

**Qualitative Research on Psilocybin-Assisted Psychotherapy for the Treatment of Mental  
Health Disorders: A Scoping Review Protocol**

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## **Abstract**

### *Introduction*

There has been a surge in research into psilocybin-assisted psychotherapy over the past decade, with many studies indicating this may be an effective novel intervention for several mental health disorders. Researchers are increasingly incorporating qualitative analysis into their studies in recognition of the rich, contextual information this provides. This scoping review aims to identify the existing qualitative research on psilocybin-assisted psychotherapy for the treatment of mental health disorders, analyse trends in research questions and methods, and recognise opportunities for future qualitative research.

### *Methods and Analysis*

The methodological guidelines set out in the JBI Manual for Evidence Synthesis (Aromataris et al., 2024) will be used to conduct the review. The review will include qualitative studies involving psilocybin-assisted psychotherapy, administered in a controlled research setting, for the treatment of any mental health disorder. Microdosing studies will be excluded. PubMed, Scopus, PsycNET, and reference lists of included studies will be searched. Two reviewers will screen papers for inclusion. Data will be extracted into a table and findings will be presented in a narrative form. Relevant qualitative research will be identified, trends in the qualitative research questions and methods will be analysed, and opportunities for future qualitative research will be discussed.

### *Ethics and Dissemination*

Ethics approval is not required. Findings will be submitted for publication in a peer-reviewed journal.

### *Key Words or Phrases*

Anxiety, depression, psilocybin, psychedelic, qualitative.

## Introduction

### *Background and Rationale*

Studies investigating psilocybin-assisted psychotherapy indicate this may be an effective intervention for a variety of mental health disorders (Castro Santos & Gama Marques, 2021; Irizarry et al., 2022; IsHak et al., 2023). Psilocybin is a classic psychedelic that occurs naturally in mushrooms of the *Psilocybe* and related genera. It is a prodrug of psilocin – a partial agonist of serotonin 5-HT<sub>2A/2C</sub> and 1A receptors, which elicits altered states of consciousness, including changes in perception, thoughts, and emotions (Griffiths et al., 2016; Halberstadt, 2015). Multiple studies have found that administration of a high dose of psilocybin in combination with psychotherapy can have significant therapeutic effects in people with mental health disorders, including depression, obsessive-compulsive disorder, and substance use disorder (Castro Santos & Gama Marques, 2021; IsHak et al., 2023). This intervention, termed psilocybin-assisted psychotherapy, typically involves three stages: preparation sessions, to ready the person for the psilocybin experience; treatment sessions, during which the psilocybin is administered in combination with supportive psychotherapy; and post-treatment sessions, whereby the experiences of the treatment sessions are integrated into the person's daily life (Horton et al., 2022).

Psilocybin has been used across the world for thousands of years for cultural, religious, spiritual, healing, and recreational purposes (Heilman, 2022). Western academic research into the therapeutic effects of psilocybin began in the late 1950s. However, psychedelic research effectively ceased in the early 1970s, following the passage of the Controlled Substances Act in the United States; countries that were signatories to the International Conventions imposed similar restrictions shortly thereafter. These regulatory restrictions across the world prevented further academic research into psychedelics for the next two decades (Heilman, 2022). However, psychedelic research began to revive in the 1990s under strict regulatory conditions (Strassman et

al., 1994; Strassman & Qualls, 1994), with several landmark studies (e.g. Griffiths et al., 2006) facilitating further research in this space in the mid-2000s.

Since then, there has been a proliferation of research into psilocybin-assisted psychotherapy. Multiple systematic reviews and meta-analyses have now been published, reviewing the safety and efficacy of the novel intervention. These reviews have captured studies that have included a variety of mental health conditions, such as depression (e.g., Fang et al., 2024; Haikazian et al., 2023; Metaxa & Clarke, 2024; Watford & Masood, 2024), substance use disorder (Kaminski & Reinert, 2023; van der Meer et al., 2023), end-of-life anxiety (Yu et al., 2021) and other mental health disorders (IsHak et al., 2023).

