

Advocates of psychedelic drug research are hoping the psilocybin trial for treating anxiety in the terminally ill, at Melbourne's St Vincent's Hospital, is the beginning of a new acceptance for the potential of the field. By *Jenny Valentish*.

Opening minds

For eight years, PRISM was the little guy. A non-profit organisation, the Psychedelic Research in Science & Medicine tried to interest universities and the psychiatric fraternity in getting Australia's first psychedelic drug trial off the ground. But despite the fact two of its co-founders are academics, every door they knocked on was slammed in their faces. Australia, it seemed, was just far too conservative to jump on the psychedelic-research bus, in the way Britain and the United States had.

"We were out in the wilderness, starting to wonder whether there was ever going to be any progress," says Dr Martin Williams. "We were feeling a bit discouraged."

Then Williams gave a talk about PRISM's efforts at a conference of Entheogenesis Australis, an organisation of which he is founding vice-president. That was December 2017. In attendance was Dr Margaret Ross, the palliative care clinician at St Vincent's Hospital in Melbourne. Afterwards, Ross contacted Williams to talk about the possibility of collaborating on a trial using a synthetic version of psilocybin – a psychedelic compound derived from mushrooms – to ease the anxiety of her patients.

Not long after that, entrepreneur Tania de Jong offered financial support to set up the charity Mind Medicine Australia (MMA) with her retired investment banker and philanthropist husband, Peter Hunt.

Days later, a second funding partner, the Vasudhara Foundation, got in touch. The beginning of Australia's foray into psychedelic medicine was coming together in the most irregular and innovative of ways.

"Those three things came together to the extent that I felt the stars were aligning – in whatever way we could believe that the stars align," says Williams. He is now the scientific officer of MMA and the co-lead investigator on Australia's first-ever psilocybin trial, which will begin at St Vincent's in April. PRISM is the study's sponsor.

Advocates believe psychedelic drugs – which include LSD, mescaline and DMT – are therapeutic medicines that could usher in a whole new paradigm of mental healthcare. Both PRISM and MMA hope this first trial – beyond benefiting palliative care patients – will finally make that a possibility in Australia.

For Hunt and de Jong, it's personal. Hunt has spoken publicly of his father's suicide; de Jong grew up with parents traumatised by the Holocaust. The couple's interest in psychedelics as medicine began in earnest when de Jong read a blog post by investor Tim Ferriss, which spoke of his support for the psychedelic research conducted by Imperial College London.

She and Hunt have also taken psilocybin themselves in a guided environment, legally, in the Netherlands.

They've now committed \$1 million to Mind Medicine Australia, but are also seeking support from the public and the government. "What we can give is never going to be enough," says de Jong. "One in five Australians is suffering a serious mental health illness and the statistics suggest that one in two Australians will suffer during their lifetime. By the current modality of pills and/or psychotherapy or psychiatric care, 50 per cent of people who seek treatment are not going to find a cure. That's the gap that we're trying to reduce."

Mind Medicine Australia launched on February 13, selling out the 492-seater Carrillo Gantner Theatre at the University of Melbourne. The keynote speaker was Professor David Nutt, the head of neuropsychopharmacology at Imperial College London. He's also now an MMA ambassador, alongside two other heavyweights of such research: Dr Ben Sessa, who conducts trials of MDMA – commonly known as ecstasy – in Britain and calls it "psychiatry's antibiotic", and Rick Doblin, founder of the US-based Multidisciplinary Association for Psychedelic Studies (MAPS), which is conducting multiple studies with psychedelic drugs including ibogaine, LSD and ayahuasca.

Nutt gave an overview of the kind of resistance psychedelic research meets, thanks to its association with 1960s counterculture that led to the drugs being criminalised.

"As a psychiatrist I can write a prescription for heroin, but I needed a police check to do research with psilocybin. They said, 'You might sell it in the street.' At \$1500 a dose? Not even in Chelsea," he joked.

In Australia, the political and public resistance may be even greater. Until now, the closest Martin Williams came to getting a trial off the ground was when he and psychiatrist Nigel Strauss put in a submission to Deakin University in 2015 for a study using MDMA to treat people with post-traumatic stress disorder. It was blocked at the eleventh hour by a professor who was worried about adverse media attention.

