Politics & Policy

WILEY

ORIGINAL ARTICLE OPEN ACCESS

Examining the Perspectives of Key Stakeholders on the Problems, Policies, and Politics Regarding Accessing Psychedelic Interventions to Alleviate End-of-Life Distress

Sarah Kratina[1] | Robert Schwartz[1,2] | Carol Strike[3] | Chris Lo[3,4,5] | Brian Rush[2,3]

[1]Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada | [2]Institute for Mental Health Policy Research, Centre for Addiction and Mental Health, Toronto, Ontario, Canada | [3]Public Health Sciences, Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada | [4]Department of Psychiatry, Temerty Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada | [5]School of Social and Health Sciences, James Cook University, Singapore

Correspondence: Sarah Kratina (sarahkratina@gmail.com)

Received: 4 April 2025 | **Revised:** 1 October 2025 | **Accepted:** 18 November 2025

Keywords: agenda-setting | end of life | existential distress | policy | psychedelic-assisted therapy | psychedelics | psychological suffering

Palabras Clave: angustia existencial | establecimiento de agenda | fin de la vida | política | psicodélicos | sufrimiento psicológico | terapia asistida con psicodélicos

关键词: 议程设置 | 临终关怀 | 生存困境 | 政策 | 迷幻剂辅助疗法 | 迷幻剂

ABSTRACT

Psychedelic interventions are not publicly available through Canada's healthcare system. Despite growing scientific evidence, public interest, and efforts to expand access to psychedelic therapies for end-of-life psychological suffering, Canadian policies remain restrictive. Efforts are underway to expand access, but knowledge gaps exist regarding the policy landscape in Canada. This study examines the barriers and facilitators to accessing therapeutic psychedelic interventions in an end-of-life context in Canada. Fifty-one stakeholders were interviewed, and thematic analysis was supplemented with legal documents and government communications from stakeholders. This multi-province study found that stakeholders described end-of-life distress as insufficiently addressed by current interventions. They discussed psychedelic therapies as a potential option, whereas some noted limited and evolving evidence, and there were heterogeneous views on appropriateness and safety. Current federal regulations provide limited access to psychedelic interventions for end-of-life distress, amidst incremental regulatory changes and political caution. Notably, provincial efforts in Alberta and Québec demonstrate progress: Alberta adjusted provincial regulations and third-party insurance coverage, whereas Québec covered family physician costs for administering and monitoring psychedelic interventions. Sociopolitical factors, notably the judicial process and underground market, may significantly influence policy development in this area. Although the problem, policy, and politics streams have partially merged, political barriers remain significant.

Related Articles:

Bache, I. 2025. "Assisted Dying/Assisted Suicide in the UK: An Idea Whose Time Has Come?" *Politics & Policy* 53, no. 6: e70090. https://doi.org/10.1111/polp.70090.

Bache, I. 2025. "The Multiple Streams Framework and Non-Politicized Issues: The Case of Assisted Dying/Assisted Suicide." *Politics & Policy* 53, no. 1: e70016. https://doi.org/10.1111/polp.70016.

Chris Lo and Brian Rush joint senior authorship.

Ireni-Saban. L. 2013. "Give Me Children or Else I Die: The Politics and Policy of Cross-Border Reproductive Care." *Politics & Policy* 41, no. 1: 5–38. https://doi.org/10.1111/polp.12004.

RESUMEN

Las intervenciones psicodélicas no están disponibles públicamente en el sistema de salud canadiense. A pesar de la creciente evidencia científica, el interés público y los esfuerzos por ampliar el acceso a las terapias psicodélicas para el sufrimiento psicológico al final de la vida, las políticas canadienses siguen siendo restrictivas. Si bien se están realizando esfuerzos para ampliar el acceso, existen lagunas de conocimiento sobre el panorama político canadiense. Este estudio examina las barreras y los factores que facilitan el acceso a las intervenciones terapéuticas psicodélicas en el contexto del final de la vida en Canadá. Se entrevistó a cincuenta y un actores clave, y el análisis temático se complementó con documentos legales y comunicaciones gubernamentales de los actores clave. Este estudio multiprovincial reveló que los actores clave describieron la angustia al final de la vida como insuficientemente abordada por las intervenciones actuales. Se analizaron las terapias psicodélicas como una posible opción, mientras que algunos señalaron evidencia limitada y en constante evolución, y hubo opiniones heterogéneas sobre su idoneidad y seguridad. La normativa federal actual ofrece un acceso limitado a las intervenciones psicodélicas para la angustia al final de la vida, en un contexto de cambios regulatorios progresivos y cautela política. Cabe destacar que los esfuerzos provinciales en Alberta y Quebec demuestran avances: Alberta ajustó las regulaciones provinciales y la cobertura de seguros de terceros, mientras que Quebec cubrió los costos médicos para la administración y el monitoreo de las intervenciones psicodélicas. Los factores sociopolíticos, en particular el proceso judicial y el mercado negro, pueden influir significativamente en el desarrollo de políticas en este ámbito. Si bien las corrientes problemáticas, políticas y políticas se han fusionado parcialmente, las barreras políticas siguen siendo significativas.

摘要

迷幻剂干预目前尚未纳入加拿大的医疗保健系统。尽管科学证据不断增加，公众兴趣日益浓厚，且各方努力扩大迷幻剂疗法在临终心理痛苦治疗中的应用，但加拿大的政策仍然受到限制。目前，各方正努力扩大迷幻剂疗法的获取途径，但加拿大的政策环境仍存在认知空白。本研究旨在探讨加拿大临终关怀中使用迷幻剂干预的障碍因素和促进因素。研究人员采访了51位利益攸关方，并结合法律文件和政府相关文件进行主题分析。这项跨省研究发现，利益攸关方认为目前的干预措施不足以有效缓解临终痛苦。他们讨论了迷幻剂疗法作为一种潜在选择，但部分人士指出相关证据有限且仍在发展变化，并且对于其适用性和安全性存在不同的看法。现行联邦法规对临终关怀中使用迷幻剂进行干预的途径有限，且监管政策也在逐步调整，政治上也较为谨慎。值得注意的是，阿尔伯塔省和魁北克省在这方面的努力取得了进展:阿尔伯塔省调整了省级法规和第三方保险的覆盖范围，而魁北克省则承担了医生实施和监测迷幻剂干预的费用。社会政治因素(特别是司法程序和地下市场)可能会对该领域的政策制定产生重大影响。尽管问题、政策和政治因素已部分融合，但政治障碍依然存在。

