Introduction: Novel, evidence-based treatments are required for treatment-resistant post-traumatic stress disorder (PTSD). 3,4-Methylenedioxymethamphetamine (MDMA) has beneficially augmented psychotherapy in several small clinical trials.
Objectives: To review the use of MDMA-assisted psychotherapy in treatment-resistant PTSD.
Methods: Systematic searches of four databases were conducted from inception to February 2020. A meta-analysis was performed on trials which were double-blinded, randomised, and compared MDMA-assisted psychotherapy to psychotherapy and placebo. The primary outcomes were the differences in Clinician Administered PTSD Scale (CAPS-IV) score and Beck's Depression Inventory (BDI). Secondary outcome measures included neurocognitive and physical adverse effects, at the time, and within seven days of intervention.
Results: Four randomised controlled trials (RCTs) met inclusion criteria. When compared to active placebo, intervention groups taking 75mg (MD -46.90; 95% CI -58.78, -35.02), 125mg (MD -20.98; 95% CI -34.35, -7.61) but not 100mg (MD -12.90; 95% CI -36.09, 10.29) of MDMA with psychotherapy, had significant decreases in CAPS-IV scores, as did the inactive placebo arm (MD -33.20; 95% CI -40.53, -25.87). A significant decrease in BDI when compared to active placebo (MD -10.80; 95% CI -20.39, -1.21) was only observed at 75mg. Compared to placebo, participants reported significantly more episodes of low mood, nausea and jaw-clenching during sessions and lack of appetite after seven days.
Conclusions: These results demonstrate potential therapeutic benefit with minimal physical and neurocognitive risk for the use of MDMA-assisted psychotherapy in TR-PTSD, despite little effect on Beck's Depression Inventory. Better powered RCTs are required to investigate further.

Disclosure: James Rucker has attended trial related meetings paid for by Compass Pathways Ltd.
Keywords: MDMA; ptsd; Treatment-resistance; psychotherapy

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Suicidality in post-traumatic stress disorder (PTSD) and complex PTSD (CPTSD)

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Introduction: International Classification of Diseases 11th Revision (ICD-11) has inserted complex post-traumatic stress disorder (cPTSD) as a clinically distinct disorder, different from PTSD. The diagnosis of cPTSD has the same requirements for the one of PTSD, in addition to disturbances of self-organization (DSO – e.g., disturbances in relationships, affect dysregulation, and negative self-concept).
Objectives: This study aimed to explore suicidality in PTSD and cPTSD. We examined also the association between clinical dimensions of hopelessness (feelings, loss of motivation, future expectations) and other symptomatologic variables.
Methods: The sample, recruited at the Fondazione Policlinico Tor Vergata, Rome, Italy, consisted of 189 subjects, 132 diagnosed with PTSD, and 57 with cPTSD, according to the ICD-11 criteria. Participants underwent the following clinical assessments: Clinician-Administered PTSD Scale (CAPS), Impact of Event Scale-Revised (IES), Beck Depression Inventory (BDI), Symptom Checklist-90-Revised (SCL-90), Dissociative Experience Scale (DES), Beck Hopelessness Scale (BHS).
Results: cPTSD showed significantly higher BHS-total ($p = 0.01$) and BHS-loss of motivation subscale ($p < 0.001$) scores than PTSD. Besides, cPTSD showed significantly higher scores in all clinical variables except for the IES-intrusive subscale. By controlling for the confounding factor "depression", suicidality in cPTSD (and in particular the BHS-total) appears to be correlated with IES-total score ($p = 0.042$) and with DES-Absorption ($p = 0.02$). Differently, no such correlations are found in PTSD.
Conclusions: Our study shows significant symptomatologic differences between PTSD and cPTSD, including suicidality. Indeed, suicidality in cPTSD appears to be correlated with the "loss of motivation" dimension, which fits well within the ICD-11 criteria of DSO.

Disclosure: No significant relationships.
Keywords: cPTSD; ptsd; Suicidality; Hopelessness

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Efficacy and safety results from the first pivotal phase 3 randomized controlled trial of mdma-assisted psychotherapy for treatment of severe chronic PTSD

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Introduction: Posttraumatic stress disorder is a prevalent mental health condition with substantial impact on daily functioning that lacks sufficient treatment options. Previous research has led to the designation of 3,4-methylenedioxymethamphetamine (MDMA) as a Breakthrough Therapy for treatment of post-traumatic stress disorder (PTSD) when administered as an adjunct to psychotherapy.
Objectives: Here we report the findings of the first randomized, double-blind, Phase 3 trial assessing the efficacy and safety of 3 sessions with a flexible dose of MDMA or placebo administered under direct observation to participants with severe PTSD ($n = 100$) as an adjunct to inner-directed psychotherapy.
Methods: Change in PTSD symptoms (CAPS-5) and functional impairment (SDS) were assessed by a central, blinded Independent Rater Pool at baseline and following each treatment session. Adverse events (AEs), concomitant medications, suicidal ideation and behavior were tracked throughout the study. Vital signs were measured during experimental sessions. The primary endpoint was 18 weeks post-randomization.
Results: Change in CAPS-5 and SDS, placebo-subtracted Cohen's d effect size, and a responder analysis will be presented. There were three serious AEs of suicidal ideation or behavior reported. MDMA was well tolerated, with some treatment emergent AEs occurring at greater frequency for the MDMA group during and after experimental sessions.

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