"Australia has a rather isolated group-think mentality, unfortunately," says Williams. "Our political class are just very, very scared and they're very risk averse. Universities likewise."

Nonetheless, with the St Vincent's trial, Williams was heartened that there was less resistance from the state Department of Health and Human Services than expected. "There's no question of trying to bend any rules – we've basically followed the process as any pharmaceutical

company might if it wanted to get a totally new drug approved for use in Australia," he says. "Then at the federal level, we need an ongoing licence, and then individual permits to import the drug, which will be donated by the Usona Institute, a non-profit organisation in the US."

At present, Williams says the costs are "a thousand here, a couple of thousand there. The greater expenses will come down the track if we are able to move into the stage of seeking approval of a new medicine. That's quite an expensive undertaking – in the range of \$100,000 to \$200,000 per drug."

Each terminally ill participant in the St Vincent's trial will receive a single dose of synthetic psilocybin, which is thought to provide relief for symptoms of anxiety for six months or more. The trial is likely to run for three years to cover all 30 participants. Recruitment begins in March and will primarily be conducted through St Vincent's. "It will be mainly outpatients, but they will have access to people who are already in their system," says Williams. "There's the potential for outside specialists to refer people to the trial as well, but they do have to come through the medical system."

It might be assumed that a trial for anxiety in terminally ill patients would be more palatable to ethics boards, politicians and the public alike than a trial for any other mental health issue. But David Nutt says that in some respects, treating terminally ill patients is more problematic for those pushing for psychedelic therapy to be rescheduled.

As Nutt tells *The Saturday Paper*, "The current licensing system is for diagnoses – and 'end of life' is not a diagnosis. But there's no reason why Australia couldn't say, 'Well, we actually don't care about licences. We want to help our people who are dying.' Let's change the way we think about this in the same way as we've changed the way, in theory, we think about cannabis. You establish principles and those principles could be rolled out to other plant products. That's what I would recommend, and that would be a way Australia could immediately go to the front of the queue."

While there have already been trials using psilocybin with terminally ill patients, at Johns Hopkins University and New York University, the Australian trial seeks to extend the studies from cancer sufferers to those with other terminal conditions.

"Our plan is not to replicate research that has been done overseas," says de Jong. "We're investing in being ready for when, and if, the regulators overseas reschedule these medicines. The projected time frame for those trial results to come out is in the second half of 2020. If the data shows success, we

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believe that Australia should be ready to reschedule these medicines, so they can be used by doctors, psychiatrists, therapists, in the prescribed area."

The outcome of the trial could potentially see psilocybin reclassified from an Australian Schedule 9 substance to Schedule 8, which means it could be prescribed with explicit government approval. The team at Johns Hopkins University have further advocated for psilocybin to be reclassified to the even more medically accessible US Schedule 4, which would make it available by prescription, albeit still within a clinical setting.

So far, Nutt's own research in Britain has included using psilocybin to treat depression, but he thinks there is wide scope for the substance to treat a variety of addictions and disorders. "The Americans did a very interesting study in tobacco smoking in which 18 per cent of the tobacco smokers stopped within a year," he says. "Another alcoholism trial's been set up. We are setting up to do an OCD study and also an anorexia study. These are disorders where people get locked into thinking the wrong thoughts but you can disrupt those."

For PRISM, treating end-of-life anxiety is a starting point. "We'd certainly like to extend into other areas of research that probably haven't even been explored elsewhere in the world," says Martin Williams.

As he notes, psychedelic drug research dating back to the 1950s and 1960s – before psychedelics were criminalised – has covered the gamut of major affective disorders and addiction issues. He says the focus might be best placed on creating personalised interventions for patients, who may find they respond better to, say, ibogaine or mescaline over LSD or psilocybin.

"There are some drugs that really haven't been looked at very carefully until now for various practical reasons, not least of which is the relatively nascent state of the global psychedelic science renaissance," Williams says. "But we may be in a position to start to really find true mental-health treatments with some of these drugs, which may suit some people much better than others." ●



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