

# Beyond Categorisation: Psychedelic Futures & Engaging with Dynamic Identities

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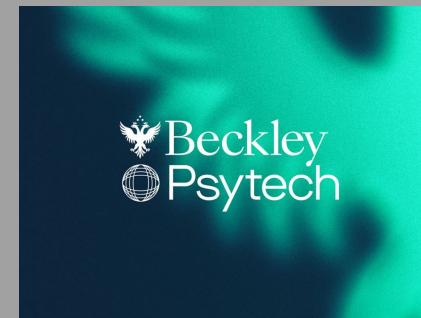
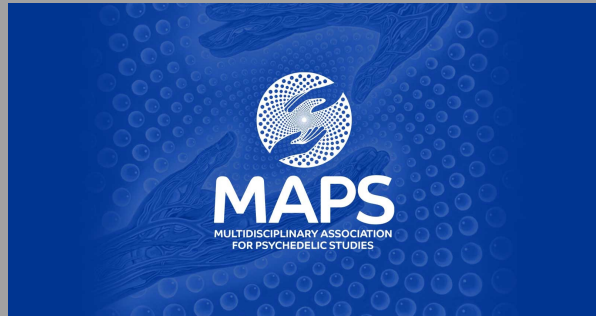


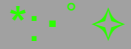
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PhD Student

# Disclosures

**NIHR** | National Institute  
for Health Research

 **Small Pharma**





# The Psychoactive Trials Group

- The vision of the Group is to undertake robust, high quality clinical trials and related research with psychoactive drugs, often combined with psychotherapy or psychological support. At the core of this vision are participants who volunteer to be part of the Group's trials.
- The wellbeing and safety of participants is the Group's first concern.
- The integrity and quality of the trial data is the Group's second concern.



# Outline



*In what contexts might categorisation of identity be useful?*

## PART ONE

- Provide an overview of representation in participant samples within clinical psychedelic research
- Outline the importance of representative study samples in research
- Explore barriers to recruiting appropriately representative samples
- Using The Psychoactive Trials Group as a case study, give examples of techniques used to improve the lack of representation in our clinical trials



# Outline



*In what contexts might identity categories be futile?*

## PART TWO

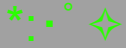
- The importance of moving beyond categories when they are no longer useful
- Introduce concepts of engaging with identities that are constantly changing
- Acknowledge there are no essential attributes that are consistent across categories
- Reflect on this in the context of matching participants with therapy pairs within psychedelic clinical trials



# Categories

## “Under-served groups”

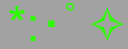
Demographic Factors	Social and Economic Factors	Health Status
<ul style="list-style-type: none"><li>• Gender</li><li>• Ethnicity</li><li>• Sexual orientation</li><li>• Age</li><li>• Education level</li></ul>	<ul style="list-style-type: none"><li>• Income/ employment</li><li>• Parental status</li><li>• Residential circumstance</li><li>• Disability status</li><li>• Carer status</li><li>• Digital literacy</li><li>• Language barriers</li><li>• Religion</li></ul>	<ul style="list-style-type: none"><li>• Disability status</li><li>• Mental health conditions</li><li>• Smokers</li><li>• Obesity</li><li>• Addictions</li></ul>



# Why is inclusion important?

- Failing to include a broad range of participants means that results may not be generalisable to a broad population
- Different groups may respond differently to an intervention due to differences in physiology or disease state. Only by studying the effects of an intervention in a range of groups can we be sure that the balance of risk and benefit is favourable for a given group
- Successful delivery of intervention to target populations is complex, with logistical, sociocultural, psychological and biological differences all having an impact. Unless we have tested if an intervention can be deployed effectively to different groups, we cannot be sure that it will work in practice.