1 | Introduction

There has been renewed interest in the potential of therapeutic psychedelic interventions (TPIs) for treating end-of-life distress along with other mental health conditions (Kratina et al. 2023; Andrews and Wright 2022). Different jurisdictions around the world are struggling with whether to attend to this potential as an emerging policy issue, and if so, how (Gardner et al. 2019; Smith and Appelbaum 2022; McGuire et al. 2024). The Canadian case offers a valuable context and potential roadmap for studying how TPIs may become integrated into medical care through the door of palliative care. The accepted palliative care framework (Sulmasy 2002)–addressing biological, psychological, social, and spiritual dimensions of suffering–provides a clinically coherent context for TPIs, which have shown preliminary promise in alleviating spiritual or existential distress (Ross et al. 2022). In Canada, the presence of the federally approved Medical Assistance in Dying (MAID) program and medically regulated cannabis in end-of-life contexts has created a unique environment, thereby encouraging the access issues to be studied in depth (Kratina et al. 2023).

In this context, the appropriateness and feasibility of using TPIs to address psychological suffering at the end of life have gained increasing attention in the Canadian healthcare system since the early 2000s (Landau 2024; Plourde et al. 2024; Kolp et al. 2007). Psychedelics have been gaining traction for treating mental disorders, such as using 3,4-Methylenedioxy methamphetamine (MDMA, also known as "ecstasy") to assist therapy for post-traumatic stress disorder and psilocybin-assisted therapy for treatment-resistant depression (Smith et al. 2022; Goldberg et al. 2020). With the exception of ketamine, legal medical access to psychedelics is only available through case-by-case approval through the federal Special Access Program (SAP) after all other evidence-based treatments have been exhausted without success. Most patients pay out-of-pocket for TPIs, as Canada's health care system and most third-party insurance plans do not offer coverage. From January 2022 to October 2024, Health Canada authorized 243 requests for the therapeutic use of psilocybin (Office of Legislative and Regulatory Affairs, n.d.; Government of Canada 2024), of which about 97% were for end-of-life distress (Office of Legislative and Regulatory Affairs 2023).

The issue of access to TPIs for Canadians with end-of-life distress is on the public agenda and is now entering the government's agenda-setting phase (Pope 2024; Spray 2023; Saville 2023; House of Commons 2023a, 2023b; Senate of Canada 2023, 2024; Riches 2022). According to a recent national poll and population-based survey, approximately 79%–82% of Canadians approved of the use of psilocybin-assisted therapy for those suffering at the end of life (Plourde et al. 2024; Nanos 2023). Additionally, about 64% of Canadians believed the government should expand legal access to psilocybin-assisted psychotherapy for those who qualify for Medical Assistance in Dying (MAID) (Nanos 2023). In an effort to use evidence to guide policy, the federal government is supporting more research aimed at establishing the safety and efficacy of TPIs for a variety of mental health conditions (House of Commons 2023a; Senate of Canada 2023, 2024; The Centre for Addiction and Mental Health 2022; Canadian Institutes of Health Research 2023).

Meanwhile, a patchwork of provincial reforms in health care policies is gradually improving access to TPIs. For instance, Alberta has been proactive—amending the *Mental Health Services Protection Regulation* and, in January 2023, introducing requirements for psychedelic-assisted therapy (Giddings 2023). As well, Alberta Blue Cross has become the first third-party insurance provider in Canada to reimburse claims for the monitoring and assessment portion of TPIs as part of its coverage options (CNW Group 2024). In December 2022, Québec set a precedent when the provincial health insurance provider reimbursed the billing of psilocybin-assisted therapy to two family physicians (Herrington 2022). These developments reflect a dynamic policy landscape that is increasingly receptive to integrating TPIs into mainstream Canadian healthcare. Driven by a mix of advocacy, lobby efforts (Therapsil 2020a, 2020b), and pharmaceutical companies positioning themselves to develop and distribute psychedelics through the SAP (Hager 2023), governmental acknowledgment of the potential medicinal benefits of these therapies for various refractory conditions is growing.

Alongside these developments, research on stakeholders' perspectives on TPIs is increasing (Corrigan et al. 2022; Kunstler 2023; Reynolds et al. 2021), particularly in the United States (Armstrong et al. 2023; Gray et al. 2023; Hearn et al. 2022; Kucsera et al. 2023; Li et al. 2023; Meir et al. 2023). Existing studies have focused on the clinical perspectives of those involved in end-of-life care, including their attitudes toward TPIs (Beaussant et al. 2020; Sholevar et al. 2023; Niles et al. 2021). These studies recognize existential or end-of-life distress as an unmet need that could be addressed by TPIs, while also highlighting the lack of clarity about how they are implemented (Meir et al. 2023; Beaussant et al. 2020; Sholevar et al. 2023; Niles et al. 2021). To date, research has focused on TPIs for cancer patients, with some early studies including those with non-cancerous terminal illnesses. The evidence supporting the use of TPIs for end-of-life distress is currently limited (Niles et al. 2021). In navigating clinical decision-making for end-of-life populations, some ethical and clinical frameworks propose proportionally weighing evidence and risk, thereby allowing individuals the choice to take risk under advisement (Marsh and Kelly 2018; Cohen 2005).

One study shed light on stakeholders' awareness of psychedelics' potential to disrupt existing care models, whether positively or negatively (Sholevar et al. 2023). Calls for more research have emphasized building a consensus-driven agenda (Beaussant et al. 2020), exploring how professional backgrounds influence perceptions of TPIs (Sholevar et al. 2023), and expanding the number of healthcare providers involved in such research (Niles et al. 2021).

Despite this growing body of research, no study has been conducted exploring Canadian key stakeholders' perceptions of the emerging policy issue regarding access to TPIs for end-of-life distress, as well as the extant and recent policy solutions within the Canadian political context. To fill this gap, we explored the perspectives of Canadian key stakeholders on the problems, policies, and political dynamics of accessing TPIs to alleviate end-of-life distress. This study examines the barriers and facilitators to accessing TPIs in an end-of-life context in Canada. This is meant to shed light on the Canadian agenda-setting landscape and stakeholder views on this therapeutic intervention, and offers insights and lessons learned from a policy perspective to those working in other jurisdictions.