Reflecting the general emphasis on quantitative studies in psychedelic research, there is a relative lack of qualitative research reported in the contemporary literature (Breeksema et al., 2024). Qualitative studies are important in evaluating the safety and efficacy of new interventions as they deepen our understanding of participant experiences and outcomes, and provide contextual insights (Levitt et al., 2018). Qualitative research also has the benefit of not being constrained by set questionnaires that may not capture important features of change or experience. Researchers are increasingly incorporating qualitative analyses into their studies in recognition of the rich information this provides (Breeksema et al., 2020). Breeksema et al. (2020) conducted a systematic review of qualitative studies involving a variety of psychedelic treatments for psychiatric disorders. Of the qualitative studies they identified that involved psilocybin, two studies related to substance use disorder (Nielson et al., 2018; Noorani et al., 2018), one study related to end-of-life anxiety, generating two papers (Belser et al., 2017; Swift et al., 2017), and one study related to depression (Watts et al., 2017). Other qualitative studies on psilocybin-assisted psychotherapy have included participants with depression (Agin-Liebes & Davis, 2022; Breeksema et al., 2024; Kaelen et al., 2018), HIV and trauma (Agin-Liebes et al., 2021), cancer-related anxiety and depression (Malone et al., 2018), tobacco addiction (Garcia-Romeu et al., 2015; Noorani et al.,

2018), and alcohol use disorder (Agin-Liebes et al., 2024; Bogenschutz & Ross, 2018; Nielson et al., 2018).

These studies have used a variety of qualitative methodologies and the research questions have focused on a range of aspects of the intervention. Considering the surge in research in this area, it is an appropriate time to review the literature. A preliminary review of the literature indicates a systematic review may be premature, given the small number and heterogenous nature of the qualitative research on psilocybin-assisted psychotherapy. However, a scoping review is appropriate to identify the relevant literature, examine the current trends in research questions and methods, and recognise opportunities for future research.

### *Objective*

The primary research question for this scoping review is:

- What qualitative research has been conducted on psilocybin-assisted psychotherapy for the treatment of mental health disorders?

The secondary research questions for this scoping review are:

- What are the trends in terms of research questions asked and methods used?
- What are the opportunities for future qualitative research on psilocybin-assisted psychotherapy for the treatment of mental health disorders?

### **Methods**

This scoping review protocol has been developed according to the guidelines and template provided by (Lely et al., 2023). The scoping review will follow the methodology outlined in the JBI Manual for Evidence Synthesis (Aromataris et al., 2024). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Extension for Scoping Reviews will be used as the reporting guideline to write the final scoping review manuscript.

### *Eligibility Criteria*

The eligibility criteria for the scoping review are summarised in Table 1. The review will include studies in which participants are adults ( $\geq 18$  years) who are being treated for any mental health disorder. Included interventions are those that combine at least one dose of psilocybin with psychotherapy in a controlled research setting. The study must include a qualitative analysis of participant data. Acceptable evidence sources are clinical trials, pilot trials, and case reports, where the full text is available in English.

Studies will be excluded if conducted in healthy adults without a mental health disorder, the intervention does not include dosing with psilocybin, does not have a psychotherapy component, or has been delivered in a setting other than a controlled research setting (e.g., a naturalistic setting). Studies that only involve microdoses of psilocybin will be excluded.

**Table 1**

*Summary of Eligibility Criteria for Scoping Review*

	Inclusion criteria	Exclusion criteria
Population	Adults ( $\geq 18$ years) who are being treated for a mental health disorder	Healthy participants Participants without a mental health disorder Age $< 18$ years
Intervention	Psilocybin-Assisted Psychotherapy – i.e., the combination of psychotherapy with at least one psilocybin dosing session.	Psilocybin dose without psychotherapy Microdosing <sup>^</sup> of psilocybin Non-psilocybin-based psychedelic assisted psychotherapy
Context/Setting	Controlled research setting	Any other setting
Outcomes	Includes qualitative analyses of participant outcomes, experiences, or perspectives	Does not include qualitative analyses
Types of Evidence Sources	Clinical trials Pilot studies Case reports Full text available in English Peer reviewed	Any other type of source Full text not available in English

<sup>^</sup> A microdose will be defined as follows:  $< 0.5$ g psilocybe cubensis dried mushroom (oral),  $< 5$ mg psilocybin synthetic (oral), or  $< 0.5$ mg psilocybin synthetic (intravenous) (Polito & Liknaitzky, 2022).

### *Information Sources and Search Strategy*

The search strategy will be developed, and peer reviewed within the research team. The databases PubMed and Scopus will be searched, and the reference lists of included studies will be manually searched for additional studies. Search terms will pair key words associated with the intervention (e.g., psilocybin) and methodology (e.g., qualitative). Search terms for the population will not be included to allow for broad coverage of mental health conditions. The full list of search terms is provided in Supplementary Materials Table 1. All citations will be uploaded to Zotero for reference management and deduplication.