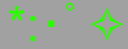




# Examples from cross cultural psychiatry

- Somatisation

- Differences among groups may reflect cultural styles of expressing distress ('idioms of distress') that are influenced not only by cultural beliefs and practices but also by familiarity with health care systems and pathways to care. (Kirmayer & Young, 1995)



# Critical Barriers

- *mistrust*: lack of understanding the value, fear, stigma of participating, and communication style of investigator/staff;
- *lack of comfort with the clinical trial process*: mistrust of process, fear, family members' opinions, and information;
- *lack of information about clinical trials*: fear and stigma of participating;
- *time and resource constraints associated with clinical trial participation*: financial burden, time commitment, transportation, and compensation and logistics;
- *lack of clinical trial awareness*: understanding the value and information (lack of awareness about the existence and importance of clinical trials)

Research article | [Open Access](#) | [Published: 31 July 2018](#)

# Inclusion of people of color in psychedelic-assisted psychotherapy: a review of the literature

[Timothy I. Michaels](#) , [Jennifer Purdon](#), [Alexis Collins](#) & [Monnica T. Williams](#)

[BMC Psychiatry](#) **18**, Article number: 245 (2018) | [Cite this article](#)

## Results

Of the 18 studies that met full criteria ( $n = 282$  participants), 82.3% of the participants were non-Hispanic White, 2.5% were African-American, 2.1% were of Latino origin, 1.8% were of Asian origin, 4.6% were of indigenous origin, 4.6% were of mixed race, 1.8% identified their race as “other,” and the ethnicity of 8.2% of participants was unknown. There were no significant differences in recruitment methodologies between those studies that had higher ( $> 20\%$ ) rates of inclusion.

## MAPS Phase 2 mdma/ptsd studies: 105 participants

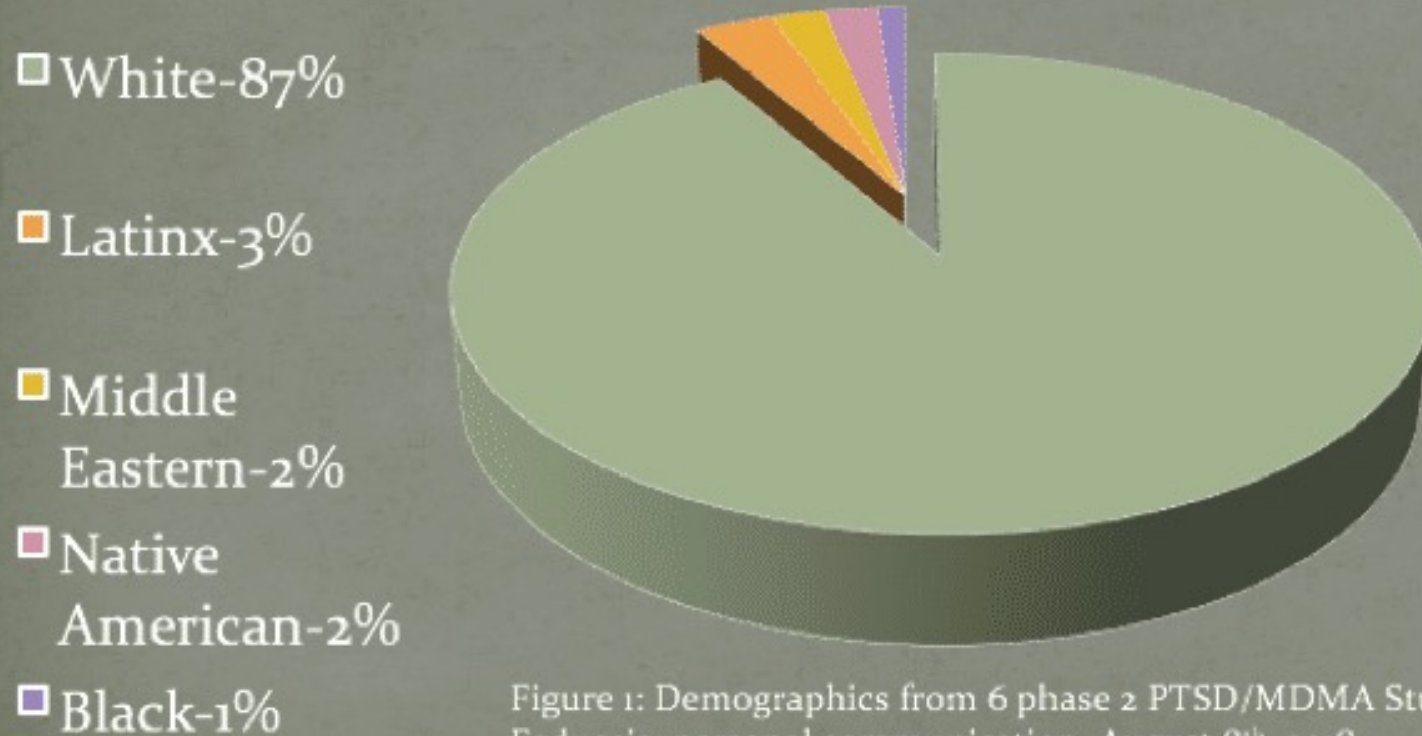


Figure 1: Demographics from 6 phase 2 PTSD/MDMA Studies. Adapted from: A. Feduccia, personal communication, August 8<sup>th</sup>, 2018

