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An international Delphi consensus for reporting of setting in psychedelic clinical trials

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Psychedelic substances exhibit complex interactions with the ‘set and setting’ of use, that is, the internal state of the user and the external environment in which a psychedelic experience takes place. Despite the known importance of these contextual variables, psychedelic research has suffered from methodological weaknesses in reporting extra-pharmacological factors and from a lack of consensus regarding their relative importance.

This study aimed to generate consensus-based guidelines for the reporting of settings in psychedelic clinical research, according to a diverse international group of psychedelic researchers, clinicians and past trial participants.

Here we conducted a large international Delphi consensus study composed of four iterative rounds of quasi-anonymous online surveys and facilitated debates. A total of 89 experts from 17 countries initially identified hundreds of potentially important psychedelic setting variables. There were 770 responses, which were synthesized into 49 distinct items that were then rated, debated and refined in subsequent rounds. The process resulted in 30 extra-pharmacological variables reaching predefined consensus thresholds, which were rated ‘important’ or ‘very important’ for reporting by at least 70% of experts. These items compose the Reporting of Setting in Psychedelic Clinical Trials (ReSPCT) guidelines, categorized into physical environment, dosing session procedure, therapeutic framework and protocol, and subjective experiences.

These 30 items represent the first international consensus regarding which specific non-pharmacological elements exert the most important influences on psychedelic drug effects, and thus warrant routine reporting in psychedelic clinical trials. These guidelines aim to significantly improve the quality of psychedelic research, much like other reporting guidelines have strengthened the evidence base of other clinical interventions.

Further empirical research is needed to evaluate the actual importance of the variables that have been included in, or excluded from, the ReSPCT guidelines, and to discern those most relevant to clinical outcomes.

Emergent study findings reveal significant ambiguities in current conceptualizations of set and setting. The ReSPCT guidelines and their accompanying explanatory document provide a new standard for the design and documentation of extra-pharmacological variables in psychedelic clinical research. Drug–context interactions warrant further attention to ensure the methodological rigor of psychedelic research.