Key Factors for Participant Retention: Research Sites' Study Data and Strategies for Preventing Attrition in Depression Trials

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What is the Methodological Question Being Addressed? Analyzed from multi-site completed placebo-controlled and open-label major depressive disorder clinical trials, are there study methodological variables, some of which have not been previously empirically explored, that correlate with participant attrition?

Introduction It is well established that major depressive disorder (MDD) randomized clinical trials (RCTs) struggle to retain participants, with a 37% mean dropout rate (Khan et al., 2000) and a 48% mean dropout rate among smartphone apps trials of the same indication (Torous et al., 2020). Poor retention can lead to biased study results, reduced power, lower internal validity, less generalizability, and higher study costs (Liu et al., 2018). Studies exploring MDD trial attrition have notable limitations, such as meta-analyses have been conducted solely on published studies (Rutherford et al., 2012) and a lack of exploring a wider spectrum of variables that potentially might correlate with retention (e.g., participant compensation and number of scales at each visit) (Rutherford et al., 2013). The goals of the current investigation were to obtain a more comprehensive understanding of reasons MDD participants withdrawal and subsequently recommend strategies to improve retention. This was accomplished by analyzing several Independent Variables theorized to be linked with participant attrition and some of which have not been previously empirically explored (e.g., number of study scales and participant compensation).

Methods The Dependent Variable in the current investigation was the number of participants who prematurely discontinued their involvement in the MDD clinical trial post-baseline visit per their decision or situation (e.g., withdrew consent or lost to follow-up), as opposed to leaving the study because of study requirements or matters out of their control (e.g., investigator discretion due to labs or adverse events). The number of participants who withdrew from the study were obtained from Closeout Report Forms submitted to Institutional Review Boards and sponsors at the conclusion of a trial. This study collected the forms from 55 fully completed outpatient MDD clinical trials across 5 US sites located in the west and east coasts. Of the 55 trials, 39 were placebo-controlled (PC; n=417 randomized participants) and 16 were open-label (OL; n=285 randomized participants). Independent Variables were factors hypothesized to have a relationship with subject-driven attrition and were obtained from each study's protocol. These variables were the number of study visits, frequency of those visits (derived by dividing study visits by weeks),

study duration in weeks, number of scales per visit, likelihood of receiving placebo, and participant compensation.

Results Pearson correlation analyses revealed that, for MDD PC studies (regardless of site geographical location), retention was significantly correlated with less study visits (r=-.40; p=.01), less study scales (r=-.39; p=.02), higher participant compensation (r=.58; p<.001), shorter study duration (r=-.37; p=.02), and less likelihood of being randomized to receive placebo (r=-.38; p<.02). For MDD OL trials, retention was significantly associated with higher visit frequencies (r=.57; p=.02) and attrition with longer study duration (r=.53; p<.05).

Conclusion The results of the current investigation can be applied in developing protocols and implementing study strategies with an eye toward managing attrition. For example, sponsors may consider tempering the use of numerous exploratory psychometric scales to potentially lessen the rate of participant dropout post-randomization. Sponsors may also choose to limit the duration of a trial or increase the frequency of visits as a means to improve participant completion. While research sites are responsible for preventing patients from enrolling into clinical trials whose sole motivation is monetary, the current investigation indicates that higher compensation for time and effort spent in a trial significantly reduces premature trial discontinuation, and thus, requires fair deliberation when developing an Informed Consent Form. Other applications from the current investigation's findings to protocol and study management aimed at lessening attrition as well as study limitations will be discussed in the poster.

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