Jan 2022

Awakn Phase II A/B Results

Ketamine for the Reduction of Alcoholic Relapse (KARE)

MRC Medical Research Council

UNIVERSITY OF EXETER

Awakn™

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Alcohol Use Disorder

"Alcohol Use Disorder (AUD) is a medical condition characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences."

AUD is a devastatingly serious condition which affects **5% of the global population** and results in more than **5% of all deaths globally**[1].

Treatment rates are very low, with only 16% of those suffering, ever seeking out treatment and from those few that do, **75% of them will relapse within the first 12 months**[2].

Since the beginning of the pandemic there has been a 57% increase in the consumption of alcohol. In the UK alcohol related deaths have also risen by 20% in that time[2].

1. Global Burden of Alcohol Use Disorders and Alcohol Liver Disease https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6966598/
2. "Treatment rates for Alcohol Use Disorders: a systematic review and meta-analysis" by Tesfa Mekonen.
3. Public health England 2021

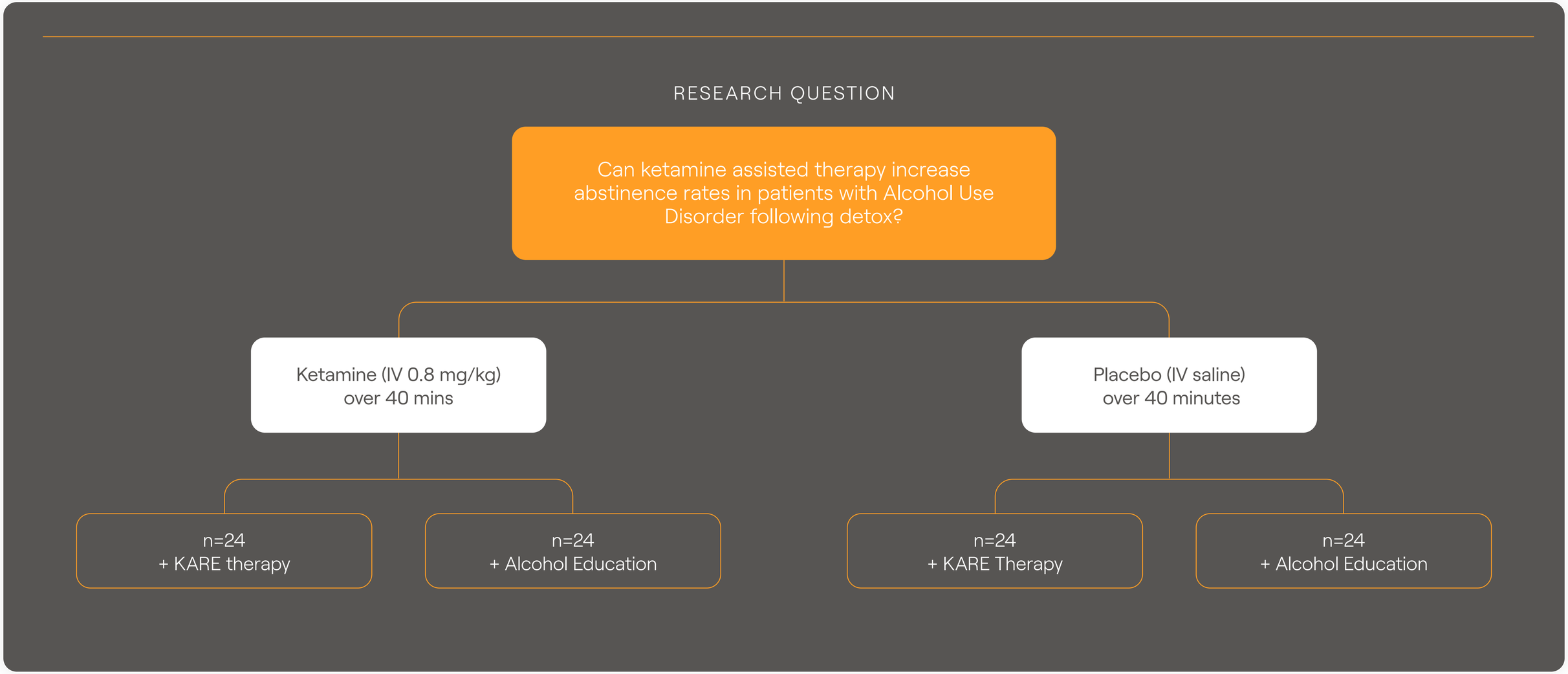
The Research Question

Can Ketamine-Assisted Therapy increase abstinence rates in patients with Alcohol Use Disorder following detox?

What is KARE?

- Four armed Phase II a/b clinical trial for reducing relapse in Alcohol Use Disorder with the NMDA Receptor Antagonist Ketamine.
- Funded by the UK State (Medical Research Council)
- Conducted by University of Exeter
- Led by Prof. Celia Morgan
- Rights to KARE exclusively acquired by Awakn Life Sciences in February 2021
- N=96
- Published: January 2022 in the American Journal of Psychiatry
- Full paper can be found here.

KARE Trial Design



KARE Treatment Protocol

The treatment protocol took place over 4 weeks and consisted of 7 therapy sessions of 1.5hrs long each, and three ketamine sessions.

