World-first psilocybin clinical trial in the treatment of Generalised Anxiety Disorder receives ethics approval

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Monash University has obtained ethics approval for a world-first clinical trial investigating psilocybin-assisted psychotherapy in the treatment of severe Generalised Anxiety Disorder.

In partnership with Incannex Healthcare Ltd, the randomised triple-blinded active-placebo-controlled trial, led by Dr Paul Liknaitzky, will assess the safety and efficacy of psilocybin-assisted psychotherapy alongside exploring how the treatment works.

Looking to recruit 72 participants, it is set to be the largest psychedelic research and development project in Australia and will include psilocybin sessions alongside a program of specialised psychotherapy.

Generalised Anxiety Disorder (GAD) is a condition that involves intense anxiety and worry most of the time and can be so excessive that everyday life becomes difficult. Experienced by more women than men, nearly six per cent of the Australian population will experience GAD in their lifetime, with current treatments providing inadequate outcomes, problematic side-effects, and high relapse rates.

Evidence is accumulating that psychotherapy assisted by psilocybin can provide significant and lasting benefits across a range of mental health and addiction disorders. Psychedelic drugs can induce states of consciousness that are often reported to be remarkable, moving, beneficial, and difficult to describe. Clinical participants also report challenging experiences that, when well supported, are often felt to be highly valuable by the participant.

Given the central role of clinical support for both safe and effective outcomes, empathic therapists with specialist training are essential. Therapists working on this trial are qualified mental healthcare workers who are currently undergoing extensive training that will also incorporate a world-first option for trial therapists to receive psilocybin under supportive conditions.

Head of Clinical Psychedelic Research at Monash University, Dr Liknaitzky says: “Previous research suggests that psychedelic therapist training can be substantially enhanced if therapists can experience well-supported psychedelic effects, becoming better equipped to accompany clinical participants through profoundly unfamiliar terrain.

“That is why we will provide the option to our research therapists to undergo supported psilocybin sessions as part of their training, a process that is likely to improve outcomes for our clinical participants.”

The impact of this aspect of training will be scientifically investigated from the perspectives of both therapist and clinical participant. Trial therapists will also work under supervision from international psychedelic experts through the duration of the trial.

Lead psychedelic trainer and therapist at Monash, Sean O’Carroll, says: “As psychotherapists, we regularly witness the psychological pain and suffering inflicted by severe GAD, a condition which is notoriously difficult to treat. It is increasingly clear that psychedelics - when used in conjunction with intensive and novel psychotherapeutic interventions - have great healing potential.

“This trial will provide us with an opportunity to make a real contribution to the field, by deepening our understanding of how to best work with these powerful substances. It’s very exciting.”

Head of Psychiatry at Monash, investigator, and medical lead on this trial, Prof Suresh Sundram, says: “This is a critical hurdle to pass in our efforts to test a novel potentially game-changing treatment for people suffering an illness which is often under-recognised, poorly treated and disabling.”

This trial, led by the Clinical Psychedelic Research Lab (https://www.monash.edu/turner-institute/paul-liknaitzky-lab) within the Department of Psychiatry and the Turner Institute for Brain and Mental Health, will be conducted at BrainPark, a state-of-the-art research facility at Monash University.

“Given the early yet highly promising results from other psilocybin trials for different conditions,” says Dr Liknaitzky, “this treatment - alongside innovations we’ve developed - may deliver a substantial step forward in the treatment of anxiety disorders.”

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