



## Short report

## United States National Institutes of Health grant funding for psychedelic-assisted therapy clinical trials from 2006–2020

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## ABSTRACT

**Background:** Medicine is currently experiencing a “psychedelic renaissance”, said by many to have commenced in 2006. Since then, clinical trials have consistently demonstrated promising findings for psychedelic-assisted therapies in the treatment of various mental health conditions and addictions. While most of this work has been privately funded, governmental biomedical research funding bodies in countries such as Australia, Canada, Israel, New Zealand, and the United Kingdom have begun supporting it. Given that the United States National Institutes of Health (NIH) is the largest public funder of biomedical research in the world, it is important to understand the degree to which the organization is supporting clinical trials of psychedelic-assisted therapies. We are unaware of existing literature quantifying direct NIH grant support for psychedelic-assisted therapy clinical trials, so we sought to answer this important question by searching all NIH grants awarded since the beginning of the psychedelic renaissance.

**Methods:** We queried NIH RePORTER, NIH’s grant database, for grants awarded from 2006–2020 mentioning the psychedelics 3,4-Methylenedioxymethamphetamine (MDMA), 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), ayahuasca, dimethyltryptamine (DMT), ibogaine, lysergic acid (LSD), mescaline, peyote, and psilocybin. We manually reviewed resulting grants to determine whether they directly funded psychedelic-assisted therapy clinical trials.

**Results:** We identified zero NIH grants directly funding psychedelic-assisted therapy clinical trials during the study period.

**Conclusion:** While governmental biomedical research funding bodies in other countries have begun funding clinical trials of psychedelic-assisted therapies during the psychedelic renaissance, NIH has yet to directly fund a single psychedelic-assisted therapy clinical trial. Concerns about risks related to psychedelics, a federal law preventing promotion of legalization of Schedule 1 drugs, and prioritization of grants for other types of studies on psychedelics may explain the dearth of NIH funding for psychedelic-assisted therapy clinical trials.

## Introduction

Psychedelic compounds such as psilocybin and lysergic acid (LSD) were investigated as psychotherapeutic catalysts starting in the 1950s. Approximately 40,000 patients received LSD-assisted therapy as part of clinical studies published between 1950 and the mid-1960s (Grinspoon, 1981), and many more received it as part of routine clinical practice during this era. Multiple studies from this period demonstrated promise for psychedelic-assisted therapy in treating alcohol use disorder, cancer-related distress, opioid use disorder, and other mental health conditions (Nichols & Walter, 2021). However, beginning in the late 1960s, after recreational use of psychedelics became

widespread and they became associated with Western Counterculture, they were criminalized in the United States and, subsequently, many other countries. Research into psychedelics’ therapeutic potential largely ceased until 2006, when publication of “Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance” (Griffiths, Richards, McCann, & Jesse, 2006) launched medicine’s “psychedelic renaissance.” In the 15 years since, several clinical trials, including a number of placebo-controlled trials (Luoma, Chwyl, Bathje, Davis, & Lancelotta, 2020), have expanded upon previous promising findings for psilocybin-, 3,4-methyl enedioxy methamphetamine (MDMA)-, and other psychedelic-assisted therapies.

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While most contemporary clinical trials of psychedelic-assisted therapies have been privately funded through philanthropy and, to a smaller degree, industry, governmental biomedical research funding bodies have increasingly begun to support them. For example, from 2012–2016 the United Kingdom's Medical Research Council provided £508,395 for a study of psilocybin-assisted psychotherapy for treatment of depression (United Kingdom Research and Innovation, 2021). In 2019, Israel became the first government to support therapeutic MDMA research when its ministry of health provided approximately \$500,000 (USD) in medical and hospital services for research into MDMA-assisted psychotherapy research for posttraumatic stress disorder (PTSD) (Ginsberg, 2020). Later that year the Canadian Institutes of Health Research granted \$17,500 (CAD) for a study of MDMA-assisted psychotherapy for race-based PTSD (Canadian Institutes of Health Research, 2019), and in 2021 it provided \$105,000 (CAD) for MDMA-assisted couples therapy for PTSD (Canadian Institutes of Health Research, 2020). In 2021, Australia's National Health and Medical Research Council announced \$15,000,000 (AUD) for clinical trials of psychedelic-assisted therapies for treatment resistant mental illness (Australian Government, 2021), and New Zealand's Health Research Council provided \$249,333.50 (NZD) for a study of LSD microdose-assisted psychotherapy for patients with advanced stage cancer (Health Research Council of New Zealand, 2021).

