

# Psilocybin-assisted Therapy for Depression: Clinical Outcomes and Future Directions

**Alan K. Davis, PhD**

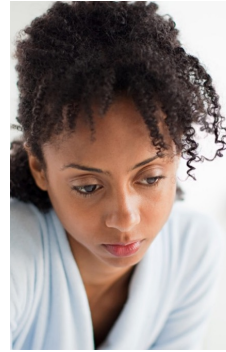
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# Hopkins Depression Trial

- Randomized wait-list controlled trial
- 24 patients with MDD
- Long-term outcomes at 3, 6, and 12-months

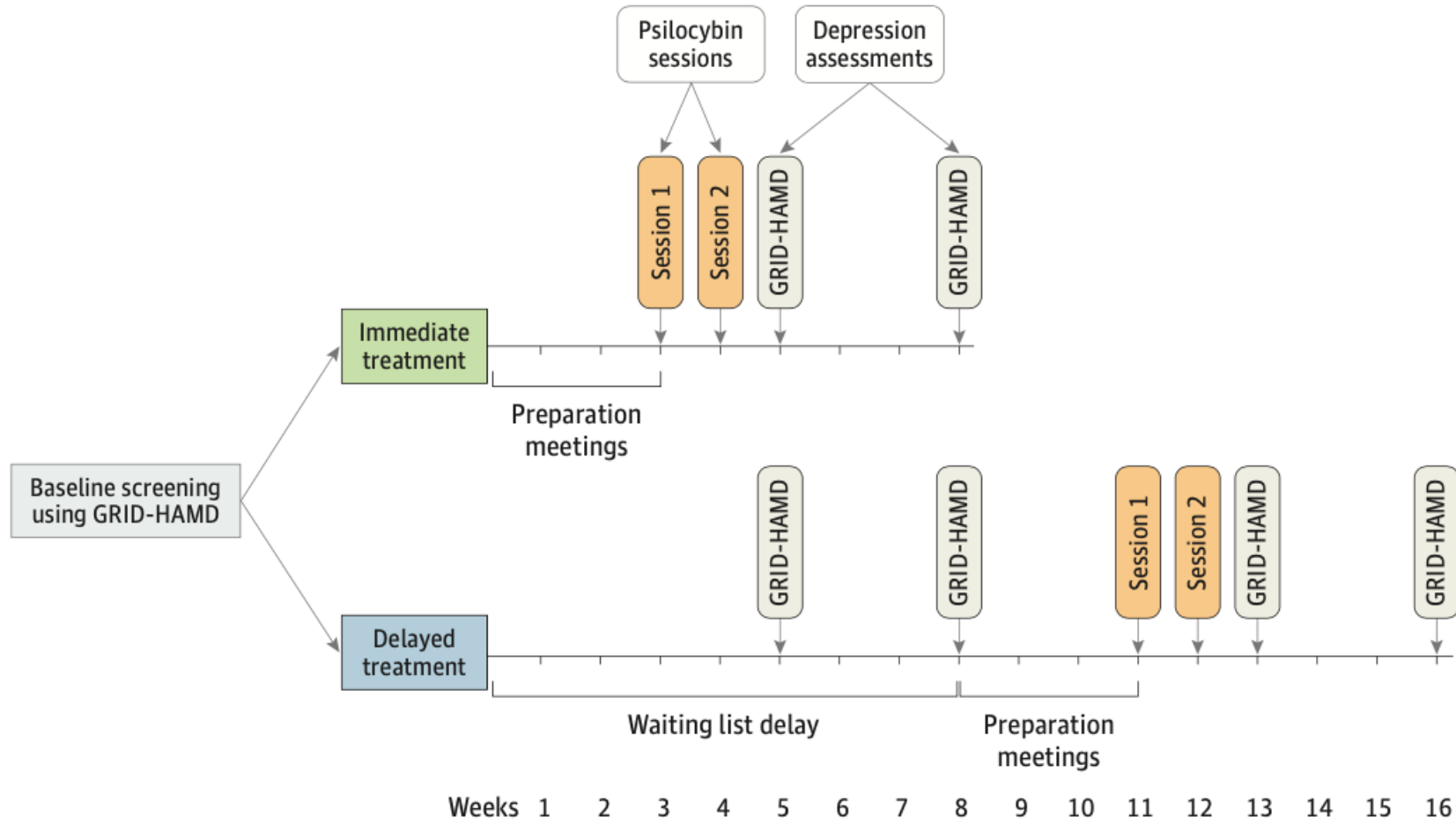


JAMA Psychiatry | [Original Investigation](#)

## Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder A Randomized Clinical Trial

Alan K. Davis, PhD; Frederick S. Barrett, PhD; Darrick G. May, MD; Mary P. Cosimano, MSW; Nathan D. Sepeda, BS; Matthew W. Johnson, PhD; Patrick H. Finan, PhD; Roland R. Griffiths, PhD

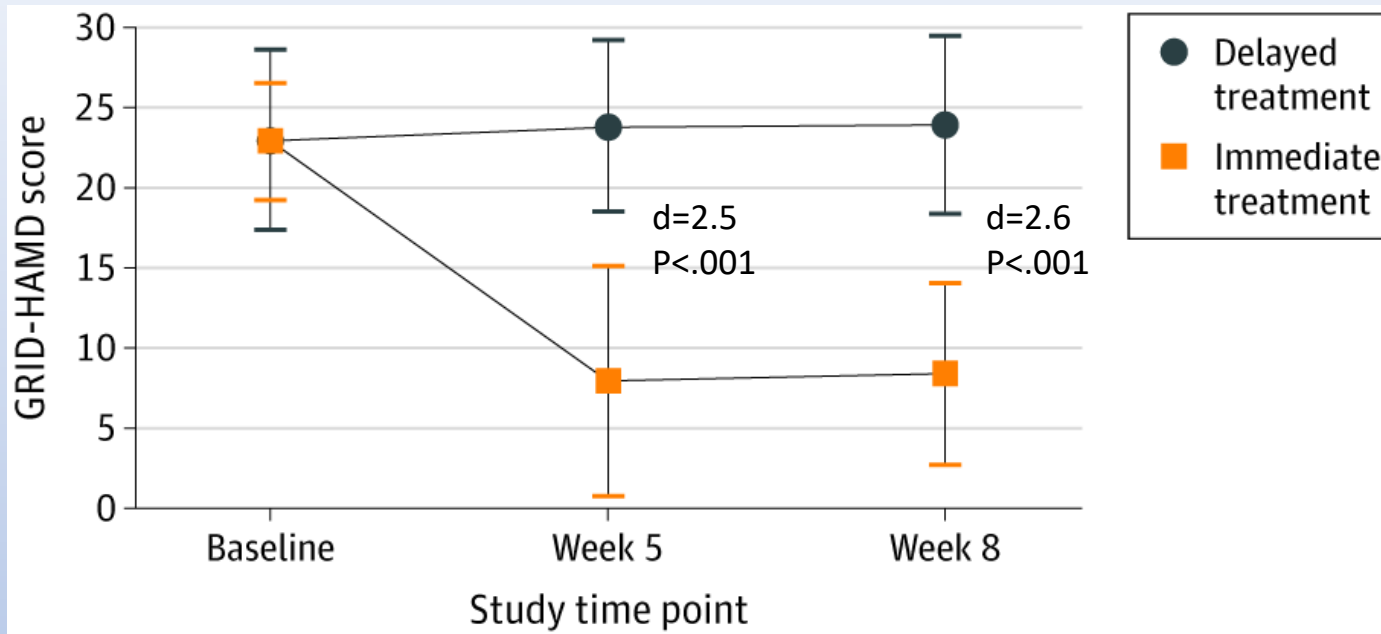
## Study Timeline From Baseline Assessment and Screening to the 4-Week Postsession-2 Follow-up Visit



