

Ketamine and psychological therapy helped severe alcoholics abstain for longer in trial

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People with severe alcohol disorder were able to stay off alcohol for longer when they were treated with low doses of ketamine combined with psychological therapy in a clinical trial.

The Ketamine for reduction of Alcohol Relapse (KARE) trial was led by

the University of Exeter and funded by the Medical Research Council.

The phase II trial is the first of its kind to examine whether a low dose of [ketamine](#) could help prevent people from quickly returning to heavy drinking after stopping, when combined with [therapy](#).

A biotech company AWAKN Life Sciences has licensed the therapy from University of Exeter to use in their clinics and partnerships. University of Exeter and Awakn have also signed an agreement with Devon Partnership NHS Trust to explore NHS readiness for ketamine-assisted psychotherapy.

The trial followed preliminary evidence that controlled ketamine therapy can reduce the numbers of alcoholics who relapse. Currently, few effective treatments exist for severe alcoholism, which has a devastating impact on lives. The KARE trial was the first trial to compare ketamine with and without therapy in any mental health context.

Published in *The American Journal of Psychiatry*, the study included 96 people with [alcohol problems](#) who were abstinent at the time of the trial. The team found that people who had ketamine combined with therapy stayed completely sober for 162 of 180 days in the six month follow-up period, representing 87 percent abstinence. This was significantly higher than any of the other groups, indicating that the therapy may also have promise for preventing relapse. This group was more than 2.5 times more likely to stay completely abstinent at the end of the trial than those on placebo.

The team also found some evidence that ketamine and therapy may prevent any drinking over six months, though the results were more mixed. Patients having ketamine also had lower depression after three months, and better liver function than those on placebo, regardless of whether it was combined with therapy or not.

Lead author Professor Celia Morgan, of the University of Exeter, said: "Alcoholism can destroy lives, and we urgently need new ways to help people cut down. We found that controlled, low doses of ketamine combined with [psychological therapy](#) can help people stay off alcohol for longer than placebo. This is extremely encouraging, as we normally see three out of every four people returning to heavy drinking within six months of quitting alcohol, so this result represents a great improvement."

Before the trial, participants were drinking every day, consuming the equivalent of 50 pints of strong beer on average per week (125 units). Participants given ketamine and therapy drank over the recommended guidelines on just five days in total over the six month trial period on average. This represents cutting the risk of death from [alcohol-related problems](#) from one in eight, to one in 80.

Professor Morgan said: "The number of alcohol-related deaths has doubled since the pandemic begun, meaning new treatments are needed more urgently than ever. Previously, there were some concerns about using ketamine in alcoholics due to liver problems, but this study has shown that ketamine is safe and well-tolerated in clinical conditions. In fact, we found liver function improved in the ketamine group due to them drinking much less alcohol.

"This was a phase II clinical trial, meaning it's conducted in people primarily to test how the safety and feasibility of the treatment. We now have an early signal this treatment is effective. We now need a bigger trial to see if we can confirm these effects.

"We're certainly not advocating taking ketamine outside of a clinical context. Street drugs come with obvious risks, and it's the combination of a low dose of ketamine and the right psychological therapy that is key, as is the expertise and support of clinical staff. This combination showed

benefits still seen six months later, in a group of people for whom many existing treatments just don't work."

Professor Anne Lingford-Hughes, of Imperial College London, is a co-author on the study. She said: "The KARE trial is a significant step towards investigating a new approach to meet the immense unmet treatment need associated with alcoholism. The trial shows that ketamine therapy may be one way we're able to reverse alcohol-related harms experienced by so many."

Research on the experiences of 12 KARE trial participants were previously published in a separate paper, published in *Frontiers in Psychiatry*, in which researchers conducted detailed interviews.

Lead author Merve Mollaahmetoglu, of the University of Exeter, said: "The experiences people describe after taking ketamine infusions suggest the drug gives a new perspective that may be helpful in psychological therapy. Ketamine induces a sense of being outside of your body that some say can stimulate an 'observer state' similar to that described in mindfulness, which may help patients take a step back, and consider thoughts and emotions. Participants told us this experience helped change their relationship with alcohol."

For one of the participants in the trial interviewed, thinking less about their own problems and feeling more connected with the world around seemed to affect their relationship with alcohol: "The sense of oneness that I felt and the sense of moving away from focusing on the worries and the small stuff is helpful in terms of improving my relationship with alcohol. Because I think I used alcohol as a self-medication and as a blocking and avoiding mechanism. And I think feeling that those issues are less prevalent or at least less important means I feel less motivated to drink."

Many of the participants saw the combination of ketamine and therapy as a beneficial combination. One interviewee said: "Not only did I get a life changing and mind-altering experience, but then the therapist did plug some new thoughts to me that made me think differently. I feel that it is really important that when you are split open, you know, in such an intense and life changing way that you are given new thoughts and you know that someone gives you something to refill that, so you do change stuff."

Anthony Tennyson is Chief Executive of AWAKN, a biotechnology company developing and delivering psychedelic therapeutics (medicines and therapies) to treat addiction, which has acquired the rights to the research. He said "We are so pleased to see such encouraging results in an area of treatment that has been stagnant for so long, leaving so many people with little or sub-par options available to them. With Ketamine being a licensed medicine, it means we can deliver this treatment now in our clinics and through partnerships, which is a radical shift in the alcohol addiction treatment industry."

Patrick Chinnery as MRC Clinical Director said: "Additional research is still needed, but it is promising that MRC funding for this study has facilitated these early results, which could lead to new ways to treat addiction. Funding this type of clinical neuroscience research, in humans, is important as it will help us improve our understanding of addiction and find more effective therapies that could prevent relapse."

The study was led by the University of Exeter in collaboration with Imperial College London and University College London.

The paper "Ketamine adjunctive to relapse prevention based psychological therapy as a treatment for alcohol use disorder" is published today in the *American Journal of Psychiatry*.

The paper on participants' experiences, entitled "This is something that changed my life: a qualitative study of patients" experiences in a clinical trial of ketamine treatment for [alcohol](#) use disorders' was published in *Frontiers in Psychiatry* on August 16.

More information: Ketamine adjunctive to relapse prevention based psychological therapy as a treatment for alcohol use disorder, *American Journal of Psychiatry* (2022). [DOI: 10.1176/appi.ajp.2021.21030277](https://doi.org/10.1176/appi.ajp.2021.21030277)

This is something that changed my life: a qualitative study of patients, *Frontiers in Psychiatry* (2022). [DOI: 10.3389/fpsyt.2021.695335](https://doi.org/10.3389/fpsyt.2021.695335) , www.frontiersin.org/articles/10.3389/fpsyt.2021.695335/full

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