2 | Method

2.1 | Study Design

This study was approved by The University of Toronto's Human Research Ethics Unit, protocol 41,093. The principal investigator and interviewer (insert initials) is a registered nurse who assists with TPIs and is also a researcher in the field of TPIs. We used a qualitative exploratory research design informed by Kingdon's Multiple Streams Framework (MSF) (Kingdon 2014). The MSF facilitates an understanding of how the three "streams" of problems, policies (also known as solutions), and politics interact, each evolving at different speeds, to bring issues onto a government's agenda (Kingdon 2014). Thus, the MSF offers an "agenda-setting" theoretical lens. The framework is particularly suited for (a) exploring how the three streams align to create a window of opportunity within a dynamic policy environment, and (b) capturing the fluid nature of policy formation for problems still being defined and recognized by the government. The MSF enables us to capture the dynamic interplay of various factors, making it particularly suitable for this study. It highlights the complexities and fluid nature of policy formation in the context of accessing TPIs for end-of-life distress.

2.2 | Participant Sampling Procedure

We used purposive sampling supplemented by snowball sampling to recruit stakeholders across Canada who belong to key stakeholder groups that were previously identified in federal end-of-life care legislative changes (Government of Canada 2020) and public health and drug policy analyses using Kingdon's MSF (Jarvis et al. 2019; Shapiro et al. 2017). Stakeholders were sampled across Canada from six stakeholder groups key to this issue: (1) clinician-researchers (e.g., palliative care physicians, psychiatrists, psychotherapists, nurses); (2) industry representatives (i.e., leaders in drug manufacturing

companies, psychedelic clinics, and not-for-profits); (3) policy-legal experts (i.e., policy directors, governmental representatives and lawyers); (4) spiritual care providers; (5) patients with a life-threatening illness; and (6) others (i.e., ethicists and a historian). Representatives of each of these stakeholder groups were primarily recruited through the Canadian Psychedelics Research and Policy Network (CPRPN). The CPRN is a pan-Canadian network of researchers, clinicians, regulators, and a variety of other groups (entrepreneurs, businesspeople, academics, and government regulators) interested in psychedelic science and policy. This group was active during the study period but is no longer in operation. Email invitations were sent to members of the CPRPN. Those who expressed interest received a consent form with study details.

To ensure diverse expertise in psychedelics, end-of-life care, and drug policy analysis, additional participants were purposively sampled outside the network. The opportunity arose to interview one industry stakeholder from the US. Although this interview did not provide a basis for systematic comparison, it offered contextual insights into how debates around TPIs are unfolding in a different jurisdiction. The sampling concluded once interviews yielded no substantially new themes relevant to the study aims. This occurred when perspectives within stakeholder groups began to converge, with subsequent interviews reinforcing rather than expanding on the thematic patterns that had been identified. The interviews were conducted between June 2022 and February 2024. Out of 78 invited participants, 51 completed the interview. Of the 27 who did not participate, 16 were clinician-researchers, three were government officials, three were from spiritual care, two were Indigenous leaders, two were lawyers, and one was an anthropologist. Twenty-two potential participants did not respond to the invitation, four declined because of self-reported insufficient knowledge of the topic, and one declined because of time constraints.

2.3 | Data Collection

All participants provided written informed consent before being interviewed and were reminded of their right to withdraw at any time without consequence. To protect confidentiality, transcripts were anonymized and identifying information was removed during data synthesis. Participants did not receive compensation. The semi-structured interview guide was informed by Kingdon's MSF and developed to help ensure a conversational style that was engaging and focused on the research objectives (Mason 2018). Questions focused on the perceived barriers and facilitators to therapeutic access to psychedelics, the roles of different stakeholders in shaping the policy environment, and the ethical and practical considerations of implementation. The semi-structured interview guide was piloted with two stakeholders to ensure clarity and relevance and refined accordingly prior to data collection. Semi-structured interviews, mostly lasting 60 min, were conducted in English over Zoom or by telephone and audio-recorded. Audio recordings were transcribed by software and corrected for accuracy. All transcripts were uploaded and managed using NVivo 14 software (Lumivero 2023). Subsequent follow-up correspondence, including documents submitted by participants, such as legal and government communications, was uploaded into NVivo. The materials were not analyzed as stand-alone data but were used to supplement thematic analysis, primarily by providing context and clarification for themes raised in interviews.

2.4 | Data Analysis

Interview and textual data were analyzed according to the six phases of Braun and Clarke's reflexive thematic analysis in discussion with the team (Braun and Clarke 2021). The analysis began by (1) familiarizing ourselves with the data, followed by (2) initial coding. These codes were then (3) developed and reorganized into initial themes according to an iterative process (Braun and Clarke 2021), which in our case was inductive. Finally, themes were (4) reviewed, consolidated, and defined using a deductive approach informed by the MSF. Finally, (6) the analysis was written up to produce a coherent narrative. Throughout this process, memos were used to track observations regarding emerging themes or unexpected findings throughout the interpretive analysis process. Ongoing dialogue with the research team and follow-up emails or video calls confirming several participants' views enhanced the reliability of the analysis and served as a method of validation. During the phase of refining, defining, and naming themes, conceptual mapping was used to explore evolving themes and enhance rigor.

3 | Results

See Table 1 for details on the participant sample. Most stakeholder participants were from Ontario (45%), followed by Alberta (25%) and British Columbia (20%). See Table 2 for an overview of study themes.

TABLE 1 | Characteristics of study participants ($N = 51$).

Stakeholder group	Number of participants (%)
Clinician-researchers	24 (47%)
Spiritual care providers	7 (14%)
Industry	6 (12%)
Policy-legal experts	5 (10%)
Patients with a life-threatening issue	5 (10%)
Other	4 (8%)
Canadian province	**Number of participants (%)**
Ontario	23 (45%)
Alberta	13 (25%)
British Columbia	10 (20%)
Québec, Saskatchewan, and Manitoba	5 (10%)

TABLE 2 | Overview of key themes structured according to Kingdon's multiple streams framework.