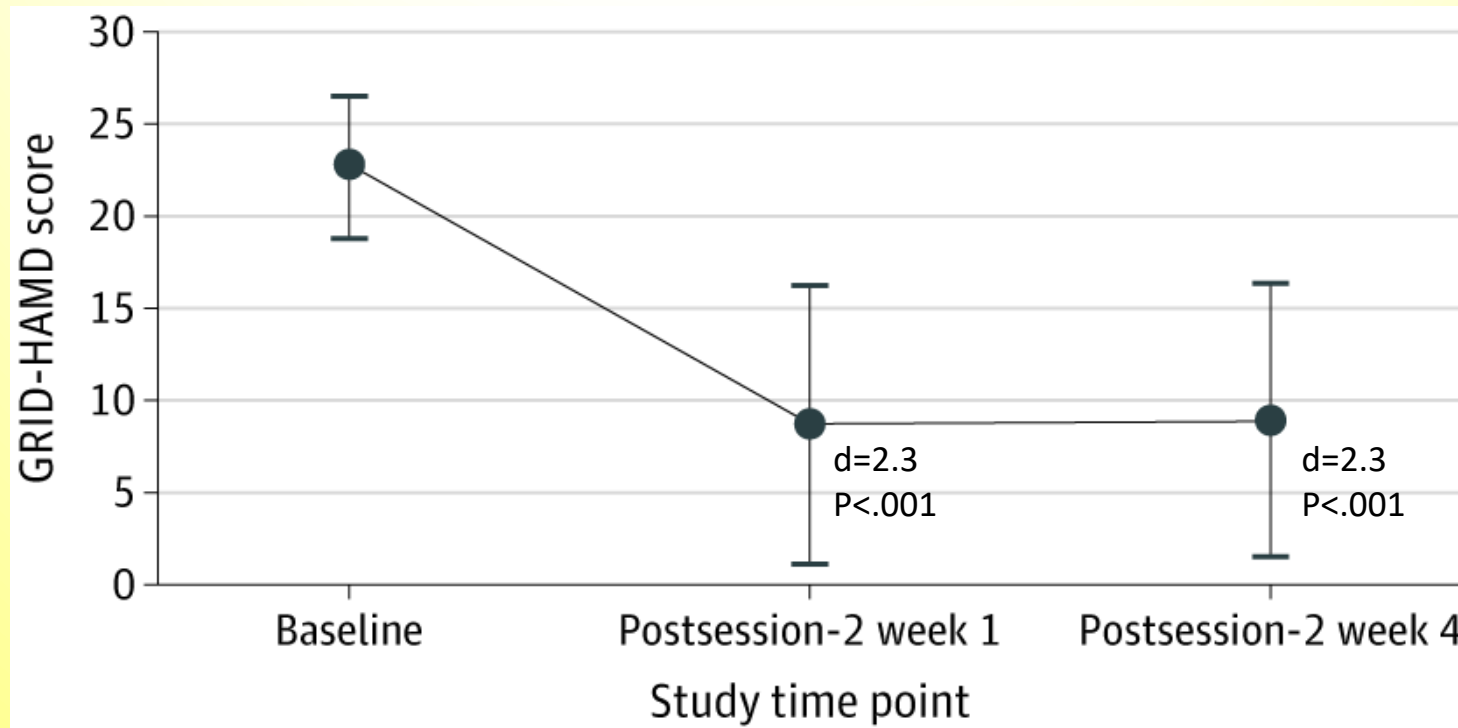
GRID-HAMD indicates GRID Hamilton Depression Rating Scale.

# Safety

- There were no serious adverse events reported in this trial
- Non-serious adverse events included:
  1. Headache
  2. Challenging emotional experiences including mild to moderate transient anxiety, fear, or sadness (no medical treatment required).
  3. Transient increase in blood pressure (no medical treatment required).



