

# Does post-traumatic stress disorder impact treatment outcomes within a randomised controlled trial of mitochondrial agents for bipolar depression?

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## Introduction

Post traumatic stress disorder (PTSD) is often comorbid with bipolar disorder (BD). Despite this, little research has been conducted to investigate the impact of PTSD on pharmacological treatment outcomes in people with BD.

## Aim

To explore depression, mania and functioning in clinical trial participants with BD alone and those with comorbid BD+PTSD.

## Methods

Participants ( $n = 148$ ) from a randomised controlled trial investigating N-acetylcysteine and nutraceuticals (in addition to treatment as usual) in those with bipolar depression were included in this sub analysis. Participants were randomised to: (i) N-acetylcysteine alone; (ii) a combination of nutraceuticals; (iii) or placebo for 16 weeks. Differences between BD and comorbid BD+PTSD on depression, mania and functioning domains were examined at six timepoints. The rate of change from baseline to week 16 and baseline to week 20 was also examined.

## Results

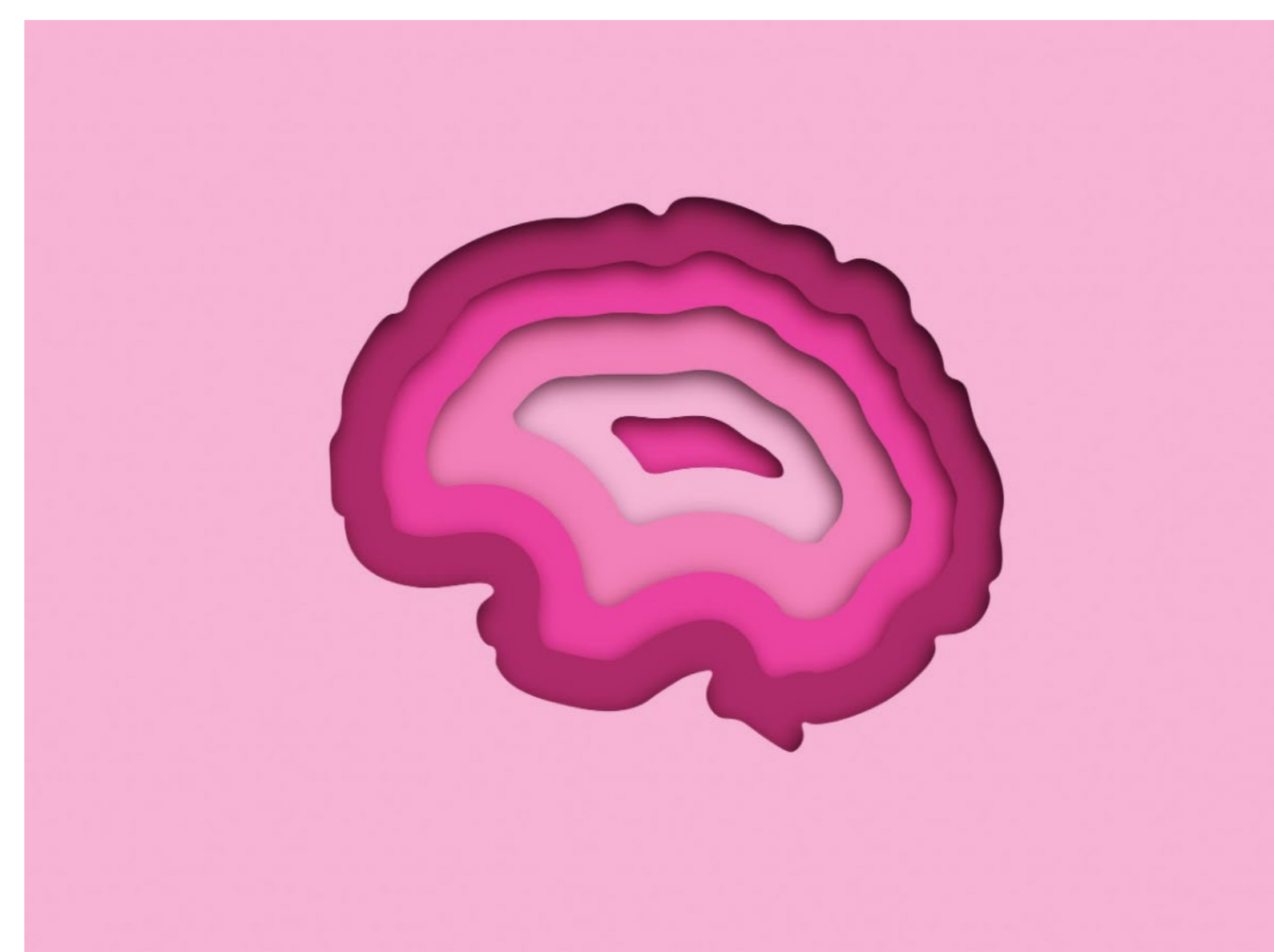
No baseline differences between BD and comorbid BD+PTSD in demographics or medication use were identified, with the exception of the BD group being significantly more likely to be married ( $p = 0.01$ ).

