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Research Article

Preventive Misconception in Clinical Trials: Implications for Informed Consent and Racial Disparities

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Abstract:

Preventive Misconception (PM) occurs when research participants overestimate the personal benefit they will receive from a clinical trial, which is testing if an agent prevents the recurrence or progression of disease. Although therapeutic misconception (TM) has been extensively studied, PM has not. This study explores the occurrence and implications of PM in participants in the three open prevention trials conducted at Emory Winship Cancer Institute. Participants completed structured qualitative interviews based on a literature review that were cognitively tested for clarity. Interviews were auto-recorded, transcribed, and de-identified. The data were analyzed using Simon et al.'s framework to assess PM prevalence.1 Among the 16 participants, four (25%) exhibited a preventive misconception. Two of the three African American participants exhibited PM, though the small sample size, due to there being only three open PM trials, limits definitive conclusions. Common themes included assumptions of direct personal health protection and underestimation of risks. This study shows that some clinical trial participants exhibit PM, especially in marginalized populations, emphasizing the need for improved informed consent processes. Misconceptions about preventive trials can compromise participant understanding, specifically an overestimation of the direct benefit of the trial. To effectively address PM, creating more precise risk-benefit explanations and interactive consent strategies is essential. Further research with a more diverse and larger sample population is necessary to confirm these findings and develop effective interventions.

Key words: preventive misconception; clinical trials; informed consent; risk-benefit perception

Abbreviations

PM- Preventive misconception

TM: therapeutic misconception

Introduction

Research ethics has long recognized therapeutic misconception (TM). TM occurs when participants confuse research objectives with personalized medical care and believe the research intervention is intended to benefit them.[2] A form of TM is a preventive misconception (PM). PM arises when individuals believe a trial that tests an intervention to see if it prevents the recurrence or progression of the disease offers a higher probability of personal health protection than is realistically provided. This false perception may lead to skewed decision-making and limit a participant's ability to weigh risks and alternatives accurately.PM takes two forms: 1) an overestimation of receiving the active intervention rather than a placebo, and 2) an overestimation of the intervention's effectiveness. Addressing PM is critical to ethically sound research practices and enriching participant autonomy. This issue becomes even

more complex when viewed through a racial lens, as systemic mistrust in healthcare research among African American populations can intensify misconceptions.[1] We report responses from 16 participants enrolled in the only three preventive trials being conducted at the Winship Cancer Institute, an NCI Comprehensive Cancer Center, over three years. The small sample size limits the generalizability and restricts the diversity of participants, particularly among racial and ethnic groups, making it difficult to draw broad conclusions about disparities in Preventive Misconception. However, to our knowledge, this study is the first to describe the prevalence of PM. Future research should aim to include a larger and more diverse participant pool across multiple institutions to enhance the robustness and applicability of the findings.

Methods

Participants in the three open preventive trials at Winship consented to this study and were interviewed using a structured qualitative interview, either in person or virtually, depending on the participant's preference. The interview was designed based on a literature review and our past research on TM and was cognitively tested to ensure clarity. Interviews were audio-recorded, transcribed, and de-identified to ensure confidentiality. We qualitatively coded the interviews to determine PM prevalence. Preventive Misconception (PM) was assessed using trial-specific questions and responses, recognizing that each preventive trial had unique objectives and designs. We consulted each trial's Principal Investigator (PI) to ensure accurate PM identification. PIs provided detailed insights into their respective trials' intended goals, risks, and benefits, which informed the development of tailored interview questions. This collaborative approach allowed us to evaluate participant understanding and identify instances of PM accurately. The question to determine PM asked the participant to report the chance that the preventive intervention would be successful, since none of the trials included a placebo. For example, for the trial testing an investigational agent designed to prevent the progression of smoldering myeloma, we asked,

1. Now that you are on the study drug, what are the chances that your smoldering myeloma will get worse in the next 3 years?
    a. No chance at all (1) → PM
    b. A little chance (2) → correct
    c. 50/50 (3) → correct
    d. High chance (4)
    e. Definitely (5)

The PI of each trial provided us with reasonable answers.