	Therapy + Ketamine	Therapy (+24hrs after ketamine)
Week 1	✓ Yes	✓ Yes
Week 2	✓ Yes	✓ Yes
Week 3	✓ Yes	✓ Yes
Week 4	✗ No	✓ Yes

KARE Patients

% = Total % in each group
DSM –5 = Diagnostic and Statistical Manual for Psychiatric Disorders, version 5
SD = Standard deviation

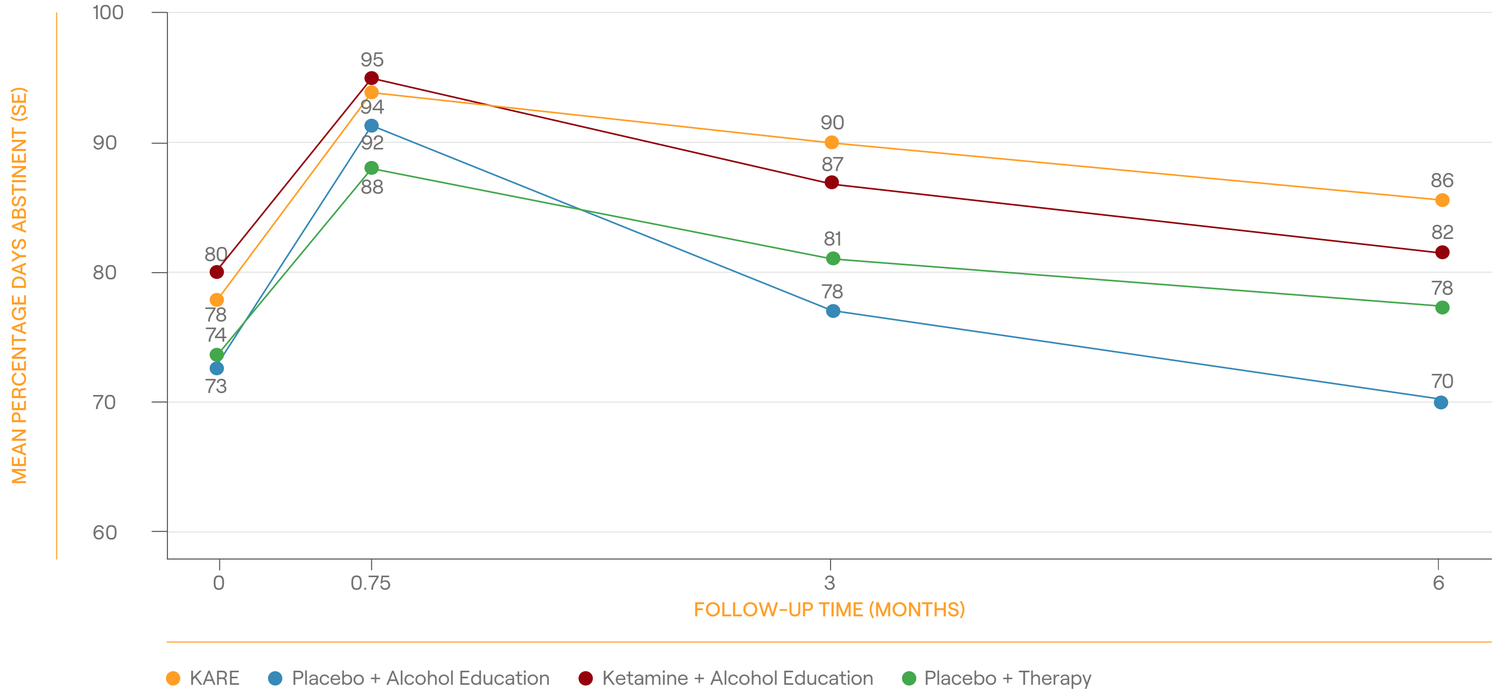
Participant characteristic	KARE (Ketamine + Therapy) (n=24)	Ketamine + Alcohol Education (n=24)	Placebo + Therapy (n=23)	Placebo + Alcohol Education (n=25)	Total
Gender; n (%)					
Male	14 (58%)	17 (71%)	15 (65%)	15 (60%)	61 (64%)
Female	10 (42%)	7 (29%)	8 (35%)	10 (40%)	35 (36%)
Age	45.2 (8.7%)	40.5 (11.10%)	47.0 (11.8%)	43.7 (10.2%)	44.1 (10.6%)
History of depression; n (%)	14 (58%)	10 (42%)	9 (39%)	7 (28%)	40 (42%)
History of anxiety; n (%)	13 (54%)	11 (46%)	12 (52%)	8 (32%)	44 (46%)
Smoking; mean (SD)	11.38 (15.47%)	7.03 (10.93%)	13.14 (20.53%)	12.96 (15.55%)	11.12 (15.86%)
Number of DSM5 criteria endorsed; mean (SD)	7.38 (2.24%)	7.79 (1.64%)	7.09 (2.35%)	6.88 (2.24%)	7.28 (2.13%)
Days since last drink at screening; mean (SD)	7.78 (9.77%)	9.95 (22.48%)	7.04 (8.84%)	9.87 (10.41%)	8.64 (13.72%)
Regular alcohol use (units per week); mean (SD)	129.82 (46.17%)	121.33 (44.46%)	137.77 (83.09%)	124.83 (95.19%)	128.43 (70.79%)
Number of Infusions; n (%)					
3	18 (75%)	20 (83%)	20 (87%)	23 (92%)	81 (84%)
2	2 (8%)	0 (0%)	1 (4%)	0 (0%)	3 (3%)
1	3 (13%)	3 (13%)	2 (9%)	2 (8%)	10 (10%)
Less than 1	1 (4%)	1 (4%)	0 (0%)	0 (0%)	2 (2%)

Results

Primary Outcome: Days Abstinent

The trial met its primary success criteria by achieving a prolonged and statistically significantly increase in rates of abstinence in the six months post treatment.