The Healthcare Challenge			
The problem of end-of-life distress • Difficulty treating end-of-life distress • Psychedelic therapies as a potential treatment for alleviation of end-of-life distress			
Topic	**Problems**	**Solutions**	**Politics**
Federal and provincial access to psychedelics at the end of life	• Shortcomings of the federal route to access ◦ Bureaucrat as gatekeeper ◦ Healthcare prescriber burden ◦ Getting access is burdensome for patients • Shortcomings of the Alberta psychedelic regulation • Influence of the underground market • Limited healthcare infrastructure • Corporate influences on intervention development and access	• Leveraging medical cannabis regulations for psychedelic policy framework • MAID as an access point: Applying the principle of proportionality • Learning from the Alberta effort	• Broader political landscape • Perceptions of government's stance • The judicial mechanism • Relative silence of professional regulatory bodies, associations, and insurance agencies • Alberta: Possible vested interests and political competition among jurisdictions

Abbreviation: MAID, Medical Assistance in Dying.

3.1 | The Healthcare Challenge: The Problem of End-Of-Life Distress

Stakeholders identified multiple aspects of the problem surrounding end-of-life distress and divergent views on how to address it. Specifically, they focused on diagnostic challenges, access to suitable interventions within the context of MAID, and many viewed TPIs as a potential treatment for existential distress. Some also identified an insufficient evidence base for these TPIs. Clinicians described psychological suffering at the end of life as "an existential distress" prompted by "the imminent or foreseeable end of their life" (Psychiatrist1). This distress can be deeply personal in nature, stemming from a loss of meaning, identity, and purpose owing to physical deterioration and was described to be distinct from depression and anxiety in other contexts.

Participants expressed that palliative care strategies for end-of-life distress are lacking, such that "MAID has become one of their few choices" (Palliative-Physician9). Psychedelics were seen as promising for existentially oriented distress: "If I recognize and screen someone with questions related to spirituality and meaning and purpose, and I recognize there is an existential distress here... that for me would be an indication to trial psychedelics" (Palliative-Physician2). Although all participants expressed interest in the potential of TPIs, some clinician-researchers questioned whether the current evidence base justified wider access.

3.2 | Problems of Federal and Provincial Access to Therapeutic Psychedelic Interventions for End-Of-Life Distress

There was considerable participant commentary on issues of access and varied from insufficiencies in federal access processes, the influence of the underground drug market, shortcomings in Alberta's regulations, the lack of healthcare infrastructure, and corporate influences on TPI development.

3.2.1 | Shortcomings of the Federal Route to Access

3.2.1.1 | Bureaucrat as Gatekeeper. Several participants expressed concern with the federal case-by-case process for access, namely the subsection 56(a) exemption of the *Controlled Drugs and Substances Act* (CDSA) and the SAP. The following quotes are from lawyers, legal advocates who regularly support prescribers and patients with Special Access Program (SAP) and exemption applications and related litigation. They highlighted that it places the government, or "some anonymous bureaucrat in Ottawa" (Lawyer2), "who [doesn't] know the patient" (Lawyer1) as the "failed gatekeeper" (Lawyer2) to TPIs. Lawyer2 also stated the following:

> [Doctors] have a duty to consider the patient's wellbeing first and act only in the benefit of the patient ...[whereas] the government does not have that duty.... The language is that they can refuse it for reasons unrelated to the patient's health, perhaps for some policy reasons, which for someone dying—that's ridiculous.... Some anonymous bureaucrat in Ottawa, who's saying, "You know, despite what this patient's going through, despite what the doctor says, I'm not sure how many things you've gone through, how many treatments you've tried. I'm the one who is making the decisions here." That's a terrible way to operate.
>
> (Lawyer2)

3.2.1.2 | Healthcare Prescriber Burden. Stakeholders' expressed that the SAP process involved "a lot of work" (Lawyer2) and that the burden of liability was a large concern: "They have to assume liability for the entire process... the actual treatment, even though they might not be sitting in on it.... And there's a lack of standards around what they exactly have to do" (Lawyer2). Another issue involved inter-provincial differences where few knowledgeable prescribers exist, as this participant highlights:

> Throughout Canada, who can do this?... It's difficult and, in some cases, impossible for a physician in another province to fill out the SAP form for a patient in a different province. Some, like Manitoba, have rules against that, where they just can't do it remotely. (Lawyer1).

Participants also discussed the challenges posed by the lack of coverage by provincial health insurance plans for TPIs. They noted the difficulty in finding physicians willing to commit the 6 to 8 h required for psilocybin-assisted therapy, particularly when it involves charging patients for this extensive time. Additionally, logistical burdens surround the practicalities of possessing a controlled substance, as the class exemption "only covers hospital pharmacies" (Lawyer1) or prescribing professionals. In many cases, despite SAP approval, after contacting "quite a few hospitals... none of them have been willing to accept the shipments" (Lawyer1).

3.2.1.3 | Getting Access Is Burdensome for Patients. Participants reported that patients faced procedural delays, lacked access to supportive and knowledgeable health professionals to help them navigate federal access points, and that access was challenging, as follows:

> For those of modest means, it's bad for rural Canadians, it's bad for the most vulnerable.... If you're in a small town, you've got to travel.... Travelling for a patient in this state ...[who is] about to take something in which set and setting are so critical.... To take a drug like psilocybin in a foreign place with a therapist they don't know... those are some of the issues. (Lawyer2)

A terminally ill patient participant expressed frustration over being directed toward an Open Label Individual Patient study by a government official:

> The implication ...[is] that I, a terminal cancer patient in palliative treatment and semi-paralyzed with anxiety about my impending death, should take it upon myself to persuade a doctor or researcher to run a trial on me, when I couldn't even get a doctor to complete an SAP application on my behalf. (Patient4)

Participants expressed frustration over the lack of support and barriers to access. One patient participant shared: "I have actually made the date for my first psilocybin session. I am committing civil disobedience, but I'm not leaving my quality of life in the hands of the federal government... They're leaving me no choice" (Patient4). Considering these challenges, one participant emphasized the appeal of underground alternatives: "[It's hard to find] the justification for doing that [getting legal federal access], instead of just getting treatment illegally underground, which is far cheaper and easier to access" (Industry7).

3.2.2 | Shortcomings of the Alberta Psychedelic Regulation

Alberta was the first province to regulate psychedelic-assisted therapy interventions in Canada. However, participants felt the regulation "doesn't go to the heart of the problem, and that's access, which the federal government controls the tap on" (Lawyer2). This is because psilocybin and MDMA must be obtained through the federal SAP. The regulations were also criticized for applying only to psychedelic-assisted therapy, which involves accreditation and hiring a psychiatrist as medical director. Further, the regulations indirectly incentivize physicians to prescribe ketamine alone for at-home use or for in-office use without therapy since that falls outside the regulations. As one stakeholder shared, "It missed the whole... piece—that what we should actually be regulating is this at-home ketamine prescription, which any doctor can prescribe for at-home use" (Industry6).

