instead, we get this information from the clinician self-reports in the survey and report this breakdown in the "Participants" section of the Method (pages 9-10).

9. The authors should clearly state the specific name of "a large health system" which they used in this study. They should write this kind of important information (also) in the main text.
Response: We have now specified the health system (Geisinger) throughout the manuscript.

Results:
10. The authors should show the demographics of the participants in the main text. It is important information for the potential readers.
Response: Thank you for this feedback. We have added demographics to the "Participants" section of the Methods (pages 8-10) as well as to the Abstract.

11. Why are the authors using SE instead of SD?
Response: As is customary in behavioral science fields, means are graphed with SEs rather than SDs to help readers intuitively visualize what differences are significant.

Discussion:
12. The authors should discuss about the limitations of this study in more detail.

Response: Thank you for this suggestion. In this revision, we have restructured the Discussion to have a separate "Limitations" section (pages 22-24). In addition to the limitations included in the previous version of this manuscript, we now include a discussion about the limitations of the clinician sample that we used (pages 22-23).

13. In the "practice variation,1 but also anticipating", "1" may be a typo.
Response: Thank you for noticing this typo. It has been fixed.

Reviewer: 4
Prof. Li YANG, Peking University School of Public Health
Comments to the Author:
The idea of comparing the aversion to pRCT within and without COVID-19, and the interventions including COVID-19 interventions and non-COVID-19 interventions is meaningful. However, this paper is not well structured or presented. The authors should revise the wording to make it more straightforward and more precise. The Introduction part is lengthy, the Methods part has no clear description of the statistical methods used, and the Discussion part does not present a conclusive trend of the aversion.
Response: Thank you for this feedback. In this revision, we have significantly restructured the Methods and Discussion sections to more clearly explain what we did and what we can conclude from our results.

1. Page 4 summary box, what "decision-science approach" is used in this study? This term is not in the main body of manuscript.
Response: Thank you for this feedback. We have revised our Methods section to say that we are "following a standard decision-science approach commonly used in social and moral psychology…" (page 12) so that our terminology matches throughout the manuscript.

2. Page 4 summary box, the authors mention 8 pRCT in layperson and 4 pRCT in clinician; however, this information is inconsistent with Table S1. In the manuscript, survey was done during the COVID-19 pandemic.
Response: Though in Table S1, we do report 9 vignettes of pRCTs in the layperson sample, the first instance of the Best Vaccine vignette inadvertently included ambiguous wording that unintentionally made the experiment condition less aversive (by implying that participation in the vaccine pRCT was voluntary, which we did not intend). For that reason, we do not include this version in our analyses in the main text. However, results from that vignette can be found on pages 26-27 of the Supplemental Materials. Not counting that vignette, we report 8 vignettes of pRCTs in the layperson sample and 4 in the clinician sample in the main text.

3. Page 4 summary box, authors mentioned tye questionaires were collected before and during COVID-19; however, the information in Result part
Response: We intended this sentence to mean that some vignettes were specific to COVID-19 situations and others were more general (and not related to COVID-19), not that the studies were done before and during COVID-19. We have clarified this sentence in the summary box: "The size of the experiment aversion effect is measured in eight pRCT vignettes (in the layperson sample) and four pRCT vignettes (in the clinician sample) that describe a range of pRCTs from pharmaceutical medical interventions to non-pharmaceutical medical interventions to public health interventions, and specific to the Covid-19 pandemic as well as more general medical situations" (page 4).

4. Page 7 line 37, what do these acronyms mean?
Response: We have now included the full study name for each acronym. See page 5.

5. Page 8 line 28, how do you define "significantly less"? The wording in this manuscript should be more precise.
Response: Thank you for this feedback. The word "significantly" is inappropriate for an introduction where we are not discussing specific results. Therefore, we have deleted this word in this section.

6. The Introduction part is lengthy (3.5 pages). Some of the information should be merged into the Methods part.
Response: We have now integrated the last paragraph of the Introduction into the Methods section.

7. Some descriptions, especially in the Introduction part are confusing.
Response: Thank you for this feedback. We have gone through the Introduction and made edits in hopes of clarifying our arguments.