With 86% abstinence observed in the KARE therapy arm compared to 70% in the placebo and alcohol education arm.

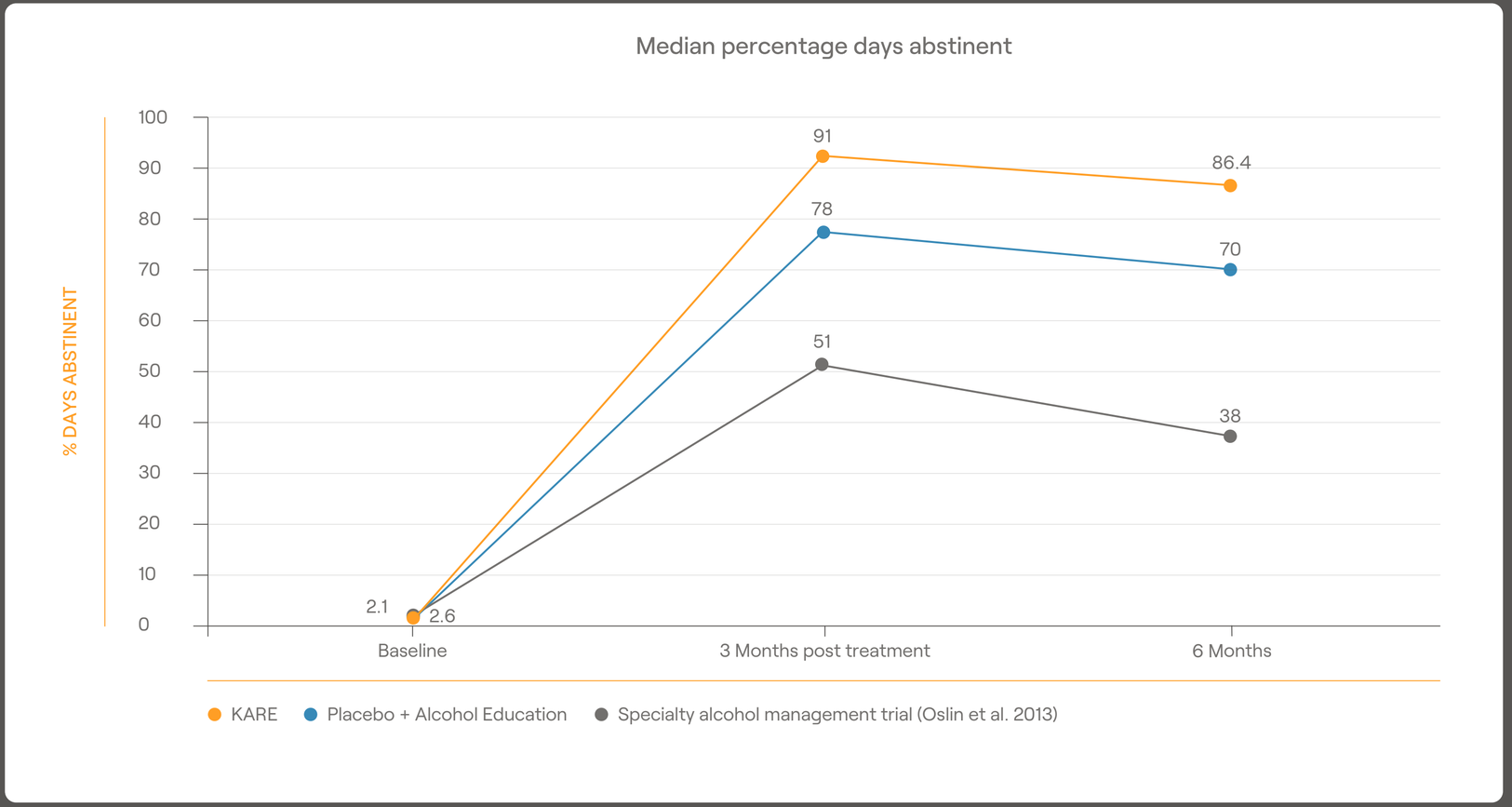


Primary Outcome: Days Abstinent

The KARE therapy produced a statistically significant increase in percentage days abstinent in comparison to the placebo and education group.

With 86% abstinence observed in the KARE therapy arm, this is more than double the 38% abstinence observed in a similar group of patients receiving industry standard treatment as usual in the US.