SOURCE: Herzberg, G. , & Butler, J. (2019, March 13). Blinded by the White: Addressing power and privilege in psychedelic medicine. *Chacruna*. Retrieved from <https://chacruna.net/blinded-by-the-white-addressing-power-and-privilege-in-psychedelic-medicine>



## The Effects of Psilocybin on Cognitive and Emotional Function in Healthy Participants

- Phase I
- 89 participants
- Randomised (1:1:1) to receive 0mg, 10mg or 25mg of psilocybin
- 92% White



## The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (TRD)

- Phase II, multisite study
- 215 participants overall , 24 at KCL
- 92% White / 89% at KCL

# **Culturally informed research design issues in a study for MDMA-assisted psychotherapy for posttraumatic stress disorder**

MONNICA T. WILLIAMS<sup>1,2\*</sup>, SARA REED<sup>1</sup> and RITIKA AGGARWAL<sup>3</sup>

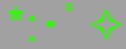
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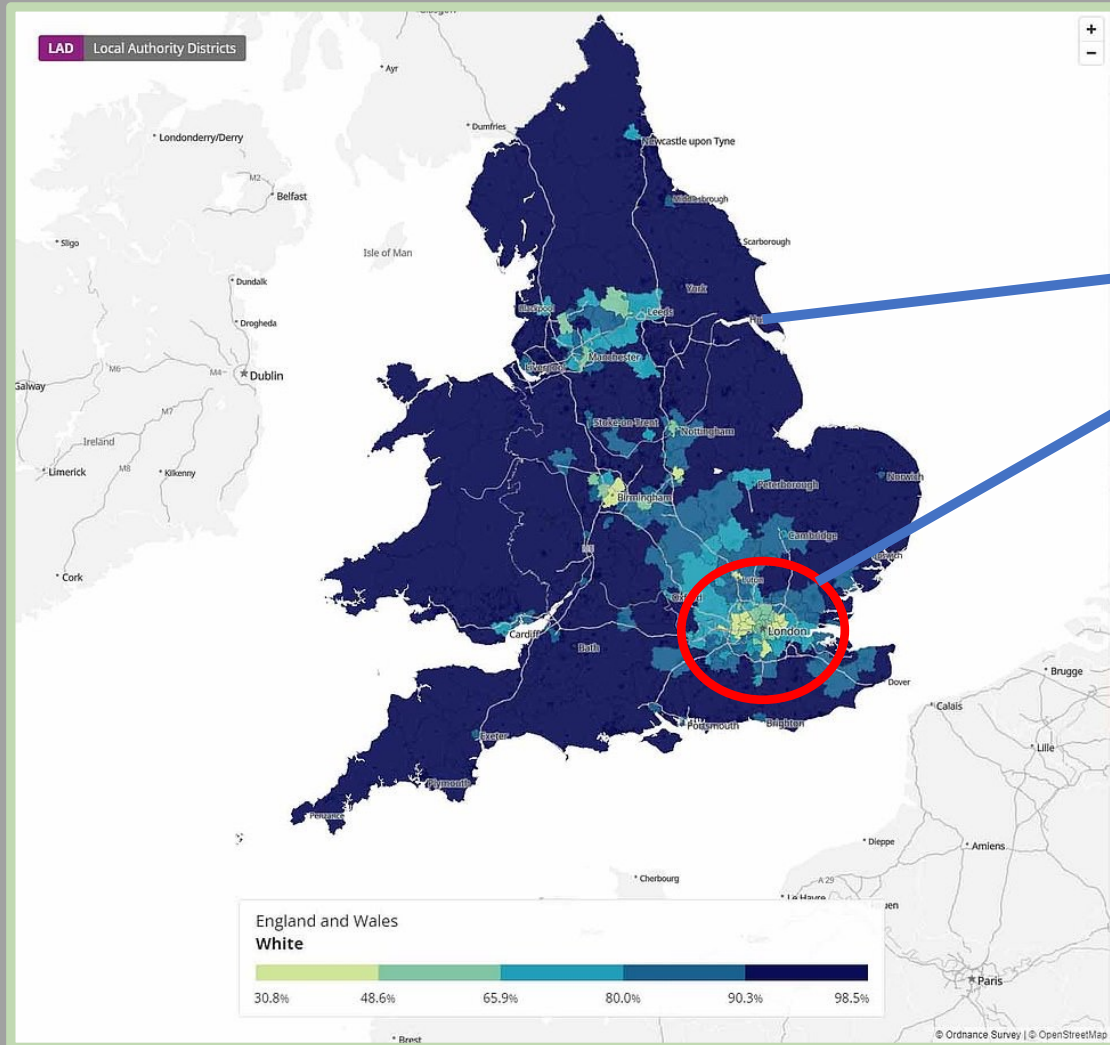
<sup>3</sup>MAPS Public Benefit Corporation, Santa Cruz, CA, USA

