A Subject-Targeted Placebo-Control Reminder Script: An In-Depth Empirical Exploration of How Subject Characteristics Moderate Placebo Response

Evan A. Cohen, Ph.D., Ball, Howard H. Hassman, DO, David P. Walling, Ph.D., D. B. Malamuth, MS, Roberta Bell, MD, Jaclyn M. Lobb, MS, Dakota Hazzard-Randolph, MS, Ashok V. Joseph, MD, and Larry Ereshevsky, Pharm.D., BCPP

Hassman Research Institute, Science Division; Collaborative Neuroscience Network; The City University of New York, Graduate School of Public Health and Policy Health; Professor, The University of Texas

ABSTRACT

INTRODUCTION

• The importance of developing strategies that manage placebo response within psychiatric clinical trials cannot be understated. It is estimated that slightly over 50% of such trials fail because of poor active drug and placebo separation (Kirch, 2016), within which major depression disorder (MDD)-double blind, randomized, placebo-controlled trials (RCTs) (Ohan et al., 2017). Further, the placebo effect has been found to be increasing over time (Kemp et al., 2005) with a large number of clinical trials reporting an increase in placebo response. As a result, the placebo effect is viewed as being at the forefront of much of the debate surrounding clinical trials, whether placebo controlled or not. Despite the lack of interventional research, there is general consensus (e.g., Alphs et al., 2012; Kirsch et al., 2014; Hassman et al., 2015) that placebo response continues to be a confounding factor. The importance of developing strategies that manage placebo response within psychiatric RCTs is often seen as a multi-faceted problem, encompassing both patient and study characteristics.

• While various methodological strategies have been implemented or recommended to reduce the placebo effect (e.g., centralized ratings, remote rater monitoring, data surveillance before and during treatment), no single method or combination of methods has been found to be effective in controlling the placebo effect (e.g., Kirsch, 2016) and different strategies may be more effective for different populations. Considering the magnitude and variability of placebo effects, it is important to better understand the factors that influence placebo response. The current investigation is among the first, as far as the authors of this poster are aware, that explicitly examined an AA population and the PCRS's impact on placebo response for such participants.

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METHODS

• The PCRS was placed on the Investigational Product (IP) because it allowed for specific measurement of the PCRS (the placebo arm) vs. other study conditions (e.g., active drug vs. placebo). All subjects were informed that the placebo and active medications were being developed to evaluate the investigational product, and that the study was a double blind, placebo-controlled study. Additionally, subjects were informed of the PCRS's role in the study and that the PCRS would be used to measure the placebo effect.

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RESULTS

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CONCLUSIONS

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