Many stakeholders criticized Alberta's regulations for designating psychiatrists as gatekeepers, overlooking other qualified "prescribing practitioners" for "the role of medical director" (Industry1). Additionally, participants critiqued the requirement for "a regulated professional, so like an OT [occupational therapist] could do it...[since] it doesn't stipulate what training [is necessary]" (Industry6). This excludes unregulated but experienced counselors with relevant skills and training, which "limits the workforce" and potentially offers more "affordable and accessible" (Industry1) treatment options. Overall, participants felt that the Alberta regulations were "grossly pushed forward... We took five months ...[and] it was non-inclusive in the forming of the regulations" (Industry6).

3.2.3 | Influence of the Underground Market

Participants noted that there has been "a lot of underground therapy going on in Canada, and has been for decades" (Psychologist1). Participants described a growing disregard for Canada's current drug laws by individuals seeking access to TPIs, psychedelic practitioners, and business owners and urged the adaptation of policies to better meet population needs, including at the end-of-life: "Right now we're in a situation where... the ones who have a constitutional right to it can't get it" (Lawyer1).

Tolerance for the sale of cannabis prior to its legislation has led some observers to conclude that a similar pattern is occurring for psychedelics. The lack of law enforcement may encourage advocates to accelerate reform by "pushing the [legal] boundaries" (Physician1) and accepting the risks as a cost of doing business. This participant elaborated:

> Business people would say... "I'll just pay the fine or I'll go to jail a couple of days... we'll just keep doing it until you let us do it." ...That's how cannabis got legalized for recreational use, not even just medical. I think that's what the advocates in the business sector... want to push it [psychedelics] that way as well. And that's maybe why also Ottawa is cautious about things because we've looked at the medical cannabis industry and that's almost collapsed.
>
> (Physician1)

This widespread use of unregulated drugs was noted as posing health risks due to unknown composition and production methods:

> I would say that our current policy right now fails to meet its goals because right now we've got millions of Canadians accessing psilocybin each year and they're doing so through an underground market... and the law is not even being enforced.... The policy needs to catch up with the will of the people, doctors, therapists, and quite frankly, with the will of the Justice Department as well, who won't even enforce the policy.
>
> (Industry7)

3.2.4 | Limited Healthcare Infrastructure

The integration of TPIs into mainstream healthcare faces significant challenges, including in end-of-life care contexts, primarily because of its "resource-intensive" nature (Psychiatrist5), requiring "specialized training" (Policy-Expert2) and "education of the various care providers" (Policy-Expert1). As Policy-Expert2 queried, "Where's the money going to come from to pay people to do this outside of clinical trials?" As Policy-Expert1 noted, setting up the necessary healthcare infrastructure encompasses numerous complexities, including establishing capital infrastructure, determining billing codes, and developing systems for monitoring and evaluation. Given that the research indicates that integration, preparation, medication, and supervised administration are necessary for effective TPIs, it seems that "we're not in any way prepared for that" (Policy-Expert1) because a comprehensive healthcare system where "those things are all working in tandem" (Policy-Expert1) is not yet in place. This same policy expert expressed that provincial health systems take on a reactive stance: "When Health Canada finally does give regulatory approval, then finally provincial health systems will start contemplating... how to start building these pieces for health system design and delivery."

3.2.5 | Corporate Influences on Intervention Development and Access

Several participants highlighted the financial and procedural challenges posed by the pharmaceutical industry's approach to psychedelics for end-of-life care. They pointed to the high costs of proprietary drugs such as Johnson & Johnson's Spravato (intranasal ketamine), as well as the strict clinical trial protocols enforced by entities such as the Multidisciplinary Association of Psychedelic Studies (MAPS) Public Benefit Corporation, now Lykos Therapeutics. There were also concerns about potential future Department of Health Canada and Federal Drug Administration (FDA) regulations limiting treatment flexibility and increasing costs, as this participant commented:

> I never used Spravato. It's expensive and there's no benefit, as far as I can tell.... Ketamine is dirt cheap... and Spravato is hundreds of dollars a dose. And you kind of need to jump through Johnson's policies for giving it. You [also] don't have dose flexibility with it beyond the two doses.
>
> (Palliative-Physician5)

Likewise, MAPS' uniform psychotherapy protocol for MDMA-assisted therapy may be perceived as a reputable brand, as Industry4 noted: "It's like buying Nike.... It's expensive, but you still buy it. It's a brand." But this was viewed as problematic because of MAPS' rigidity and proprietary control over research data. Several participants felt that MAPS' cautious distribution of psychedelics to independent researchers and clinicians through the SAP—along with their protective stance on clinical trial outcomes to safeguard market authorization—is restrictive. These strategies may hinder the accessibility and development of psychedelic treatments in end-of-life care.

Lastly, some industry stakeholders mentioned that the profitability of psychedelics at end-of-life is limited, such as this participant:

> From a business financial perspective, it hasn't really made any changes, because [we're] donating that material to those [end-of-life] patients... It's so low volume, and it's so infrequent that you'd have to charge a lot of money for it to break even.
>
> (Industry5)

However, this approach supports one pharmaceutical drug manufacturing company's "mission of improving access to psychedelics to improve mental health and wellness" (Industry5) and the development of the wellness industry.

3.3 | Solutions to Federal and Provincial Access for Therapeutic Psychedelic Interventions for End-Of-Life Distress

Participants shared a range of ideas and strategies to address the problems discussed in the above sections. Some of the participants recommended leveraging existing medical access policies, such as for medical cannabis and MAID. Others suggested building on the existing strengths and principles of good medical protocols—such as increasing public trust in TPIs, drawing on the ethics of proportionality (of harms/benefits), and recognizing appropriate thresholds for evidence for treatment of those with end-of-life issues.

