Combining Cannabidiol with Prolonged Exposure Therapy for PTSD: Design and Methodology of a Pilot Randomized Clinical Trial

Casey Straud1, John Roache1, Bret Ginsburg1, Rais Baig2, Van King3, Stacey Young-McCaughan1, Alan Peterson1
1University of Texas Health Science Center at San Antonio 2South Texas Veterans Healthcare System

OBJECTIVES/GOALS: There is increasing evidence that cannabidiol (CBD) has promising potential to treat PTSD. However, more research is warranted to fully understand the benefits of CBD for PTSD. This poster will describe the design and methodology of one of the first ever pilot RCTs examining CBD (vs. placebo) combined with prolonged exposure therapy for PTSD. METHODS/STUDY POPULATION: This study is an early Phase II double-blind, pilot RCT. Participants are 24 individuals 18-65 years old who meet DSM-5 criteria for PTSD on the CAPS-5 and were recruited from local hospitals and the community. Individuals complete a standardized baseline assessment with an independent evaluator to assess study eligibility. Participants who meet study inclusion are randomized to 18 days of CBD 250mg (BID) or placebo delivered in combination with 10-sessions Prolonged Exposure (PE) psychotherapy over 2 weeks. Individuals begin medication 3 days prior to beginning PE to ensure steady state. Participants complete self-report and biomarker outcomes at select timepoints during study participation, and are also asked to complete a 1-month follow-up assessment following treatment. RESULTS/ANTICIPATED RESULTS: This aims of this study are to: 1) examine the safety, feasibility, and PTSD symptom reductions associated with the combined intervention; 2) evaluate biomarkers associated with the endocannabinoid system and stress response; 3) determine the association between changes in biomarkers and PTSD symptoms following treatment. It is expected that CBD+PE will be safe and feasible, and that there will be a detectable signal of CBD vs. placebo in the reduction of PTSD symptoms. It is also anticipated that CBD will have higher levels of endocannabinoids and lower stress response levels compared to placebo. Lastly, we expect that greater changes in biomarkers will be associated with lower levels of PTSD severity following treatment. DISCUSSION/SIGNIFICANCE: Although there is growing interest in cannabinoids for psychiatric conditions, such as PTSD, controlled trials are limited and have yet to examine the proposed intervention for PTSD. If successful, this study will enhance the feasibility of a larger, adequately powered RCT to address immediate and long-term improvements for PTSD treatments.

A novel truncating variant of EBF2 disrupts human adipocyte differentiation in lipodystrophy syndromes: an example of a discovery from a clinical translational pipeline

Maria C. Foss-Freitas1, Noel Wys1, Miriam Udler2, Lynne Pais2, Andre Monteiro da Rocha3, Ormond A. MacDougald1, Elii A. Oral1, Tae-Hwa Chun1
1University of Michigan 2Harvard Medical School

OBJECTIVES/GOALS: Aiming to better understand the molecular pathogenesis of familial partial lipodystrophy (PL), we initiated whole-exome sequencing for our patients with PL syndromes. A novel variant of early B cell factor 2 (EBF2) was identified. Here