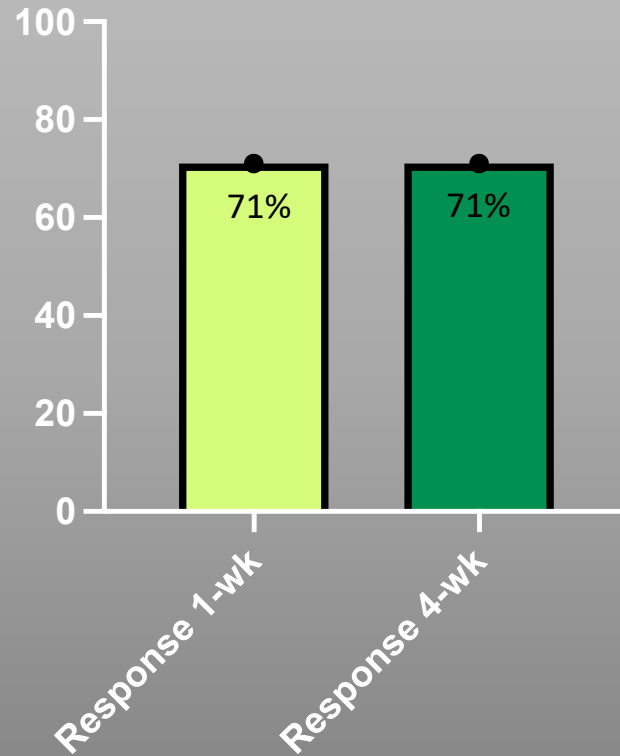
**Depression scores decrease after psilocybin treatment but do not change in those participants in the comparison group (waitlist)**



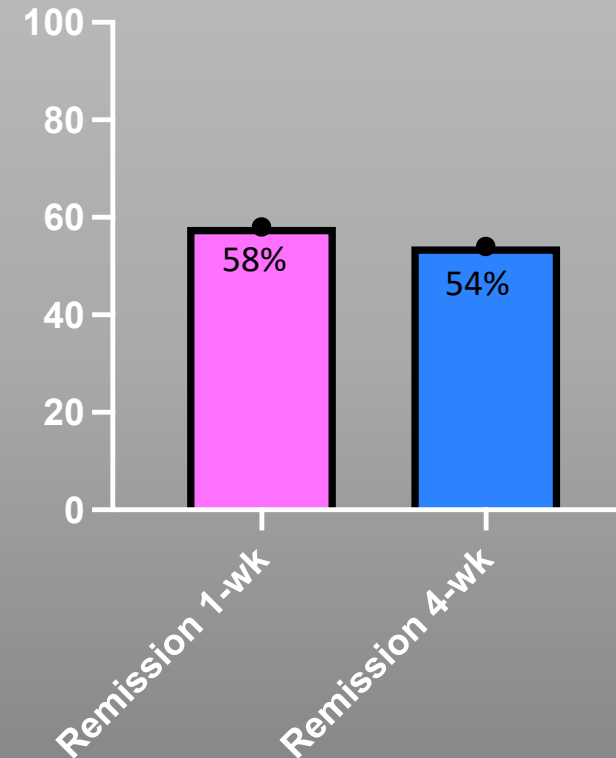
**After all participants have psilocybin therapy, depression scores decrease substantially at 1-week and 4-weeks after treatment is over**

# Response & Remission

Proportion of participants meeting criteria for clinically significant response (>50% decrease in depression scores)



Proportion of participants meeting criteria for clinically significant remission ( $\leq 7$  in clinician rated GRID-HAMD score)



**Almost three-quarters had a clinical response (at least 50% drop in depression scores) to the treatment and about one-half were in complete remission from depression at 4-weeks**