3.3.1 | Leveraging Medical Cannabis Regulations for Psychedelic Policy Framework

Many participants advocated for a regulatory approach modeled after medical cannabis regulations, while emphasizing the need for flexibility. For instance, Lawyer2 stated, "I think the best regulatory model going forward is one that doesn't put patients and doctors in straitjackets in terms of what they can do." This participant further proposed a system whereby the federal government oversees the psilocybin regulations just as "they oversee the cannabis regulations." Doctors would prescribe psilocybin, though not in the traditional sense, as Lawyer2 explained:

> It's not a prescription because it doesn't have a DIN [Drug Identification Number]. But the doctor, kind of like [with] the cannabis regulations—they would sign off on it, and they could sign off on a volume of it, and they could set out whatever parameters they want to set out... so there's flexibility. I think that flexibility would be best.

Several participants emphasized people's rights to "grow their own, because different strains do have different effects" or "have someone else grow [it] for you" (Lawyer1). This perspective is influenced by medical cannabis policies, where court cases have hinged on human rights issues (Smith, n.d.; Malmo-Levine and Caine, n.d.; Parker, n.d.). For example, Psychologist1 clarified that this would "specifically [be] based on section 7 of the *Charter of Rights and Freedoms* (Canada Act 1982) that says that Canadians have the right to liberty and security of persons." These cases highlighted a key conflict:

> [Users must choose between a] legal but inadequate treatment and an illegal but more effective one... It's... court ruling[s]... that led the courts to compel Health Canada to rewrite the Controlled Drugs and Substances Act to introduce cannabis for medical purposes, regulations which allow both the use of organic THC or CBD and the ability [of people] to grow their own. Our argument in court will be [that] the parallels between medical cannabis and medical psilocybin are very strong.... I see SAP as being restrictive of one's right to medical autonomy in the same way that the courts ruled that the restriction to cannabis was a violation of that autonomy.
>
> (Psychologist1)

3.3.2 | MAID As an Access Point: Applying the Principle of Proportionality

Many participants suggested that if patients can access MAID, then they should also have access to psychedelics: "Why not have the option to help someone to improve their quality of life? The option for them to end it is still there" (Patient1). General-Practitioner1 expanded on this end-of-life trajectory: "Psychedelic-assisted therapy should be a part of those treatments that are offered people before they actually choose death, because death is non-reversible." Participants were "incensed that they [patients] now have the right to die, but they do not have the right to try [psychedelics]" (Psychologist1). Psychiatrist3 was "uncomfortable with the notion that people have a federally protected right to access an intervention that will end their life, but not an intervention [psychedelics]... [for] which preliminary evidence at least suggests might also alleviate that kind of suffering."

Within an end-of-life context that includes MAID and palliative sedation as treatment options, the guiding principle of proportionality may take on new importance. Ethicist1 explained: "We have a case where people are dying and are willing to take on additional risks than they may have otherwise because of their condition." This principle seeks the balancing of benefits and risks according to circumstance, ensuring that patient care aligns with their unique needs:

> The drugs that we use in palliative care are remarkably powerful, but we still use them because a good palliative philosophy employs proportionality.... Even though we know these drugs are incredibly dangerous... we even do palliative sedation on people... if their experience of existence is... profoundly overwhelming, [and includes symptoms of] end-of-life anxiety.
>
> (Ethicist2)

Commenting on the issue of proportionality, a patient participant shared:

> I'm dying! This is absurd. This is a repeat of the whole morphine argument, like the fight to give palliative patients access to morphine and fentanyl.... So my argument is similar.... I know that the risk is not with the drug itself... the risk is with set and setting. So, I don't have a condition that's contraindicated. And I'm asking for a safe setting in the form of a therapist's office and guided therapy. So, they themselves are standing in the way of a safe procedure.
>
> (Patient4)

Many participants emphasized that the end-of-life context demands a different threshold of evidence for clinical decisions compared to other care contexts: "In palliative care, I don't really care about evidence.... In my mind, at the end-of-life... if it's working for my patient in front of me, why not" (Palliative-Physician2)? As another palliative care physician noted,

> Most things in palliative care don't actually have level-I evidence supporting them... [But] I don't think the evidence is all that shaky [for psychedelics]. I think it's probably as good as it's going to get.

> It's certainly as good as it gets for most palliative indications.
>
> (PalliativePhysician1)

3.3.3 | Learning From the Alberta Effort

Alberta was the first and only province in Canada to implement requirements for psychedelic-assisted therapy through an amendment to the Mental Health Services Protection Regulation (Government of Alberta 2022). Some strengths were identified. Alberta's implementation of provincial regulations for psychedelic-assisted therapy was thought to foster positive public perception and trust. As one physician expressed: "The government's checked this out and said that it's okay and they have these safeguards in place.... It gives the public a sense of trust and increased confidence that these programs are safe, whether they work or not" (Family-Physician1). Additionally, participants noted that a strength of Alberta's approach is its regulatory flexibility for end-of-life care, allowing patients to receive treatment at home, thus addressing their practical limitations in accessing therapy in an accredited institution. PalliativePhysician5 praised this aspect of the regulations: "[I]f there's anything good about the regulations, it's that they've recognized that, and I hope it stays there."

3.4 | The Politics of Accessing Therapeutic Psychedelic Interventions for End-Of-Life Distress

Participants discussed several political factors influencing TPI policy development in Canada. They pointed to the broader political landscape, government stance at the federal and provincial levels, the silence of professional bodies, and the role of the judiciary. These factors underscore the complexity of the policy environment and suggest that a multifaceted approach is needed to improve access.

3.4.1 | Broader Political Landscape

Participants described the resistance to psychedelic policy change as institutional "ossification" and a "bureaucratic status quo" (Policy-Expert1)—with politicians often gauging public opinion before making decisions. Policy-Expert1 further commented on how politicians typically avoid similar controversial policy issues:

> [They're] holding their finger up to see which way the wind of public opinion is blowing.... For the most part, they didn't see joint policy reform and access to psychedelics as a hot-button issue that was going to make or break their election.
>
> (Policy-Expert1)

This cautious approach was seen to balance liberal and conservative values, placing medical psychedelics "right smack in the middle of the crosshairs of all of that" (Policy-Expert2). Participants noted the historical resistance from regulatory bodies and politicians to medicalizing substances like cannabis, a stance influenced by broader international drug prohibition policies.