** Treatment as usual specialist outpatient alcohol care in US taken from a trial (Oslin et al. 2013) was chosen as a descriptive comparator as KARE will likely be delivered in outpatient settings.*

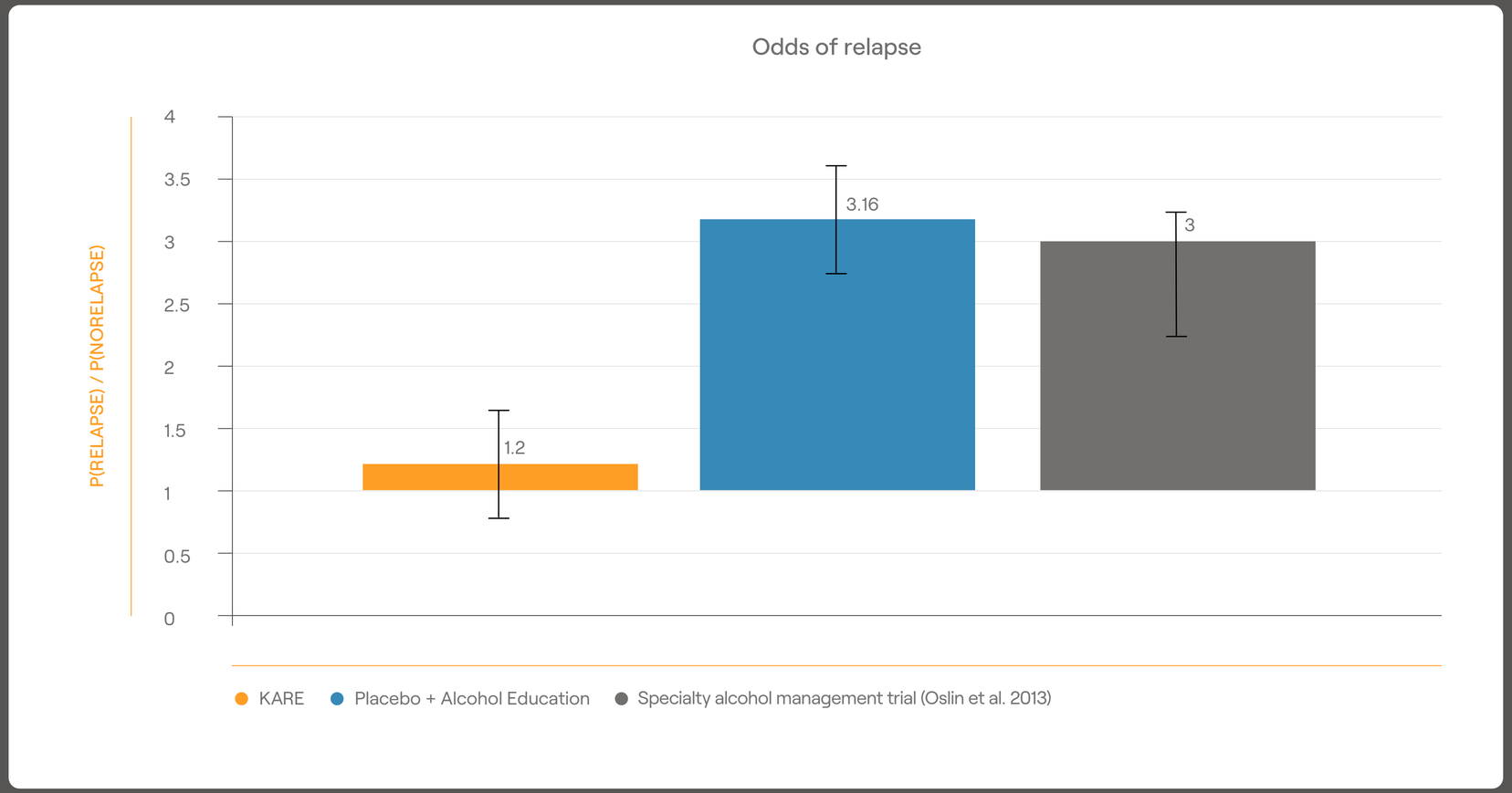


Co-Primary Outcome: Relapse

The KARE group were 2.7 more likely than the placebo education group and 2.5 times more likely than those in the industry standard treatment as usual study to have no Heavy Drinking Days in the 6 months after treatment.

Heavy Drinking Days, defined as 65g of alcohol for men, 52g for women in a single day, is an FDA and EMA regulatory endpoint guideline.

** Treatment as usual specialist outpatient alcohol care in US taken from a trial (Oslin et al. 2013) as KARE will likely be delivered in outpatient settings.*



