Computer-assisted Cognitive Behavior Therapy in a Randomized Controlled Trial of the Effects of SSRI on Depressive Symptoms and Immune Function in People with HIV in Philadelphia, USA

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Many people with HIV (PWH) experience depressive disorders, with rates as high as 45%. Treating depression in this group can improve well-being, quality of life and ability to adhere to HIV treatment and is thus an important public health goal. This randomized controlled trial investigated the effects of a selective serotonin reuptake inhibitor (SSRI) and improvement in depressive symptoms on innate immunity and inflammation in people with HIV (PWH). Computer-assisted Cognitive Behavior Therapy (CCBT) was implemented for participants in both conditions concurrent with the pill condition as an ethical alternative to SSRI vs placebo due to concerns about the use of a standard placebo control group in a study with a vulnerable population. Eligible participants were randomized to 10 weeks of double-blind therapy with either SSRI (escitalopram) or placebo. Participants in both groups were paired with a therapist and offered six sessions of CCBT over the course of the study and use of the computer program *Good Days Ahead* (GDA) to learn concepts and skills of Cognitive Behavior Therapy (CBT) and provide practice of CBT techniques while supported by sessions with a therapist who helped them tailor what they learned to their identified problems and goals. The sample (*N*=93) was 85% Black; 63% men; 61% never married; 47% with high school diploma or less, with mean age = 49.97 (sd 11.66). The sample's mean HAM-D17 score at baseline was 19.31 (5.07) overall. Participants showed a significant reduction in depressive symptoms from pre-treatment to post-treatment, with a final HAM-D17 score of 8.19 (7.46) in the pooled sample. In the placebo group (*n*=50), the average HAM-D17 decreased from 19.38 (5.31) at baseline to 9.26 (7.64) at final visit, with average decrease of 10.12; in the escitalopram group (*n*=43), it went from 19.23 (4.83) to 6.95 (7.12) with average decrease of 12.28. The entire sample had an average decrease of 11.24. There was a nominal difference in mean reduction in HAM-D17 scores favoring the group that received active escitalopram (approximately 2 points), but the effect size for the drug vs placebo difference was small (d=0.31) and was not statistically significant. Moreover, the small specific drug effect was dwarfed by the large degree of improvement experienced pre-post by the group treated with CCBT plus placebo (d=1.5). The large effects for improvement in HAM-D17 in both drug and placebo groups may reflect the benefit of treatment with CCBT as well as the effects of almost weekly study appointments and interactions with supportive study staff during data collection. These results suggest that by ensuring that all participants had the opportunity to receive CCBT, the study achieved the ethical goal of providing clinical benefit to many participants whether or not they received active antidepressant medication. While antidepressant treatment is indicated for PWH with depression, the findings indicate that CCBT may augment pharmacotherapy for depression or serve as stand-alone treatment among PWH.