8. The method part should contain your sampling method, study population, and statistical analysis method. However, the methods part did not include the information and was not well structured.
Response: Thank you for this feedback. We have significantly restructured the Methods section to include additional information about the study setting, participants, study design, and data analysis.

9. Page 10, line 43, why 700 participants can be “broadly representative”?
Response: While our lay sample is not perfectly representative of the general public, we wanted to highlight in our “Study setting” section (page 8) that previous research has shown that participants recruited through crowdworking platforms like the ones we used in this study are broadly representative of the U.S. population (especially compared to other methods like using student volunteers). That being said, we report all demographic information we have about our participants in the “Participants” section (pages 8-10), and in the Discussion section we acknowledge that these individuals may not perfectly represent all demographic segments of the general population (pages 22-23).

10. Page 13-14, the description of participants and scenarios should be listed in Tables.
Response: Thank you for this feedback. We have added demographics to the “Participants” section of the Methods (pages 8-10) as well as to the Abstract. However, given the number and length of vignettes, we believe it would be unwieldy to include all the details of all the vignettes in the main text. These details can be found in full on pages 8-13 of the SM.

11. Page 19 line 28, wrong citation.
Response: Thank you for noticing this typo. It has been fixed.

12. Could the author try to summarize under what circumstances the lay people/ health workers can be less aversion to pRCT?
Response: The data presented in this paper allow us to identify the scope of the problem (i.e., that significant proportions of laypeople and clinicians are averse to experiments across a number of different vignettes) and bring awareness of the problem to the medical community. However, they can not speak directly to how we can improve the design and implementation of pRCTs. Thus, in this paper, we are simply describing the baseline level of experiment aversion—a baseline that, we found, persisted during the pandemic when pRCTs plausibly might have been more appreciated—not yet investigating the solution.

That said, in the Discussion, we describe a pattern of results where the least aversion was seen for pharmaceutical interventions for Covid-19 compared to the non-pharmaceutical interventions for Covid-19. Here, we speculate that people recognized that no one knew which drugs or vaccines were safe or effective and so the illusion of knowledge was less likely to bias their feelings about experiments. While the same level of uncertainty exists for non-pharmaceutical interventions, people appear to continue to assume that someone already knows what works, even during a novel pandemic.

In addition, we are currently developing new studies that probe whether experiment aversion is reduced when ethics oversight and front door notice are explicitly included in the description of the pRCT, especially when consent is not possible, as is often the case for pRCTS. We look forward to publishing those results in the future.

VERSION 2 – REVIEW

REVIEWER	de, Kazuki Osaka University
REVIEW RETURNED	15-May-2024

GENERAL COMMENTS	Thank you for giving me the opportunity to review the revised version of this article. The authors have partially addressed the comments in their corrections. However, further revisions are needed before the manuscript can be considered further. My comments are listed below. COMMENTS: AR, authors' response; AC, additional comment(s) Methods: 1. The authors should explain about the allocation/randomization methods of this study. AR: Thank you for this feedback. We have clarified that participants were randomized to vignettes "using the Qualtrics survey software, such that aside from participants who dropped prior to completing the survey, the same number of participants are allocated to each vignette" (page 10). AC: I understood the authors used the Qualtrics, the process/method of the allocation/randomization is still unclear. 2. It is also important to consider how the ratio of clinicians was determined/estimated before conducting the study. AC: 3. The authors should clearly state the specific name of "a large health system" which they used in this study. They should write this kind of important information (also) in the main text. Discussion: 4. The authors should discuss about the limitations of this study in more detail. AR: Thank you for this suggestion. In this revision, we have restructured the Discussion to have a separate "Limitations" section (pages 22-24). In addition to the limitations included in the previous version of this manuscript, we now include a discussion about the limitations of the clinician sample that we used (pages 22-23). AC: Over the half of the clinicians are RN, and it also can be a limitation. The authors should mention about this in the Limitation section. Competing interests: 5. AC: The authors mentioned that "none of the authors have competing interests to report", but several authors belong to the Geisinger. They also used the platform for this study. This can be competing interests which should be declared.