(Received: May 1, 2019; accepted: June 13, 2019)

- Diversifying research teams
- Training to encourage cultural competency
- Inclusive design of inclusion/exclusion criteria
- Informed sensitivity throughout screening and consent processes



# Representative Targets



Using data from CENSUS and The Office for National Statistics....

Average of London and National (whole UK) proportions

	London (%)	UK (%)	Recruitment Target (%)
<b>White (ALL)</b>	<b>59.8</b>	<b>86</b>	<b>72.9</b>



	London (%)	UK (%)	Recruitment Target (%)
<b>White</b>	<b>59.8</b>	<b>86</b>	<b>72.9</b>
English, Welsh, Scottish, Northern Irish or British	44.89	81	62.695
Any other white background	15	4.5	8.625
<b>Mixed or multiple ethnic groups</b>	<b>5</b>	<b>2.2</b>	<b>3.6</b>
White and Black Caribbean	1.46	0.8	1.13
White and Black African	0.8	0.3	0.55
White and Asian	1.24	0.6	0.92
Any other mixed of Multiple ethnic backgrounds	1.45	0.5	0.975
<b>Asian or Asian British</b>	<b>18.5</b>	<b>7.5</b>	<b>13</b>
Indian	6.64	2.5	4.57
Pakistani	2.74	2	2.37
Bangladeshi	2.72	0.8	1.76
Chinese	1.52	0.7	1.11
Any other Asian background	4.88	1.5	3.19
<b>Black, African, Caribbean or Black British</b>	<b>13.3</b>	<b>3.3</b>	<b>8.3</b>
African	7.02	1.8	4.41
Caribbean	4.22	1.1	2.66
Any other Black, African or Caribbean background	2.08	0.5	1.29
<b>Other ethnic group</b>	<b>3.4</b>	<b>1</b>	<b>2.2</b>
Arab	1.3	0.4	0.85
Any other ethnic group	2.14	0.6	1.37

# Ongoing Trials

- Psilocybin in Depression Resistant to Standard Treatments (PsiDeR) Study ✨ ✨ ✨

“PsiDeR” (pronounced like “cider”)

- Phase 2
- Single centre
- Placebo controlled (25mg vs. 0mg psilocybin)
- Open-label extension (25mg psilocybin)
- Target sample: 60 participants
- Funder: NIHR



PsiDeR

**NIHR** | National Institute  
for Health Research

	Recruitment Target (%)	Recruitment Target (n=60)	Current Recruitment (n=28)
<b>White</b>	<b>72.9</b>	<b>44</b>	<b>18</b>
English, Welsh, Scottish, Northern Irish or British	62.695	38	13
Any other white background	8.625	5	5
<b>Mixed or multiple ethnic groups</b>	<b>3.6</b>	<b>2</b>	<b>4</b>
White and Black Caribbean	1.13	1	2
White and Black African	0.55	1	1
White and Asian	0.92	1	0
Any other mixed of Multiple ethnic backgrounds	0.975	1	1
<b>Asian or Asian British</b>	<b>13</b>	<b>8</b>	<b>2</b>
Indian	4.57	3	2
Pakistani	2.37	1	0
Bangladeshi	1.76	1	0
Chinese	1.11	1	0
Any other Asian background	3.19	2	0
<b>Black, African, Caribbean or Black British</b>	<b>8.3</b>	<b>5</b>	<b>1</b>
African	4.41	3	1
Caribbean	2.66	2	0
Any other Black, African or Caribbean background	1.29	1	0
<b>Other ethnic group</b>	<b>2.2</b>	<b>1</b>	<b>0</b>
Arab	0.85	1	0
Any other ethnic group	1.37	1	0