# Long-term outcomes

Original Paper

## Efficacy and safety of psilocybin-assisted treatment for major depressive disorder: Prospective 12-month follow-up

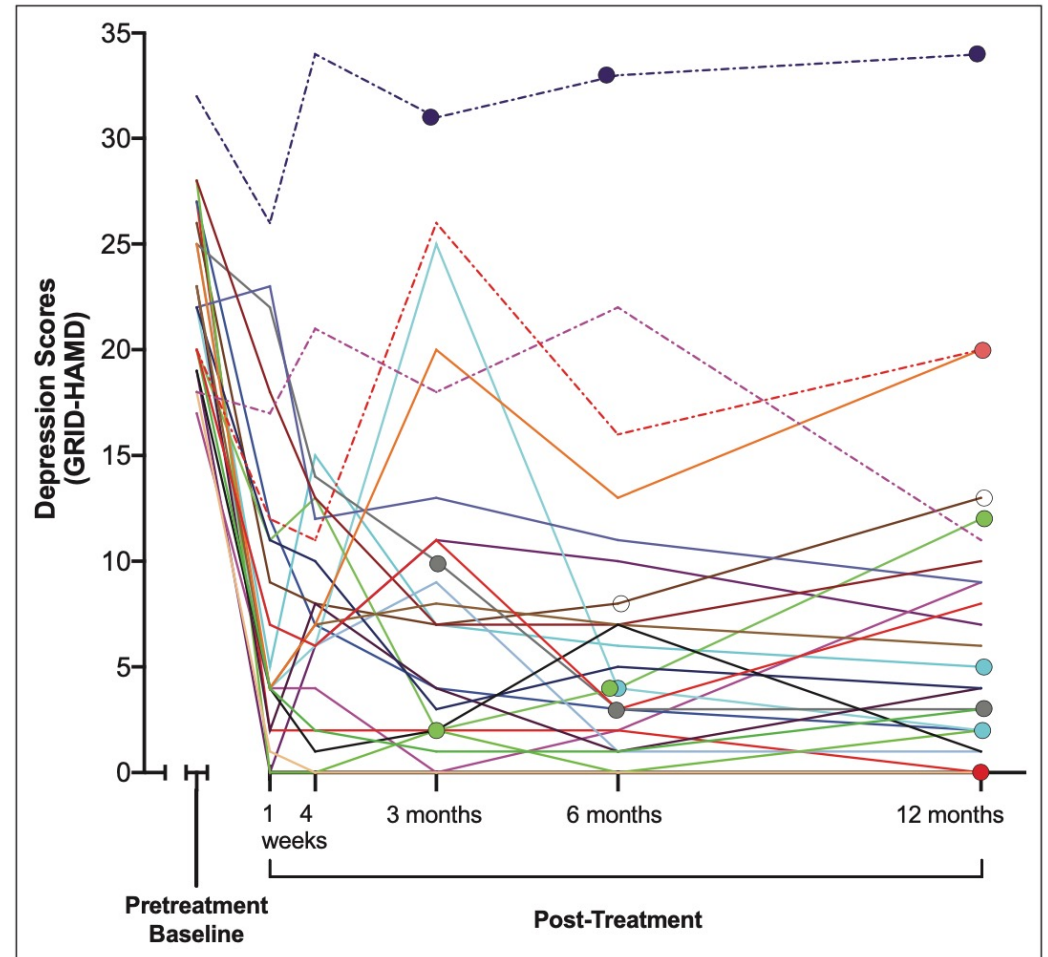
Natalie Gukasyan<sup>1</sup> , Alan K Davis<sup>1,2</sup> , Frederick S Barrett<sup>1</sup>, Mary P Cosimano<sup>1</sup>, Nathan D Sepeda<sup>1</sup>, Matthew W Johnson<sup>1</sup> and Roland R Griffiths<sup>1,3</sup> 



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At 12-months after treatment:

- 75% clinical response
- 58% in remission
- No serious adverse events during follow-up
- No psilocybin use outside of trial



# Conclusions & Future Directions

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Psilocybin-assisted therapy is safe and efficacious for people with depression

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Current Phase III studies are underway, leading to FDA review for approval in 2024/2025.

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Lack of inclusion for diverse study participants is a major limitation.

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If approved by the FDA, much work will need to be done to make this available to the public. Workforce will need training to do this treatment. Sites will need to be modified for this interdisciplinary endeavor.

# Thank you!

Dr. Alan Davis

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More information at [cpdre.org](https://cpdre.org)

## Resources

Courses in Psychedelic Bioethics; Psychedelics 101

25 Hour Online Continuing Education Program

Undergraduate Minor in Psychedelic Studies

Multidisciplinary 3-day Training for Clinicians

Interdisciplinary Conference - Psychedemia

Clinical Training in Research (graduate/post-grad)

Psychedelic Science Consortium of Centers/Programs

Psilocybin trial for Veterans with PTSD

Psilocybin versus 5-MeO-DMT trial for lung cancer patients with depression

Trials in development for marginalized communities: BIPOC, Spanish-speaking, and LGBTQIA