### *Study Selection*

After duplicates have been removed, all citations will be exported into Microsoft Excel for study screening and selection. Two independent reviewers will screen and select the studies and interrater reliability will be assessed at the abstract screening stage. All disagreements will be discussed with a third reviewer until resolved. In the first stage of screening, potentially eligible and ineligible studies will be identified by reviewing the titles and abstracts and assessing these against the inclusion/exclusion criteria. In the second stage of screening, the full text of potentially eligible studies will be assessed against the inclusion/exclusion criteria.

### *Data Extraction*

One reviewer will independently extract the data from the included papers into a tool created by the research team (see draft at Table 2). The extracted data will include information about the author(s), year and type of publication, study design, population, and research questions. The data extraction tool will be updated and refined as required. The completed tool will be peer reviewed by a second reviewer.

**Table 2***Draft data extraction form*

	<b>Guidance</b>	<b>Example</b>
<b>Author</b>	E.g., Smith; Smith & Hunt; Smith et al. (for more than 2 authors)	Belser et al.
<b>Title of source</b>	Full title of the article	Patient Experiences of Psilocybin-Assisted Psychotherapy: An Interpretative Phenomenological Analysis
<b>Publication</b>	Journal name	Journal of Humanistic Psychology
<b>Year</b>	Year the article was published	2017
<b>Country</b>	Country in which the study took place	USA
<b>Study design</b>	E.g., Clinical Trial, pilot trial, case report	Quantitative double-blind, crossover, placebo-controlled pilot study
<b>Study context</b>	Note whether the participants are part of a broader study/clinical trial	Participants had previously been enrolled in a Phase II clinical trial
<b>Sample size</b>	Total sample size	13
<b>Age (years)</b>	Age range and mean	18 - 76 years (M = 50 years)
<b>Gender</b>	Frequency of participant genders	Missing
<b>Mental health disorder(s) of participants</b>	E.g., Depression, anxiety, anorexia	Projected life expectancy of at least 1 year, and a primary diagnosis of acute stress disorder, generalized anxiety disorder, anxiety disorder due to cancer, or adjustment disorder with anxiety
<b>Research question(s)</b>	Qualitative research questions	We address research questions regarding the form and content of participant experiences during the psilocybin dosage sessions, descriptions of their subjective experiences of this psychological intervention in context, and their understandings of the embedded meanings of their lived experiences
<b>Intervention details</b>	Include dosage of psilocybin and course of psychotherapy. E.g. 25 mg; 2 preparatory sessions, dosing session; 1 integration session.	Two drug administration sessions, separated by 7 weeks, a total of nine sessions of adjunctive psychotherapy with two licensed psychotherapists conducted before, between, and after the two 8-hour drug administration sessions, and 6 months of follow-up



		assessment. Regarding the two drug administration sessions: Participants were randomly assigned to one of two oral dosing sequences: first, psilocybin (0.3 mg/kg) and second, niacin (250 mg) or first, niacin (250 mg) and second, psilocybin (0.3 mg/kg).
<b>Control group</b>	Note whether control group qualitative data were collected /analysed	No
<b>Data collection method</b>	E.g. semi-structured interviews	Semi-structured interviews
<b>Timing of data collection</b>	Timing of qualitative data collection in relation to PAP (e.g. 1 week after dosing)	5 participants interviewed within 1 week of second dosing session. 8 participants interviewed at 1 year follow-up.
<b>Analysis method</b>	E.g. thematic analysis, interpretative phenomenological analysis	IPA

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### *Synthesis and presentation of results*

Data will be cleaned and synthesised by one reviewer in Microsoft Excel. The process to identify, select and exclude studies will be visualised in a PRISMA flow diagram. The findings will be presented in a narrative form, addressing the review objective and questions. A summary of the key findings and extracted data will be provided in a table. The approach to synthesising and presenting results may change as the review process progresses.

### *Ethics and dissemination*

This scoping review will synthesise information from published and publicly available literature. As such, ethics approval will not be required to conduct this scoping review. An article reporting the results of the scoping review will be submitted for publication in a peer-reviewed journal.

### **Conclusion**

This scoping review will deliver a comprehensive overview of the qualitative research on psilocybin-assisted psychotherapy for the treatment of mental health disorders. It will also identify

gaps in the literature. The information disseminated in this review may help inform the design of future qualitative research into this subject.

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**Conflict of interest**

The authors involved in this scoping review do not have a conflict of interest to declare.

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