Ps i DeR

# How will your inclusion/exclusion criteria enable your trial population to match the population that you aim to serve?

## The Safety and Efficacy of Psilocybin in Participants with Treatment Resistant Depression (P-TRD)

Phase II, multisite study

215 participants overall , 24 at KCL

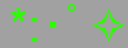
92% White / 89% at KCL



P-TRD	PsiDeR
Failure to respond to an adequate dose and duration or 2,3, or 4 pharmacological treatments for the current episode	Have failed to respond to 2 or more antidepressants prescribed at the minimum effective dose for at least 6 weeks OR at least 1 antidepressant prescribed at the minimum effective dose for at least 6 weeks AND a course of evidence-based psychotherapy given for at least 6 sessions.
HAM-D score of $\geq 18$	HAM-D score of $\geq 14$

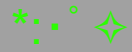
How will your inclusion/exclusion criteria enable your trial population to match the population that you aim to serve? - Ongoing Trials ✨💡

- Psilocybin assisted treatment for Post Traumatic Stress Disorder
  - Diagnosis not required from external healthcare provider → Increased accessibility
- MDMA assisted psychotherapy for Post Traumatic Stress Disorder
  - Inclusion of those with childhood trauma permitted (if other criteria met/risks low)
  - C-PTSD not an exclusion → increased clinical judgement/flexibility



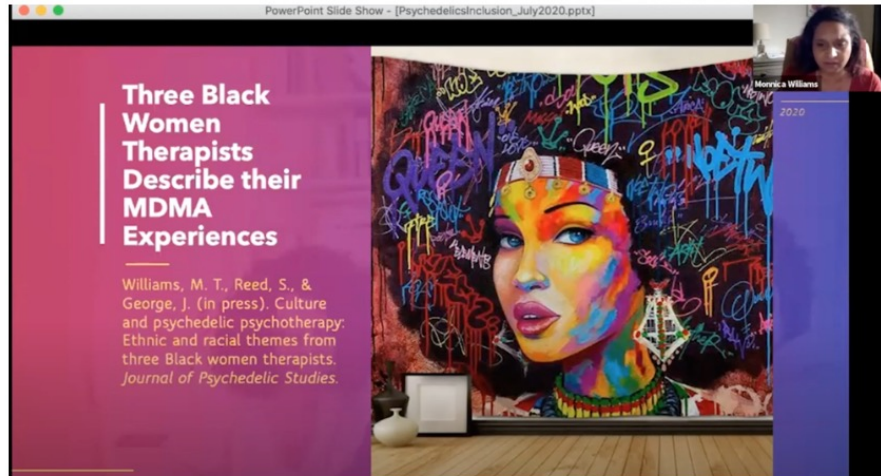
# Supervision & Training

- Group supervision every 6 weeks
- Support provided by a Systemic Psychotherapist with a *“passion for anti-oppressive and anti-stigmatizing practices”*
- Provide discussion space to discuss group’s vision
- Space to work through conflicting opinions and perspectives



Case study:  
when things get uncomfortable





Underrepresented: Diversity in  
Psychedelic Research



Underrepresented II: Diversity in  
Psychedelic Research



# DOUBLE BOOK-KEEPING

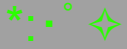
## MATERIAL

- Rooted in societal structures
- Sensitive to what one might experience as part of a particular group
- Not something one can “put down”
- Often in relation to the ‘other’