Psychiatrists in the United States appear divided on psychedelic treatments, with 43% moderately or strongly believing that psychedelics hold therapeutic potential in a 2018 national survey (Barnett, Siu, & Pope, 2018). Despite this lack of consensus, respondents were strongly supportive of research in this area, with 81% moderately or strongly believing that therapeutic applications of psychedelics deserve further research. In the United States, the National Institutes of Health (NIH) is the primary federal government agency that funds biomedical research. NIH is also the world's largest public funder of biomedical research (United States National Institutes of Health, 2018). Therefore, the organization has the potential to heavily influence the direction of psychedelic-assisted therapy research, so it is important to understand NIH's financial support for work in this area. NIH previously funded psychedelic-assisted therapy clinical trials in the 1960s (Pahnke, Kurland, Unger, Savage, & Grof, 1970). However, while we are unaware of any specific NIH policy prohibiting funding for psychedelic-assisted therapy clinical trials, we have observed that many in the psychedelic research community believe that NIH is currently unwilling to fund trials in this area. We were unable to locate published works investigating NIH funding for contemporary psychedelic-assisted therapy clinical trials, so we analyzed NIH grants awarded from 2006–2020 to quantify funding awarded for such trials to determine whether this belief may be based in reality.

## Methods

In January 2021, we performed separate searches for several psychedelic compounds and their abbreviations via NIH RePORTER, NIH's funded research project database. We used the terms "5-methoxy-N,N-dimethyltryptamine", "5-MeO-DMT", "ayahuasca", "dimethyltryptamine", "DMT", "ibogaine", "lysergic acid", "LSD", "3,4-Methylenedioxymethamphetamine", "MDMA", "mescaline", "peyote", and "psilocybin". We restricted results to completed years of the "psychedelic renaissance" (2006–2020), and two authors manually reviewed resulting grants to determine whether they explicitly aimed to fund psychedelic-assisted therapy clinical trials for any indication. Grants unrelated to psychedelic-assisted therapy clinical trials or funding them only indirectly were excluded.

## Results

Of 1,216 initially resulting grants, 1,212 were excluded due to not involving psychedelic-assisted therapy clinical trials. The remaining four

grants (5M01RR000425-37, 5M01RR000425-38, 5M01RR000425-39, and 5M01RR000425-40) were excluded because they were clinical research center awards for a facility where a clinical trial of psilocybin-assisted therapy occurred and did not directly fund a psychedelic-assisted therapy clinical trial. Therefore, we identified no grants directly funding psychedelic-assisted therapy clinical trials from 2006–2020. Further details of our NIH RePORTER search are presented in Fig. 1.

## Discussion

NIH's lack of direct grant funding for any psychedelic-assisted therapy clinical trials during the psychedelic renaissance is surprising given the strong societal need for novel psychiatric treatments and the promise already demonstrated by psychedelic-assisted therapy clinical trials. Why NIH has not yet supported a contemporary psychedelic-assisted therapy clinical trial is unclear. In 2019 NIH Director Francis Collins and United States Food and Drug Administration Director Norman Sharpless wrote that research on "psychedelic drugs holds promise for uncovering mechanisms of [mental] illness and possible interventions (Sharpless & Collins, 2019: 1)." Despite these optimistic views, Drs. Collins and Sharpless reported that NIH funding for psychedelic research of any kind remained largely unchanged from 2013, despite numerous promising clinical trials of psychedelic-assisted therapies being completed since then.