3.4.2 | Perceptions of Government's Stance

Participants highlighted that "their emphasis right now... has a lot to do with just trying to support clinical trials and then trying to make policies based on that" (Palliative-Physician9). One participant highlighted the challenge Health Canada faces:

> Health Canada... can't do anything in the public perception unless it's evidence-based... and all that kind of fearmongering that happened in the 60s and 70s, it's kind of political suicide. So, they're cautious... otherwise, like, you know the other side is gonna say that "you make all these bad decisions."
>
> (Family-Physician5)

Regarding Health Canada's use of evidence to inform decisions on granting access to psilocybin for Canadians at end-of-life through the SAP, a participant shared the following:

> [Health Canada] weigh[s]... scientific evidence...[as] evidence from well-designed clinical trials will carry significant weight. Where there's information that's... given less weight... they weigh things on this sort of hierarchy of evidence, but they haven't set out a clear threshold.
>
> (Lawyer1)

However, this participant also mentioned that Health Canada "seem[s] to have a lower standard for people who are terminally ill."

3.4.3 | The Judicial Mechanism

A key pathway for policy change on socio-culturally contentious issues is through the judicial system, as this participant described:

> The government's not going to make rules that make it hard to be the government.... It's really up to the judicial system to hold regulators and hold elected officials and their decisions accountable—hold ministers accountable. So, I'd say it's up to the judicial system to keep the playing field fair to the extent they can and not worry about politics.
>
> (Lawyer3)

Another participant identified a historical pattern, in that significant policy changes in Canada have often resulted from judicial intervention. This view suggests a similar path might be necessary for psilocybin, as this industry representative clarified:

> For policymakers... one of the biggest challenges... will be finding the political courage to do what's

> right in a system that frequently relies on the courts to push to lead the charge in human rights.... It's an unfortunate but necessary way to get things done in Canada... Every single major [medical] policy change in the last 25 years has been done that way: medical cannabis, again [a] court case, [but] government lost, [which] forced [it] to make regulations. Medical assistance in dying, same thing; safe injection, same thing. Prostitution, same thing; abortion, same thing. Everything is like that.... It's the court that makes the decision...at which point the politicians can go "Not my decision, it's the judge's decision." ...I look at it as political cowardice.
>
> (Industry7)

However, Lawyer2 expressed cynicism about the government's willingness to enact substantive changes in accordance with court decisions without political safety:

> [Government's] always fighting.... There have been times where... the activists have won a [cannabis] court case, and then the government changes a comma in the legislation and says, "Everything's fixed, start again. Do your giant case and your appeal again, and maybe we'll change another comma." I'm just super cynical about the government's desire to do much... they're probably driven by public polls, and maybe they think being too open for the liberal government will give the conservatives an option.

3.4.4 | Relative Silence of Professional Regulatory Authorities and Insurance Agencies

Participants identified a lack of support from professional regulatory authorities and liability insurance agencies for TPIs:

> Our regulatory bodies are not actually proactive in providing guidance in the psychedelic space.... They're much more inclined to look at supporting physicians using ketamine.... They are very reluctant to make a statement even about supporting physicians who are using psilocybin. They basically say, "Well, if you are practising within your scope of practice, we'll support you." ...That is a barrier because we don't have enough physicians that actually have psychedelics formally within their scope of practice.
>
> (Palliative-Physician4)

Some participants emphasized the influence of legislation on professional bodies, such as Palliative-Physician4, who stated, "When the legislation changes, then we will see the colleges and our professional bodies having to change, but it's not going to be the other way around."

3.4.5 | Alberta: Possible Vested Interests and Political Competition Among Jurisdictions

In Alberta, the decision to implement a regulatory framework for TPIs was described as a "bold but appropriate decision" (Industry1). However, this top-down approach sparked concerns about possible vested political interests. Indeed, some participants were skeptical about the motivations behind the regulatory changes, suggesting the initiative might not have been entirely transparent or inclusive. For instance, concerns were raised about decisions that benefited certain individuals with direct ties to the industry, including owners of ketamine clinics and connections with Members of Parliament, as this participant makes clear:

> He does have two ketamine clinics in Alberta. And [name] also treated a member of parliament at their facility, so there's a lot of less than arm's-length-reach nonsense that went on to the detriment of the public.
>
> (Industry6)

Some informants expressed criticism about a lack of thorough consultation, evident in this remark: "It was poorly thought out ...[and] there was no patient participation or client participation" (Psychiatrist6). Others were not clear as to why Alberta led the way in creating psychedelic therapy regulations, as noted by this informant:

> I still haven't ever gotten a good answer for why did Alberta move forward and change regulation and put service standards in?... I often think some of that is driven by big P Policy. It's driven by the government in power—kind of their ideology or their platform.
>
> (Industry1)

Despite these criticisms, some participants perceived that Alberta's leadership in establishing psychedelic-assisted therapy regulations shows it is a risk-taker, as this individual highlighted:

> Maybe [because it is] a more conservative government... but it seems to step out and be competitive amongst the other jurisdictions in Canada.... My sense is Alberta taking that step, [it] is actually pushing the federal government and the other provinces to look to that final step, after the SAP of legal regulated access.
>
> (Industry1)

4 | Discussion

By analyzing stakeholder content through problem, policy, and political streams, we clarified the relationships among these elements and identified their degree of convergence. We also discussed the conditions that would likely be necessary to create a window of opportunity for placing policy change on the federal government's agenda.

4.1 | Convergences Among the Multiple Streams

The challenge of alleviating psychological suffering in individuals at the end of life has brought attention to policy issues surrounding access to TPIs for this population. In recognition of the clinical importance of this issue and the relative lack of treatment options, there has been increasing activity and convergence within and across the three streams as stakeholders seek to adapt existing policies to allow for expanded access that is appropriate to the level of evidence.

There is some convergence and interaction between the problem and the solution streams, leading to the evolution of both the solutions and a deeper understanding of the issues surrounding suffering at the end of life. Specifically, the federal government has implemented a case-by-case access approach, but it was reported as onerous for all involved—government, patients, and providers—and failing to adequately meet patient needs. The restricted access to TPIs also raises ethical concerns about proportionality, given the finality of MAID and the severity of palliative sedation as alternative treatment options.

In response, some advocates and patients are trying to push for political change through the courts. This includes a class action lawsuit against Canada's federal government for a constitutional right of access to psilocybin-assisted therapy (Federal Court of Canada, n.d.). The problem of restricted access to psychedelics is often framed as a *Charter* rights issue (Pope 2024; Lewin and Sagara, n.d.), echoing arguments used in MAID and cannabis cases (Smith, n.d.; Government of Canada 2016; Do 2015). Other solutions involve adapting medical cannabis regulations developed with limited evidence (Canadian Agencies for Drugs and Technologies in Health (CADTH) 2020; Rubin 2017; Allard v. Canada, n.d.; Hitzig v. Canada 2023) amidst public pressure and learning from the implementation of Alberta's regulatory approach, despite its reported shortcomings, to better shape policy.

