

A Double-Blind Trial of Psilocybin-Assisted Treatment of Alcohol Dependence

Lead Investigator: Michael P. Bogenschutz, M.D.

Co-Lead Investigator: Stephen Ross, M.D.

NYU Langone School of Medicine

About the study

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The **Experimental Therapeutics Research Group** at the **NYU School of Medicine** is conducting a study to investigate the effectiveness of psilocybin-assisted therapy for alcohol problems

Several lines of evidence suggest that classic hallucinogens such as psilocybin can facilitate behavior change in addictions such as alcohol dependence

Our study is a multi-site, double-blind active-controlled clinical trial (n = 180, 90 per group) contrasting the acute and persisting effects of **psilocybin** to those of **diphenhydramine** in the context of outpatient alcoholism treatment

Extensive screening and baseline assessments are completed, including thorough safety screening and assessment of participant characteristics that could potentially moderate treatment response

The drug will be administered during 8-hour sessions in a comfortable living-room-like outpatient setting under close medical and psychiatric monitoring

The drug administration sessions occur in the context of an extended version of Motivational Enhancement Therapy (Motivational Enhancement and Taking Action, META) with the addition of standardized preparation before and debriefing and follow-up after the psilocybin administration sessions

Drinking outcomes and changes motivation, self-efficacy, craving, depression, anxiety, and spiritual dimensions of the medication experience, are measured for a total of **54 weeks**

Study Design

Study period	Week	Treatment	Assessment
Period 1	-4 to -1		Screening
Pre-treatment	-1 to 0		Baseline
Period 2	0	1 (META)	
Pre-Randomization	1	2 (META)	
	2	3 (PSI)	
	3	4 (PSI)	
Period 3 Double-blind Phase	4	Psilocybin 25mg/70kg	5 (PSI) Diphenhydramine 50 mg
	4.1		6 (PSI)
	5		7 (META)
	6		8 (META)
	7		9 (PSI)
	8	Psilocybin 25-40mg/70kg*	10 (PSI) Diphenhydramine 50-100 mg**
	8.1		11 (PSI)
	9		12 (META)
	10		13 (META)
	12		14 (META/PSI)
	24		
	36		
Period 4	37	15 (PSI)	
Open-label	38	Psilocybin 25-40mg/70kg*	16 (PSI) Psilocybin 25mg/70kg
	38.1		17 (PSI)
Extension phase	39		18 (META/PSI)
	42		19 (META/PSI)
	54		

Participation requirements

You may be eligible to participate in this study if you are a male or female, age 25-65, who:

Wants to stop or decrease their drinking

Are not participating in any formal treatment for alcohol dependence other than 12-step/AA

Have a family member or friend who can pick you up and stay with you overnight after 2 medication administration sessions, at weeks 5 and 9 of the study

How to join

**For more information, or if you would like to participate in the study,
please contact our study team:**

Email: alcoholdependencestudy@nyumc.org

Phone: (212) 263-0912