Our past research on TM has demonstrated that participants' statements about receiving direct medical benefits from a study do not always indicate a true misunderstanding of the study's purpose.[3] Rather, these statements can sometimes reflect hope rather than an actual belief that the trial is designed to provide personal benefit. This distinction is crucial when assessing TM, as relying solely on participants' expressions of expected benefit may overestimate the prevalence of misconception. As our prior work has shown, some participants understand the experimental nature of clinical trials but still express optimism about potential positive outcomes. This highlights the need for nuanced TM assessments that account for cognitive understanding and emotional influences. For this study, we asked our tested TM questions, which are available in a Supplementary File

Results

Participant Demographics and Themes of Responses

Of 19 patients approached, two declined and 17 enrolled; due to technical issues, data from participant #15 were excluded, leaving 16 for analysis.

Demographics: The group consisted of 11 White, 3 Black or African American, 1 Asian or Pacific Islander, and 1 participant identifying as Swiss American under "some other race." There were no Latino, Hispanic, Native American, or Aboriginal participants.

Pm Findings and Evidence

Of the sixteen participants, four (25%) demonstrated clear evidence of preventive misconception (PM), exhibiting varying levels of misunderstanding regarding potential personal benefit. Two out of three African American participants displayed PM, though the sample size limits definitive conclusions. The PM analysis included participants from three clinical trials: SOLARIS, Myeloma, and RTOG. PM responses were identified in three participants from the Myeloma trial and one participant from the RTOG trial. No PM responses were observed in the SOLARIS trial.TM Findings: None of the participants in this study demonstrated evidence of therapeutic misconception. While some expressed hope for personal benefit from participation, their responses reflected an understanding that the study's primary purpose was research rather than a mistaken belief that it was designed to provide individualized medical treatment. This aligns with prior findings that hope for benefit does not necessarily indicate a misunderstanding of the research context.

Discussion

The findings suggest PM is a concern, with one-fourth of our participants expressing it. Preventive trials present distinct and complex communication challenges. Terms like "preventive" suggest positive associations that may inadvertently foster misconceptions. Misunderstanding the distinction between preventive and therapeutic objectives can lead participants to overestimate personal benefits and underestimate the associated risks of the trial. Interestingly, even though a fourth of our participants demonstrated PM, none had TM, showing how the nuances of misunderstandings must be explored.

Racial Disparities in PM

The protocol's secondary aim reflects the hypothesis that African American participants may experience a higher rate of PM due to historical and systemic disparities in healthcare trust. Addressing these disparities requires culturally sensitive consent practices that emphasize transparency and respect for autonomy. Further exploration is necessary to understand how sociocultural factors influence PM.

Recommendations for Enhancing Informed Consent

1. Explicit Risk-Benefit Clarifications: Clearly distinguish between individual benefits and study objectives, emphasizing the uncertainty inherent in experimental interventions. Clear language should describe both absolute and relative risk.
2. Interactive Consent Sessions: Incorporate questions and interactive dialogues where participants explain their understanding of the trial's purpose, risks, and benefits.

Limitations

The accrual was low due to the institution's limited number of PM trials, so the results are suggestive only. More research expanded to other institutions is needed. We offer this essay as an introduction to PM to stimulate further research.

Conclusion

This study's findings establish that some trial participants experience PM, with notable implications for ethical research practices and informed consent processes. PM compromises participants' understanding of trial objectives, particularly regarding the personal benefits and risks of preventive agents. This study also highlights potential racial disparities in PM. However, further research with a more diverse and larger sample size is needed to draw definitive conclusions. Addressing PM requires enhanced informed consent practices, including explicit risk-benefit clarifications. Our research on PM continues the excellent research on TM and adds additional information to investigators striving to avoid TM. Examining Preventive Misconception, a type of Therapeutic Misconception, provides deeper insight into misunderstandings that can occur in clinical trials and highlights the need for improved strategies to enhance informed consent

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