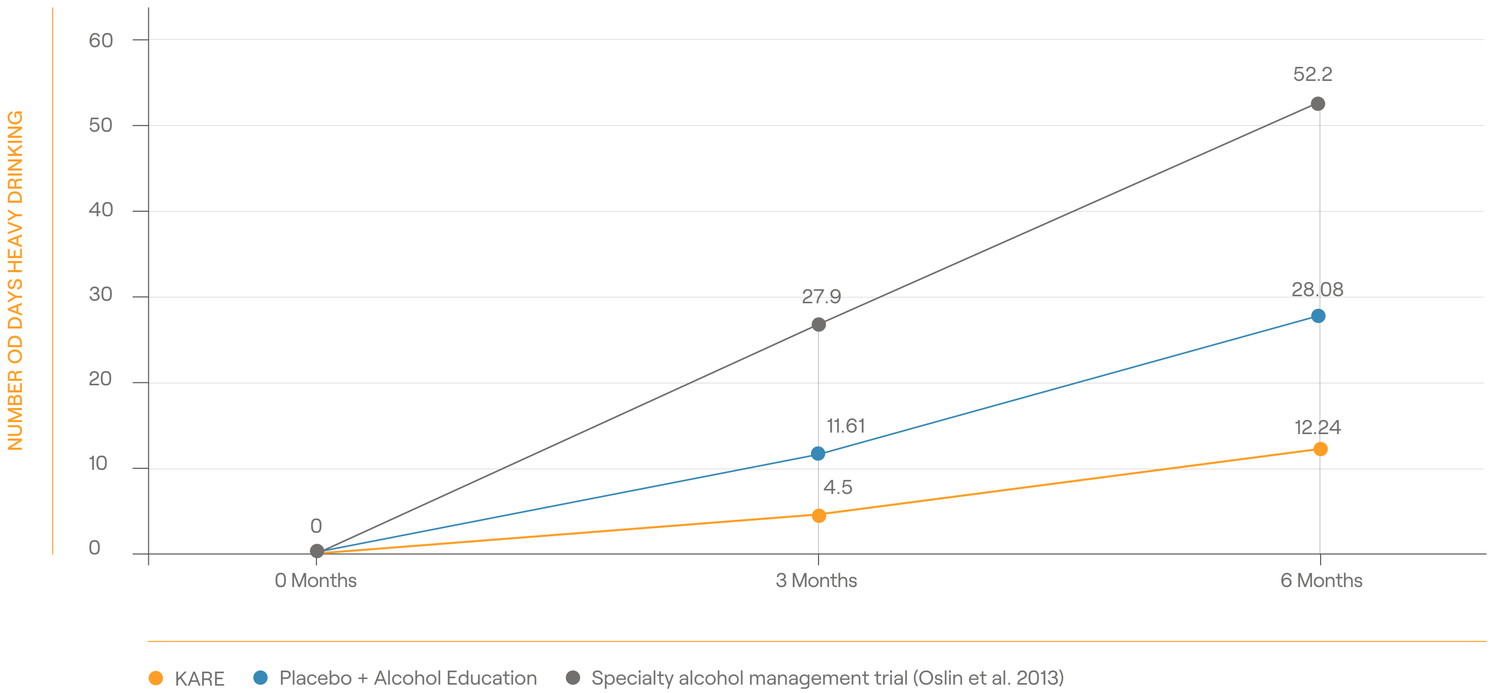
Exploratory Analysis: Number of Days Heavy Drinking

While not one of the trials primary endpoints, we saw a statistically significant reduction in ‘Heavy Drinking Days’ when comparing KARE to placebo and education group.

When comparing KARE to the industry standard treatment as usual in the US, we can see 77% reduction in Heavy Drinking Days.

Heavy Drinking Days is a primary endpoint used by EMA and FDA when assessing marketing authorization/ regulatory approval.

** Treatment as usual specialist outpatient alcohol care in US taken from a trial (Oslin et al. 2013) as KARE will likely be delivered in outpatient settings.*