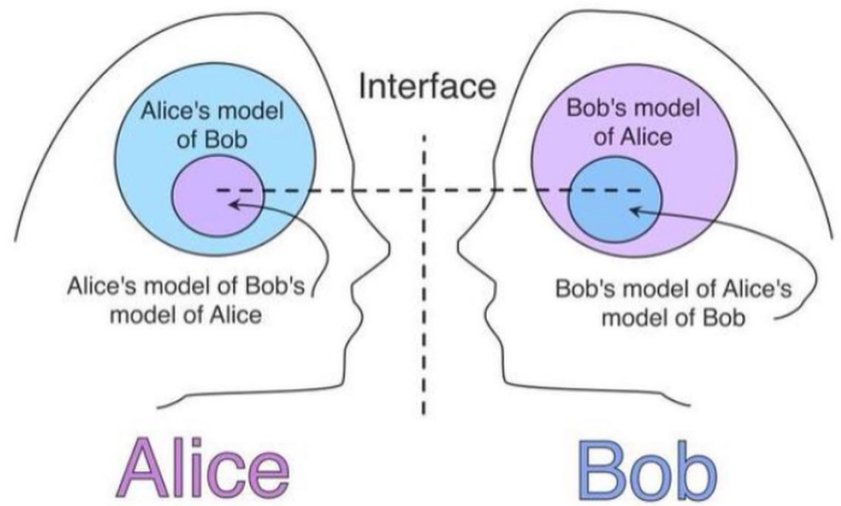
## EXPERIENTIAL

- Relational aspects of our identity
- No essential/fixed quality of *being* that is consistent across a group
- Requires flexible and dynamic attitudes- willing to update
- Agency as a relationship & not something one “has”



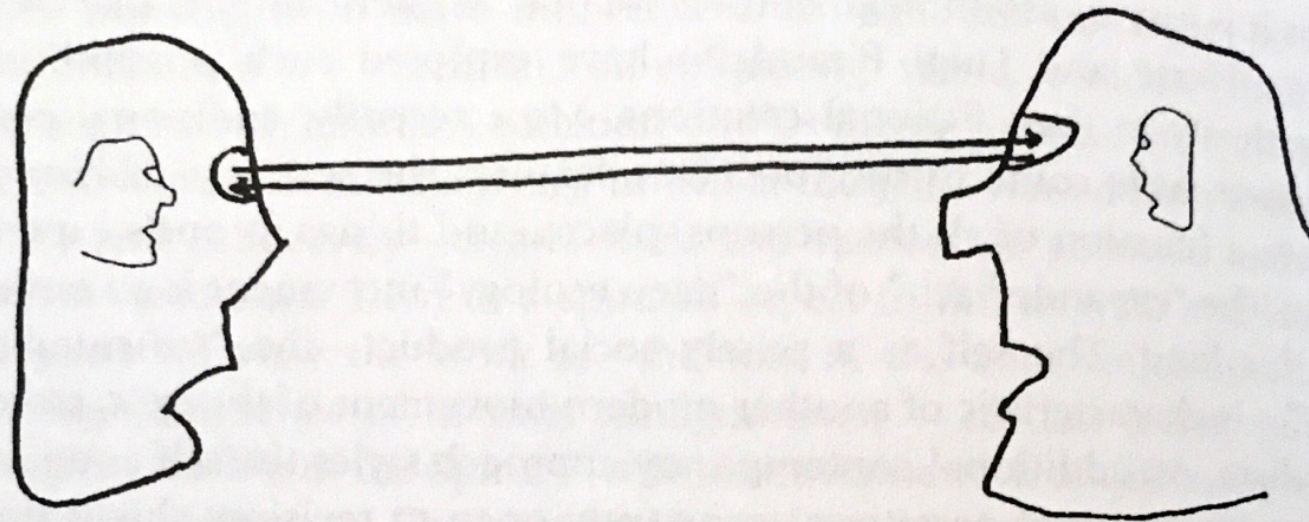
# Patient-centered care

- Previous experiences of psychotherapy?
  - Modalities?
  - Preference for demographics?
  - ~~Ethnomatching!~~
- Previous psychedelic experience?
  - If yes, how did they go? What substances?
  - If no, how do they view psychedelics?
- Parental status/ childhood trauma
- Co-morbidities (e.g. ADHD, anxiety symptoms, past addiction)
- Support networks/ relationships
- Responsibilities/ Work/ Free time



Alice

Bob



**Self-recognition through the Other.**

Thank you! ☆══════ ☆☆☆ ══════☆

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@catbirdmeow

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