

The challenges ahead for psychedelic medicines.

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Introduction / Issues: There is extensive public, commercial and scientific interest in the recent “renaissance” of psychedelic medicine with a range of potential therapeutic application areas including mood disorders and addictions. However, the conduct of psychedelic research and clinical trials comes with a particular set of challenges that need to be addressed.

In this talk I outline two sets of challenges. The first set address technical issues regarding the design and implementation of psychedelic randomised controlled trials. In particular, because of the strong psychoactive nature of psychedelic drugs successful masking is difficult to achieve. When de-masking is coupled to effects of expectancy, suggestibility and therapeutic alliance with research team members, it is likely that the effect sizes reported from psychedelic randomised controlled trials that fail to control these factors will be over-estimated. Some trial designs and measurement tools are suggested that could be considered for use in psychedelic randomized controlled trials. Another broad set of challenges exist in terms of research practices, including industry influence, researcher and funder bias, which will be discussed.

Finally, little attention has been paid to the health economics of psychedelic medicines and the regimens that are being tested within. If these are not cost-effective and accessible, if introduced as medicines they would only serve to entrench existing healthcare inequities in many societies.