Participants’ Beliefs About Preventive Efficacy in the HPTN 069/ACTG 5305 Trial: Preliminary Data Using the PREMIS Measure

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Background

A “preventive misconception” is an overestimate of the probability of benefit or personal protection afforded to a participant in a clinical trial of an unproven intervention. Participants’ beliefs about preventive efficacy in HIV prevention trials may be influenced by social desirability, the therapeutic optimism as well as the benefits afforded by the prevention package provided to all participants, both conceptually and practically.

Methods

The PREMIS measure was administered at the week 4 and week 40 visits to participants in HPTN 069/ACTG 5305 (NCT01550154), a multicenter trial in the United States that included four arm comparing investigational maraviroc-containing regimens (maraviroc/emtricitabine) for preexposure prophylaxis in men and women who have sex with men at risk of HIV infection.

We calculated descriptive statistics for all responses. We used Pearson chi-square tests, McNemar tests, and Bowker tests to assess response differences by demographic characteristics.

Results

The PREMIS measure was completed by 175 participants at week 4 and 429 participants at week 40. Because the responses at week 4 and week 40 did not differ significantly among those who completed the measure at both visits, we only have data from the week 40 visits reported here.

When asked about their confidence in the study medications would prevent them from acquiring HIV, 25.5% believed they were in a study group that would be best for them while 35.1% believed a study doctor chose the group that would be best for them.

Most participants (62.7%) believed they were assigned randomly to their study group, whereas 9.8% believed a doctor chose the group to which they were assigned.

Most trial participants expressed high confidence in a prevention package provided to all participants is difficult, both conceptually and practically. There are ethical concerns regarding preventive misconception. However, disaggregating a preventive misconception from therapeutic optimism as well as the benefits afforded by the prevention package provided to all participants is difficult, both conceptually and practically.

In a previous study, we developed and refined a brief measure of the preventive misconception (PREMIS) using qualitative interviews that focused on cognitive testing of proposed survey items with HIV prevention trial participants (Sugarman 2016).

The purpose of this study was to collect preliminary quantitative data using the PREMIS measure in an HIV prevention trial.

Conclusions

Most trial participants expressed high confidence in a prevention intervention due to its benefit related to the belief that all of the study groups had a high likelihood of benefit.

To place these data into context, future work should assess the effect of preventive misconception in biomedical HIV prevention trials.

LITERATURE CITED


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Country of Research

United States

Key Population

Men who have sex with men