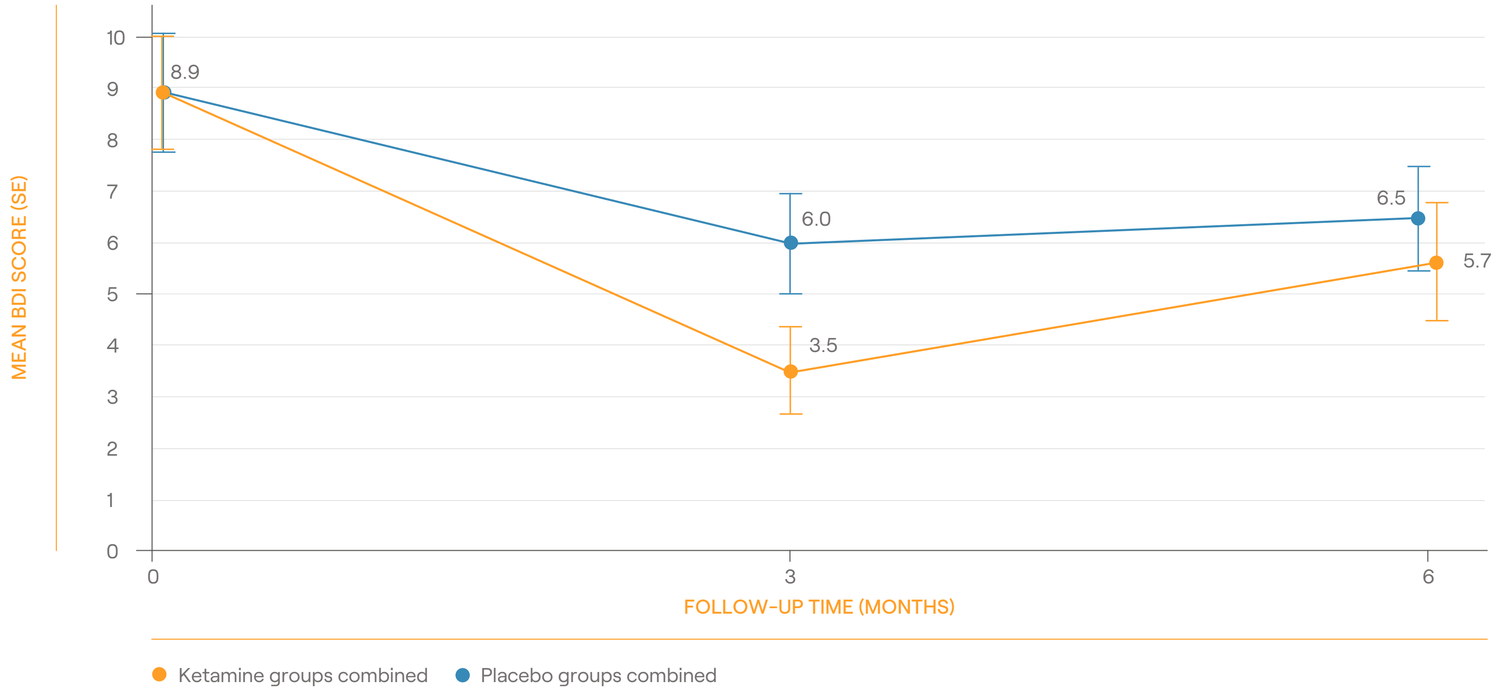


Secondary Outcomes: Depression

We excluded people who were taking anti-depressant medication at the time of the trial. This resulted in a minimally depressed sample with lower depression than a typical group of patients with Alcohol Use Disorder.

There was a statistically significantly reduction in depression in the ketamine groups vs placebo groups at 3 months.

This shows that ketamine is an effective antidepressant in patients with Alcohol Use Disorder.

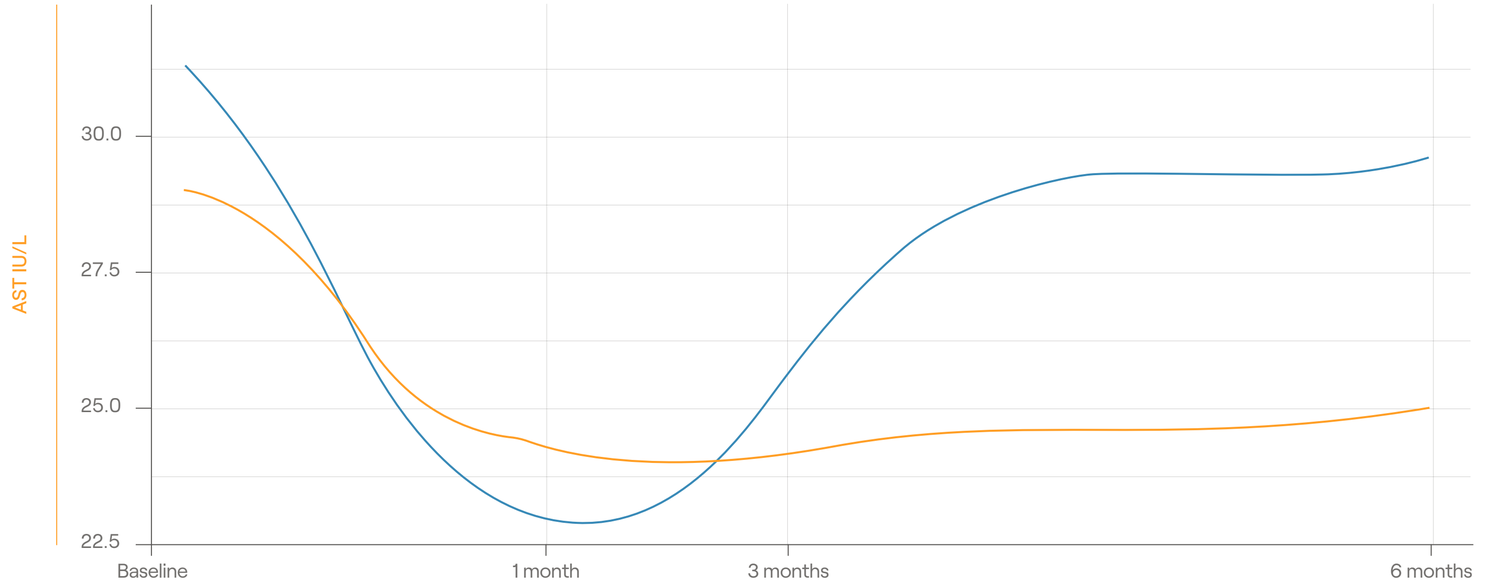


Secondary Outcomes: Liver Function

There was a statistically significantly improvement in liver function at 6 months post trial. This was measured across 4 different validated biomarkers of liver function.

Our data indicates that ketamine is not only safe for the treatment of Alcohol Use Disorder, but is also associated with an improvement in liver function.

Liver disease is the now second most common cause of preventable death in the UK.