On the basis of analysis of stakeholder interview data using the MSF, the level of convergence between the politics and problems streams is the least developed. This may be because changing drug policy is a major undertaking, with widespread and significant implications for public health, research, the economy, law enforcement practices, and social attitudes towards drug use. Additionally, those at end-of-life seeking access to TPIs are a relatively small clinical population, which no doubt lowers the political priority. The recent FDA ruling rejecting Lykos Therapeutics' drug application for MDMA in combination with their model of assisted therapy for PTSD due to the methodological and safety flaws in the phase 3 clinical trials (Reardon 2024), also raises political stakes. This ruling may prompt Health Canada to adopt a more cautious approach, raising the necessary threshold for evidence. It could also increase skepticism or opposition among the public, clinicians, and policymakers.

Meanwhile, the underground market continues to be an illicit venue where Canadians with serious or life-threatening conditions find solutions to access TPIs, though this does not resolve the policy issue of restricted medical access. Although accessing TPIs through the underground market poses safety risks due to a lack of quality control, it also functions as a policy feedback mechanism (Béland et al. 2022) by undermining prohibitionist policies and potentially shifting public perception and increasing demand for regulated access. However, this may also provoke more punitive responses. Although the underground cannabis market contributed to greater medical access through broader public use (Health Canada 2024; Goodman et al. 2024; Shim et al. 2023), it remains uncertain if psychedelics will follow a similar path.

4.2 | Challenges and Opportunities in Policy Alignment

Despite a compelling opportunity for policy creation, the streams have not fully merged, passing through a policy window for end-of-life applications and onto the governmental agenda. This may largely be due to the cautious political climate and the limited size of the affected clinical population, diminishing the urgency needed to elevate the issue to the federal agenda. The fragmented state of proposed solutions, although informative, has not yet come together into a policy approach identified as sufficient and effective to address the complexities of increasing access. It seems likely that, unless there is better alignment with the political stream, the limited appetite for bold federal policy shifts will continue, producing only incremental changes.

To create the conditions conducive for a policy window for agenda setting, it seems the federal government and professional regulatory agencies need a stronger evidence base to support guidelines for TPI access at the end of life. An integrated and comprehensive policy proposal that provides an economically sustainable and clinically feasible solution would require active collaboration with multiple stakeholders. Stronger advocacy efforts are needed to raise the profile of the issue of end-of-life distress and to build greater political momentum. Leveraging the judicial mechanism and human rights arguments can challenge existing prohibitive policies. At the same time, public education and awareness campaigns can shift the national mood and create a more receptive political environment for policy change. However, all of this seems to depend on more definitive research.

Kingdon's Multiple Streams Framework describes how the problems, policies, and politics streams converge through a policy window of opportunity and onto the government's agenda. Before entering the policy window, policies may drift around in a “primeval soup” for long periods of time before a successful candidate rises to the surface (Kingdon 2014). Overall, the findings of this study shed light on the “primeval soup” state of the pre-agenda setting phase of the policy process, which is an extension of the original use of the term to refer only to the policy stream. This metaphor serves as a useful heuristic device to capture how ideas emerge, float round, “soften up” and evolve until the conditions are conducive for them to come together into viable policy proposals (Brewster 2022; Jones et al. 2016; Gains and Stoker 2011). Our findings indicate that we are in the early, fluid stage of policy development, marked by emerging awareness of issues such as the clinical need, research gaps, and

ethical concerns, which are being defined and debated within a cautious political climate.

5 | Limitations

This study was cross-sectional in nature, with overrepresentation from central Canada. We were not successful in recruiting other important stakeholders, especially caregivers, insurers, and government officials. There may be selection bias with an overrepresentation of stakeholders who are biased in favor of greater research and/or clinical use of psychedelics. We did not systematically compare TPIs to other psycho-spiritual interventions; future work could examine the integration of TPIs across various modalities. The sample does not reflect all Canadian stakeholder perspectives on this topic. Future directions should aim for more comprehensive sampling and consider systematic longitudinal follow-up of stakeholders' perceptions, given the rapidly evolving nature of TPIs in Canada.

6 | Conclusion

This study provides the first systematic account of the evolving landscape of TPI policy and practice in Canada, situating it within the agenda-setting phase of the policy change cycle. The study highlights the influence of federal and provincial regulations, judicial processes, and the underground market on access to TPIs for end-of-life distress. By clarifying where convergence is occurring and where alignment is missing, this analysis identifies levers for policy change. Although convergence among the problem, policy, and politics streams is partial, significant barriers remain for policy change. Any of the following would contribute to overcoming these obstacles: more robust clinical trial evidence, stronger advocacy, involvement of professional regulatory bodies, and leveraging judicial mechanisms to create a receptive political environment. Incremental provincial developments could drive bottom-up change by creating a more favorable environment for effective and sustainable policy reform at the federal level, even within a politically cautious climate.

Canada's experience offers lessons and insights applicable to global settings where access to TPIs is emerging as a policy consideration. Canada's existing rights-based frameworks for interventions such as MAID and medical cannabis, therapeutic interventions with limited initial evidence, can provide a policy foundation to advance psychedelics. Evidence thresholds are politically contingent and may shift in response to high-profile international regulatory decisions, as seen with the FDA's ruling on MDMA-assisted therapy (Reardon 2024). Canada's lessons for the international landscape suggest that policy change for TPIs is not solely a function of increasing research evidence. It also depends on aligning rights-based advocacy, political opportunity, and public pressure, while considering how underground markets can serve as both a policy pressure point and a public health safety concern. Meanwhile, international developments can affect the domestic agenda on TPIs for end-of-life populations.

For policymakers, our findings highlight that partial stream convergence inhibits policy reform, and that judicial mechanisms, grassroots, and provincial action can be used to advance access even in the absence of immediate federal action. For clinicians, researchers, and professional bodies, the results underscore the need to engage in evidence-building and guidelines development for existing TPI access to ensure safe and ethical access.

Funding

The authors have nothing to report.

Ethics Statement

This study was approved by The University of Toronto's Human Research Ethics Unit, protocol 41,093.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Research data are not shared.

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