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SET AND SETTING RESEARCH: POTENTIAL IMPLICATIONS FOR FUTURE APPROVAL

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No conflict of interest

1. Why and how
2. Psychotherapy research
3. Terminology
4. Examples
5. Conclusions and Proposals

- **Training of therapists** in evidence-based psychotherapies + process research on **therapists' in-session behaviors**/patient outcomes.
- **PSIPET** ($n=35$) Psilocybin/niacin. MDD. PI: Johan Lundberg, Karolinska Institutet.
- **CAPSI** ($n=100$) Psilocybin/low dose. Cancer related major depression. PI: Johan Lundberg, Karolinska Institutet.
- **The Nordic Network for Psychedelic Science** (2021) Dea Siggaard Stenbæk, University of Copenhagen & Neurobiology Research Unit (NRU); Henrik Børsting Jacobsen, University of Oslo (UiO).
- **PsyPal** ($n=100$) Psilocybin/low dose. PI: Robert Schoevers, University Medical Center Groningen.

Set and Setting – Why?



Set and Setting – How?

Safe & Secure and Avoid discomfort (the importance of the full experience)

- Prepare patients for the experience
- Guide/help them through the experience
- Help them reflect on the dosing experience in relation to their life/situation/well-being

Psychotherapy Research

- Effectiveness
- Mechanisms of Change
 - *Specific Factors*
 - *Common Factors*

Importance (and confusions) of Terms

- **Psychotherapy** = use of psychological principles for modifying behaviors, cognitions, emotions
- Therapy
- Psychological support
- Basic support
- **Set and Setting**
- Psychedelic Assisted Psychotherapy/Therapy (PAP/PAT)
- **Psychedelic**/psilocybin/MDA...**Treatment**

Study	Design	N	Diagnosis	Therapists	Credentials (lead)	Prep	Psilo	Int	Frame
Moreno et al. (2006)	RCT	9	OCD	Dyad	Trained sitters	2	4	-	Basic support
Grob et al. (2011)	RCT	12	Cancer	Team	-	1	2	-	Basic support
Johnson et al. (2014)	Open L	15	Tobacco	Dyad	Psychologists	4	3	12	CBT
Bogenschutz et al. (2015)	Open L	10	AUD	Dyad	Therapists	5	2	7	MET
Carhart-Harris et al. (2016)	Open L	20	TRD	Dyad	Psychiatrists	1	2	3	Basic support
Ross et al. (2016)	RCT	29	Cancer	Dyad	Therapists	4	2	6	Eclectic psychotherapy
Griffiths et al. (2016)	RCT	51	Cancer	Dyad	Monitors	3	2	6	Basic support
Davis et al. (2020)	RCT	24	MDD	Dyad	Facilitators	2	2	3	Supportive psychotherapy
Anderson et al. (2020)	Open L	18	Demoral	Dyad	Therapists	5	1	5 / 7	SEGT
Carhart-Harris et al. (2021)	RCT	59	MDD	Dyad	Psychiatrists	3	2	3	Basic support + ACE
Bogenschutz et al. (2022)	RCT	93	AUD	Dyad	Psychiatrists	5	2	7	MET + CBT
Goodwin et al. (2022)	RCT	233	TRD	Dyad	Psychologists, psychiatrists etc	3	1	2	Basic support
Schneier et al., (2023)	Open L	12	BDD	Dyad	Psychotherapists	4	1	2	Manualized supportive procedures
Peck et al., (2023)	Open L	10	AN	Dyad	Psychologists	2	1	3	Basic support + AN specific
Von Rotz et al. (2023)	RCT	52	MDD	Single	Trained therapist	2	1	3	Basic support
Sloshower et al. (2023)	RCT	19	MDD	Dyad	Therapists	2	2	6	ACT
Raison et al. (2023)	RCT	104	MDD	Dyad	Psychologists or MDD physicians	6-8h	1	4h	Basic support

Moving Forward

- Individual/group, number of sessions, spreading of sessions
- Frame: specific/common factors
- The role of music/physical environment
- Number of facilitators, competence, training
- Measures / objective measures
- Alternative research designs, eg. single case experimental designs (SCED) or factorial designs



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