**Table 1:** Descriptive statistics for baseline demographic and illness features for BD alone and BD+PTSD

Characteristics	Descriptive statistic	BD alone	BD+PTSD	Test-statistic
		$n = 125, 84.46\%$	$n = 23, 15.54\%$	
Age $t$	M(SD)	46.4 (12.7)	44.4 (9.5)	$t(38.26) = -0.87$ , $p = 0.38$
%Female $\chi$	%(n)	63.2 (79)	73.9 (17)	$\chi^2 = 0.97$ , $p = 0.32$
Relationship status %Married/defacto $\chi$	%(n)	46.6 (62)	21.7 (5)	$\chi^2 = 6.08$ , <b><math>p = 0.01</math></b>
Illness features				
-Age of formal BD diagnosis $t$	M(SD)	35.4 (11.7)	34.5 (9.3)	$t(36.13) = -0.41$ , $p = 0.68$
-Self report duration of illness (in years) $t$	M(SD)	25.4 (12.2)	25.5 (9.7)	$t(36.54) = 0.05$ , $p = 0.95$
Number of hospitalisations $U$	Median (IQR)	1.0 (4)	2.0 (5)	$U = 1164.50$ , $Z = -0.78$ $p = 0.28$
Medication at baseline				
-Antidepressant %Yes $\chi$	%(n)	54.4 (68)	69.6 (16)	$\chi^2 = 1.82$ , $p = 0.17$
-Mood stabiliser %Yes $\chi$	%(n)	72.0 (90)	52.3 (12)	$\chi^2 = 3.56$ , $p = 0.05$
-Antipsychotic %Yes $\chi$	%(n)	57.6 (72)	65.2 (15)	$\chi^2 = 0.46$ , $p = 0.49$
-Benzodiazepine %Yes $\chi$	%(n)	18.4 (23)	26.1 (6)	$\chi^2 = 0.72$ , $p = 0.39$

Note. Abbreviations: PTSD = Post traumatic stress disorder, BD = Bipolar disorder  
**Bolded p values highlight significant values.**  $t$  = t-test,  $\chi$  = chi square,  $U$  = Mann Whitney

There were also no significant differences between BD and comorbid BD+PTSD on domains of depression, mania or functioning over time.



## Conclusion

There were no differences in clinical outcomes over time within the context of an adjunctive randomised controlled trial between those with BD alone compared to those with comorbid BD+PTSD. This study provides limited evidence to suggest that similar pharmacotherapy regimens (measured at baseline and within the context of an

adjunctive clinical trial) provided comparable clinical outcomes over 16 weeks regardless of the presence of comorbid PTSD. Furthermore, this study examines the specificity of bipolar depression in comorbid BD+PTSD, adding to the much-needed literature understanding of this comorbidity.



Differences between groups in psychosocial factors may provide targets for specific support for people with comorbid bipolar disorder and PTSD