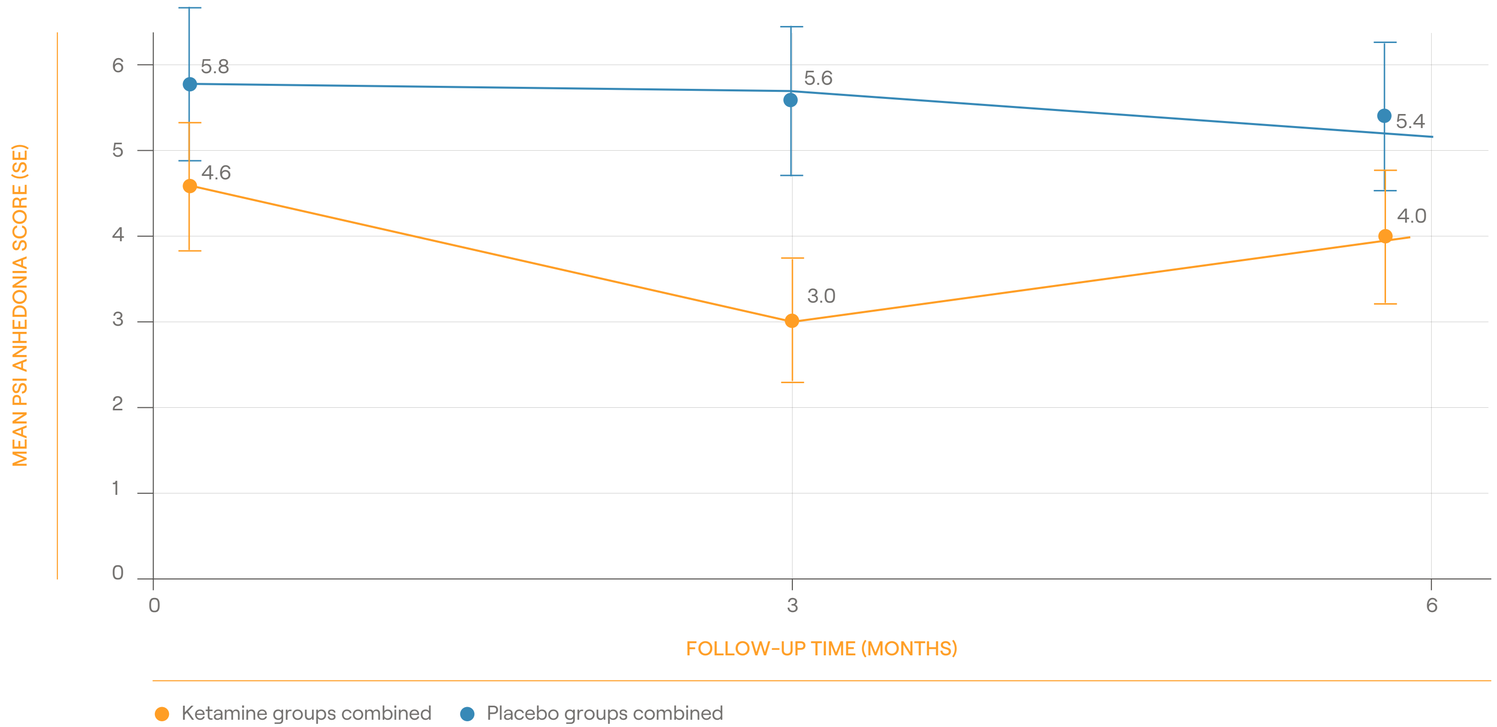


Lines fitted using LOESS curve smoothing

Secondary Outcomes: Anhedonia

Anhedonia which is the inability to experience pleasure, is common across a number of mental health problems. Ketamine helped to increase the ability to experience pleasure.

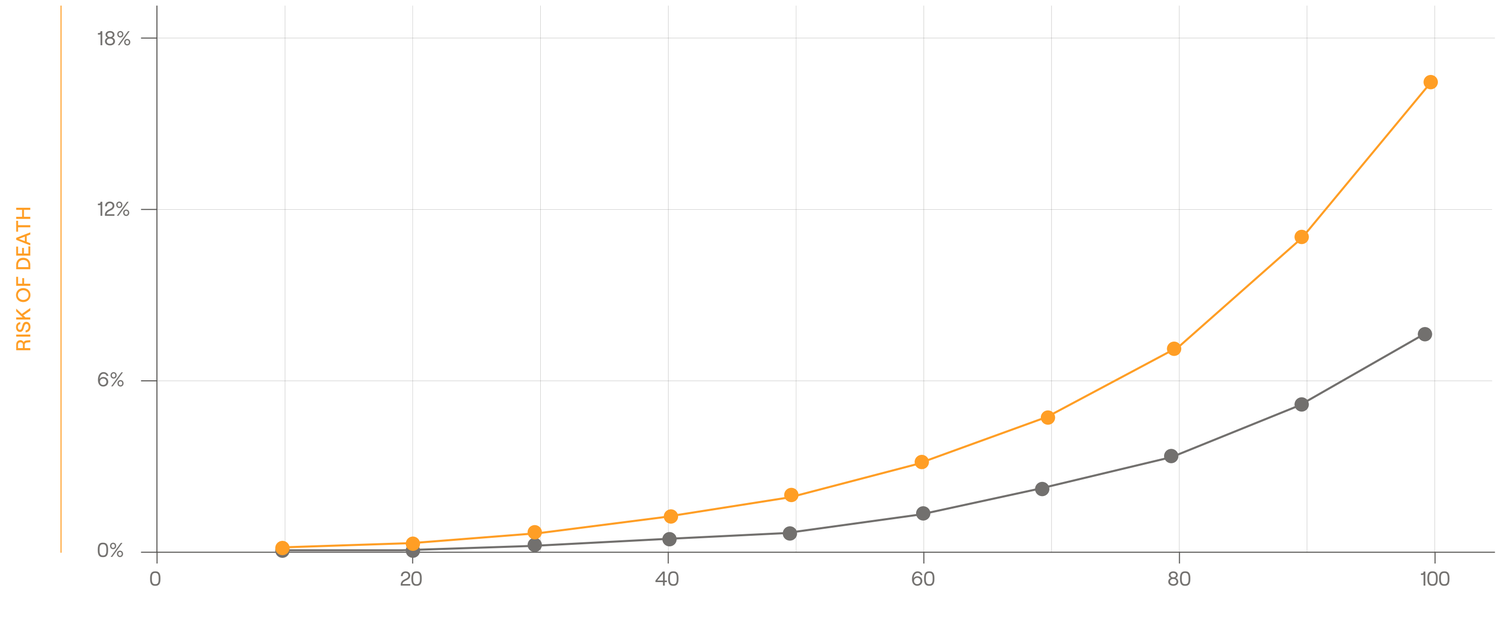
The impact of ketamine on anhedonia shows how the treatment goes beyond reducing alcohol consumption.



