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Psilocybin-assisted psychotherapy for the treatment of Major Depressive Disorder: Preliminary results from a randomized controlled trial

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Background

Major Depressive Disorder (MDD) is a prevalent condition that confers substantial public health burden. Current approved treatments, including pharmacotherapy and psychotherapy, are limited in effectiveness and adherence. Recent evidence suggests that one or two administrations of psilocybin under psychologically supported conditions produces antidepressant effects in cancer and treatment-resistant depression populations.

Aims and Method

This is a randomized waitlist control trial investigating the immediate and enduring antidepressant effects of two psilocybin administration sessions (20mg/70kg and 30mg/70kg) given in the context of psychotherapy in patients diagnosed with MDD.

Outcome measures include the GRID-Hamilton Depression Rating Scale (GRID-HAMD) scores at Baseline (≥17 required for enrollment) and 1- and 4-weeks after the second psilocybin session.

As of December 2018, a total of 12 participants completed the intervention and the 1- and 4-week assessments:

- Mean age = 39, *SD* = 14
- Female = 67%
- Mean Years with depression = 16.8, *SD* = 13.7

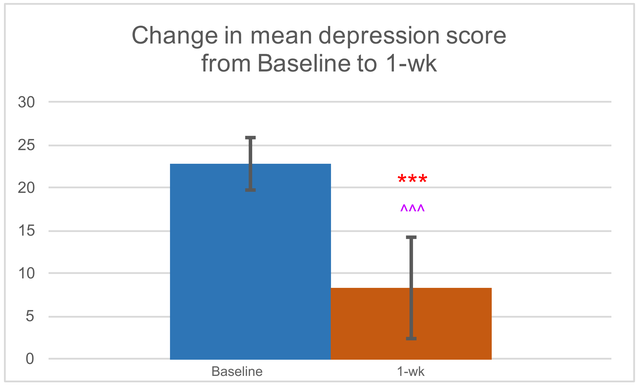
Data Analyses

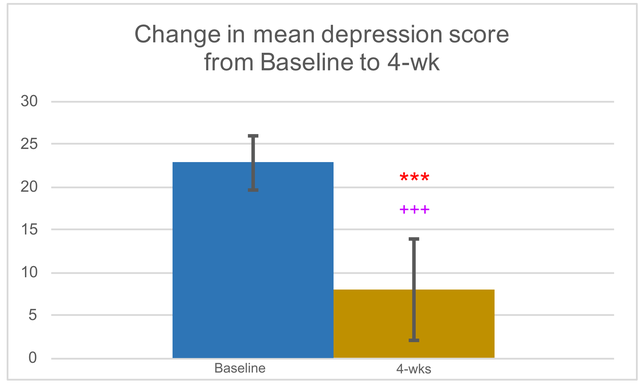
For primary statistical analysis we combined Baseline and 1- and 4-week follow-up data from the waitlist and immediate treatment groups to examine overall treatment effect of the psilocybin intervention. We combined groups because only 3 participants had completed the waitlist condition at time of analysis.

We calculated the reduction in depression scores (% decrease) at 1-wk and 4-wks, the proportion of participants with a clinically significant response (>50% decrease in GRID-HAMD scores) at 1-wk and 4-wks, and the proportion of participants meeting criteria for remission (≤7 on the GRID-HAMD) at 1-wk and 4-wks. Additionally, we used a paired samples t-test to compare mean depression scores from baseline to 1-wk and 4-wks.

Lastly, we plotted mean GRID-HAMD scores at all time points in two separate figures (bottom of results), one for each condition, to present trend data for the treatment effect.

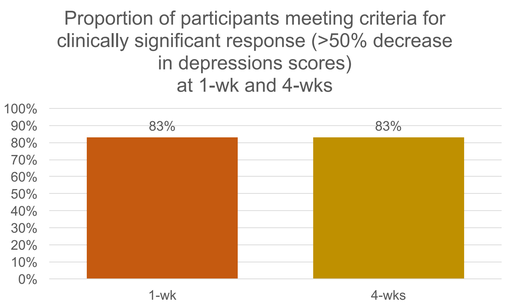
Results

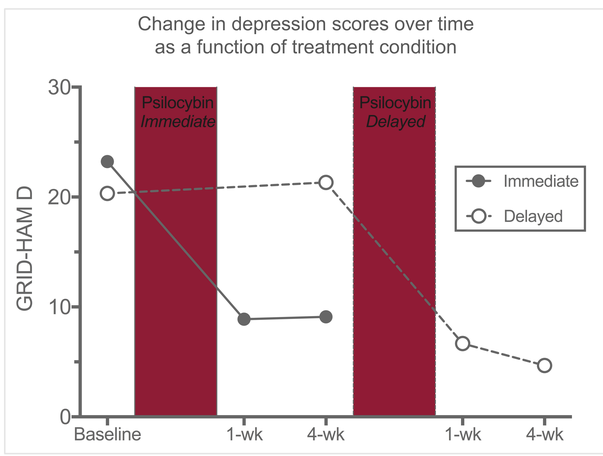


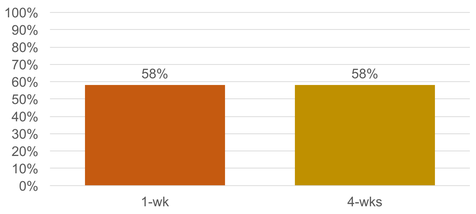


Mean GRID-HAMD scores: Baseline = 22.8 (*SD* = 3.1), 1-wk = 8.3 (*SD* = 6.9), 4-wks = 8.0 (*SD* = 5.9)

*** $p<.001$; ^^^ Effect size: Cohen's d = 2.7; +++ Effect size: Cohen's d = 3.1







Conclusions

These preliminary data extend previous studies in depressed cancer patients and patients with treatment-resistant depression by suggesting that psilocybin-assisted psychotherapy may be efficacious for treatment of MDD in the general population. The overall effect of this intervention across conditions is 3-4 times above the threshold considered a "large" effect (>0.80). Furthermore, the trend of changes in depression scores by condition suggests that these effects are not accounted for by the passage of time. Future analyses of a larger patient sample will include statistical comparison of waitlist and immediate treatment conditions as well as assessment at long-term follow-up time points at 3, 6, and 12-months.

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