Our review of grants revealed that NIH has funded many basic science studies on psychedelics. Past psychedelic basic science studies, including a study revealing the structure of LSD interacting with the human serotonin receptor, studies assessing the neural underpinnings of MDMA's pro-social effects, and a study demonstrating neurotoxic effects of the psychedelic ibogaine on the cerebellum in rats, were also specifically mentioned by Drs. Sharpless and Collins in their writing (Sharpless & Collins, 2019). Given the large number of such studies encountered in our review, it is possible that NIH may be prioritizing funding for this type of psychedelic research, putting investigators seeking grants to study psychedelics' medicinal potential at a competitive disadvantage. Support for this hypothesis also comes directly from George Koob, Ph.D., director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), an institute within NIH. Dr. Koob has repeatedly stated that NIAAA will not fund psychedelic-assisted therapy clinical trials due to concerns about psychological risks of psychedelics, though contemporary trials have had a strong safety profile (Dos Santos, Bouso, Alcázar-Córcoles, & Hallak, 2018). In 2017, Dr. Koob said stated, "I taught undergraduates for 30 years, and I had numerous cases where people came up and told me about their brother or sister or cousin who had taken a psychedelic and it ended up triggering a long-term schizophrenia-like illness. As a scientist I don't have any objection to studying [psychedelics'] mechanism of action. But I'm not going to be funding any grants for people to treat alcoholism with psilocybin, or LSD, or any other psychedelic. In my view, the danger outweighs the benefits (Bleyer, 2017)."

United States federal law might also be obstructing NIH's ability to fund psychedelic-assisted therapy clinical trials. In 2021, United States Representative Alexandria Ocasio-Cortez introduced a bill in the United States House of Representatives aimed at stimulating more therapeutic psychedelic research by repealing a 1996 federal law prohibiting use of funds from the United States Department of Health and Human Services (HHS), which oversees NIH, for "any activity that promotes the legalization of any drug or other substance in Schedule I [a United States Drug Enforcement Agency classification that includes many psychedelic compounds] (Jaeger, 2021a)." By conducting clinical trials of psychedelic-assisted therapies, researchers could potentially be seen as performing activities promoting medical legalization of psychedelics, a possibility that may be leading NIH to withhold grant support. Representative Ocasio-Cortez's proposed legislation, previously defeated in a 2019