Mortality rate

The data shown in this graph demonstrates the exponential increase in risk of death with increasing grams of alcohol consumed.

Based upon the alcohol consumption rates of the 96 people in this trial, 12.5% would have died from alcohol related disease within one year, this was reduced to 1.25% after the treatment.



Graph ref: Nutt & Rehm, 2014 Journal of Psychopharmacology

Safety: Adverse Events

- Majority of adverse avents were mild
- Of the 96 patients I the trial, only 8 had any adverse event, most of while were mild.
- No serious adverse events took place.

Severity Rating	Frequency
Mild	42
Moderate	3
Severe*	1
Serious	0

* low mood

Adverse event	Frequency
LOW MOOD	8
LOW ENERGY	6
CONFUSION	3
LACK OF COORDINATION	3
TEARFULNESS	3
UNSTEADINESS	3
DIZZINESS	2
HEADACHES	2
HYPERTENSION	2
IMPAIRED CONCENTRATION	2
INSOMNIA	2
NAUSEA	2
ANAESTHETIC SHIVERS	1
ANXIETY	1
DRY SKIN	1
FLAT AFFECT	1
IMPAIRED MEMORY	1
NERVOUSNESS	1
NUMBNESS	1
SUICIDAL IDEATION	1

Key Conclusions

Key Conclusions

Primary Outcomes

1. KARE therapy significantly increased abstinence over all other groups.
2. Odds ratio of relapse was reduced with the KARE therapy.

Secondary Outcomes

1. Ketamine groups showed increased liver function across several markers.
2. Ketamine groups saw reduced depression and anhedonia (inability to experience pleasure) at 3 months.

Exploratory Analysis

Heavy drinking days were reduced in the KARE group compared to all other groups.

Safety

Ketamine was well tolerated and had a good safety profile, adverse events were predominantly mild and only reported by 8/96 patients. No serious adverse events happened.

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Appendix:
Qualitative Results

“This Is Something That Changed My Life”: A Qualitative Study of Patients’ Experiences

In conjunction with the KARE study, a further study was conducted on the qualitative patient outcomes during the trial. This has also been published in Frontiers in Psychiatry, click here for the full paper.

Aim

The study aimed to examine participant experiences of ketamine infusions and how these relate to therapeutic mechanisms in a clinical trial setting.

Conclusion

Provided in a supportive and professional environment, ketamine treatment led to a significant change in their relationship with alcohol. Ketamine induced ego dissolution and dissociation were reported to be related to the transformational effects on relationship with alcohol.

KARE Patient: Case Study

Male, 47 drinking up to seven bottles of wine a night and regularly blacking out, sometimes finding himself in police custody.

Marcus has stayed voluntarily clean for the first time in 30 years. Starting his mid 20s drinking had broken his marriage and was disrupting his employment.

In one recent episode, Marcus bought a car and drove to Wales to visit his mother's grave – all while so inebriated that he had no memory of any of it. "I came to in custody – the police could have told me I'd stolen a Jumbo jet and I've had had to accept it." he said. "I have no recollection whatsoever."

"I've taken part in therapy so many times before, and I've always relapsed. It's never felt like it would stick. This time, there seems to be something about the combination of factors that is really helping.

"Often it starts with just one or two drinks when I'm feeling low, and then I feel guilty so I drink more, and before you know it, it's a full binge. I know it's early days but this feels different. I'm confident I'm going to remain sober for the rest of my life."

Patient Extracts

"And it helped family wise, relationship wise, in every single avenue of my life. It's changed it"

"I wouldn't be here now if it wasn't for it. I can definitely say that."

"In a non-cheesy way, it actually probably changed my life around and kept me alive"

"I feel I have much less desire to drink now than I used to. And I think what it is, I actually, I think I enjoy it less now"

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