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# Adjunctive Ketamine With Relapse Prevention-Based Psychological Therapy in the Treatment of Alcohol Use Disorder

Meryem Grabski <sup>1</sup>, Amy McAndrew <sup>1</sup>, Will Lawn <sup>1</sup>, Beth Marsh <sup>1</sup>, Laura Raymen <sup>1</sup>, Tobias Stevens <sup>1</sup>, Lorna Hardy <sup>1</sup>, Fiona Warren <sup>1</sup>, Michael Bloomfield <sup>1</sup>, Anya Borissova <sup>1</sup>, Emily Maschauer <sup>1</sup>, Rupert Broomby <sup>1</sup>, Robert Price <sup>1</sup>, Rachel Coathup <sup>1</sup>, David Gilhooly <sup>1</sup>, Edward Palmer <sup>1</sup>, Richard Gordon-Williams <sup>1</sup>, Robert Hill <sup>1</sup>, Jen Harris <sup>1</sup>, O Merve Mollaahmetoglu <sup>1</sup>, H Valerie Curran <sup>1</sup>, Brigitta Brandner <sup>1</sup>, Anne Lingford-Hughes <sup>1</sup>, Celia J A Morgan <sup>1</sup>

## Affiliations

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## Abstract

**Objective:** Early evidence suggests that ketamine may be an effective treatment to sustain abstinence from alcohol. The authors investigated the safety and efficacy of ketamine compared with placebo in increasing abstinence in patients with alcohol use disorder. An additional aim was to pilot ketamine combined with mindfulness-based relapse prevention therapy compared with ketamine and alcohol education as a therapy control.

**Methods:** In a double-blind placebo-controlled phase 2 clinical trial, 96 patients with severe alcohol use disorder were randomly assigned to one of four conditions: 1) three weekly ketamine infusions (0.8 mg/kg i.v. over 40 minutes) plus psychological therapy, 2) three saline infusions plus psychological therapy, 3) three ketamine infusions plus alcohol education, or 4) three saline infusions plus alcohol education. The primary outcomes were self-reported percentage of days abstinent and confirmed alcohol relapse at 6-month follow-up.

**Results:** Ninety-six participants (35 women; mean age, 44.07 years [SD=10.59]) were included in the intention-to-treat analysis. The treatment was well tolerated, and no serious adverse events were associated with the study drug. Although confidence intervals were wide, consistent with a proof-of-concept study, there were a significantly greater number of days abstinent from alcohol in the ketamine group compared with the placebo group at 6-month follow-up (mean difference=10.1%, 95% CI=1.1, 19.0), with the greatest reduction in the ketamine plus therapy group

compared with the saline plus education group (15.9%, 95% CI=3.8, 28.1). There was no significant difference in relapse rate between the ketamine and placebo groups.

**Conclusions:** This study demonstrated that treatment with three infusions of ketamine was well tolerated in patients with alcohol use disorder and was associated with more days of abstinence from alcohol at 6-month follow-up. The findings suggest a possible beneficial effect of adding psychological therapy alongside ketamine treatment.

**Keywords:** Alcohol; Ketamine/Esketamine; Psychotherapy; Substance-Related and Addictive Disorders.

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