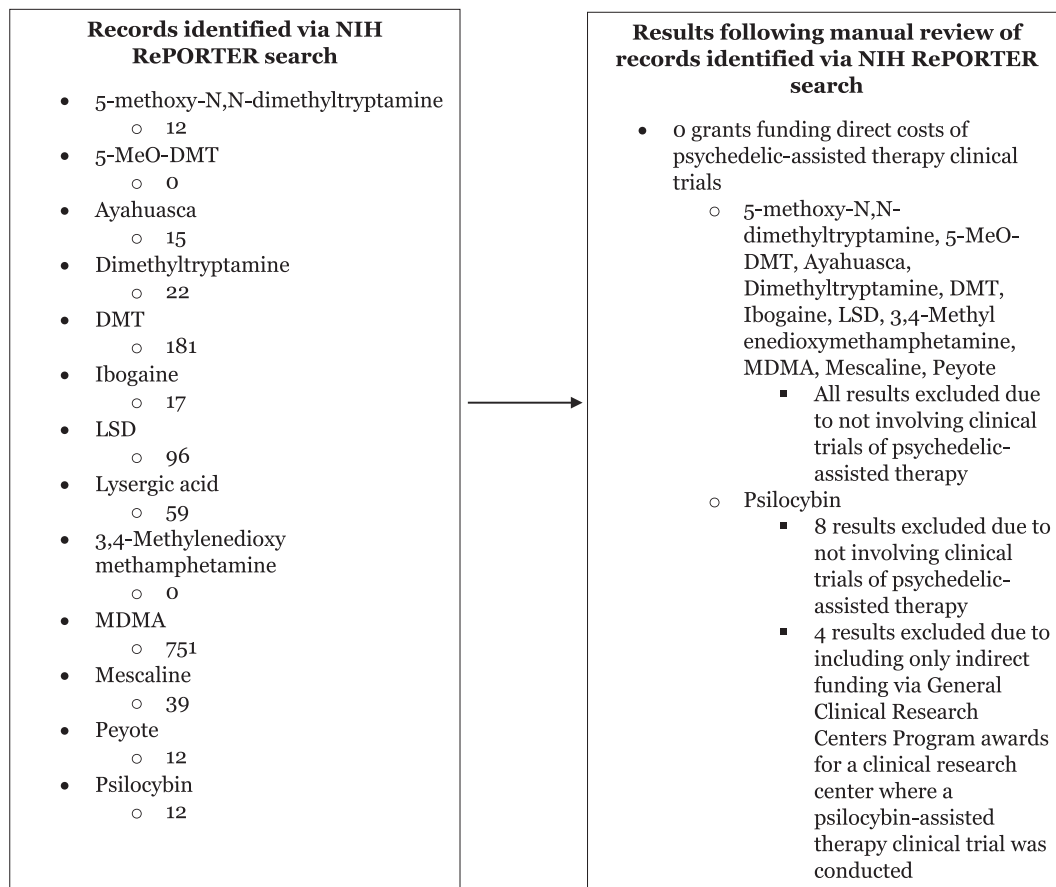


Fig. 1. Summary of search results for NIH grants directly funding clinical trials of psychedelic-assisted therapy for any indication.

vote, was again defeated by a bipartisan vote of 140-285 in July 2021 (Jaeger, 2021b).

Another possible explanation for our findings is that no investigators or only a few submitted psychedelic-assisted therapy clinical trial grant proposals to NIH during the study period. Because data on rejected NIH grant proposals are not publicly available, we are unable to determine how many, if any, psychedelic-assisted therapy grant proposals have been rejected.

Given NIH's apparent hesitance to enter the psychedelic-assisted therapy clinical trial space, philanthropy has been the primary funder of these trials, though psychedelic-focused philanthropic organizations are unable to support many of the research proposals they receive. Researchers unable to secure philanthropic support for psychedelic-assisted therapy clinical trials may have the option of collaborating with industry since psychedelic biotechnology startups, many backed by venture capitalists, have begun conducting such trials recently. However, many investigators, particularly those in academia, are reluctant to do so because of possible conflicts of interest arising from such collaborations. Concerns have also been raised by some within medicinal psychedelic research about safety risks associated with industry's arrival given biotechnology startups' lack of experience conducting clinical trials with such powerful psychoactive compounds. Other concerns about industry's growing role include potential commodification of psychedelic compounds that have long served as traditional medicines and sacraments for indigenous peoples and questions about whether industry will promote equitable access to psychedelic treatments if they are brought to market (Love, 2021). Given high risk of failure and financial loss, it may also be unlikely for industry to conduct clinical trials of psychedelic-assisted therapies for rare conditions or conditions viewed

as difficult-to-treat such as functional neurologic disorders or personality disorders.

Another potentially serious downside from NIH's lack of support for psychedelic-assisted therapy research stems from the fact that countless academic researchers, including many in the developing world, are solely reliant on NIH funding for their research. NIH's lack of support is a serious hindrance for many academic researchers interested in pursuing this work, since industry may not seek to collaborate with some of them due to considering their areas of research focus unappealing. As a result, NIH's lack of support for this research may leave some academic researchers unable to contribute to the development of psychedelic-assisted therapies, potentially meaning overlooked treatments for patients. From a nationalistic perspective, NIH's lack of support may also be putting the United States scientific community at a competitive disadvantage against countries choosing to support this area of rapidly increasing importance.

Recently, it appears that NIH may be reevaluating its approach to medicinal psychedelic research. During a May 2021 Senate budget hearing, Francis Collins told senators that scientists have "begun to realize that [psychedelics] are potential tools for research purposes and might be clinically beneficial (Ponieman, 2021)." He then went on to state that he had recently spoken with NIH leadership about planning a workshop to reevaluate NIH's role in medicinal psychedelic research. Given the growing evidence of psychedelic-assisted therapy's therapeutic promise and the potential for NIH to catalyze psychedelic-assisted therapy research around the world, this potential reappraisal of NIH's approach to medicinal psychedelic research seems warranted.

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## Declarations of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Dr. Barnett has received stock options from CB Therapeutics as compensation for advisory services. He also receives monetary compensation for editorial work for DynaMed Plus (EBSCO Industries, Inc) and owns personal stock in Compass Pathways. Dr. Welleff and Ms. Parker report no financial relationships with commercial entities.

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