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Amplifying PTSD Treatments with MDMA

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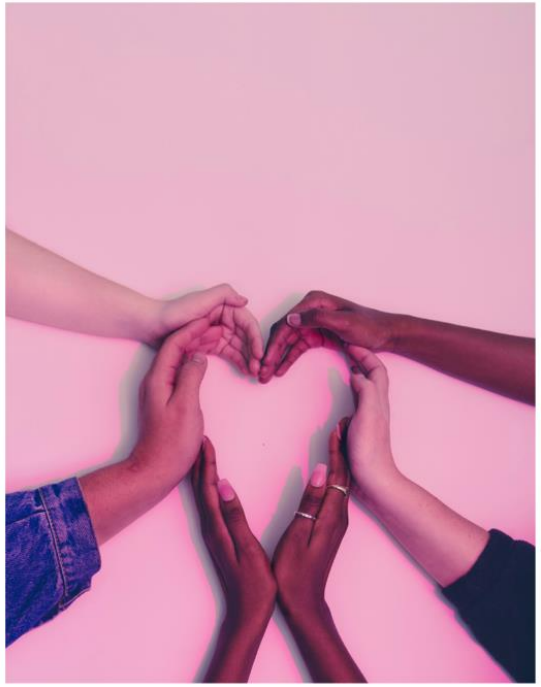

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Disclosures

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I have the following relevant financial relationship with a commercial interest to disclose:

I am the Founder of Remedy, a psychotherapy clinic.

I am a trainer, supervisor and consultant for Lykos Therapeutics.

I have received research funding from MAPS.

I have been a consultant for the California Institute for Integral Studies, San Diego VA, Emory University, Portland Psychotherapy Centre.

Why MDMA for PTSD?

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- Was used as an adjunct to psychotherapy until 1985
  - Predominantly for relationship distress, PTSD, anxiety
- Early use in couples therapy

(e.g., Shulgin & Shulgin, 2005; Greer & Tolbert, 1986, 1998)

- Why combine existing, stand-alone treatments with MDMA?

Cognitive Processing Therapy

(Resick, Monson, & Chard, 2017)

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- CPT - Individual treatment for PTSD
- Focuses on meaning-making and the experience of natural emotions associated with trauma
- Differentiates natural emotions from secondary emotions, which are amplified by ”stuck” beliefs
- These beliefs are central to why the emotional response is maintained
  - The more frequent or stronger the belief, the stronger the emotion
  - E.g., Stuck belief - “No one will protect me” – panic, fear
  - Shifted belief, Natural emotion – sadness, grief

Cognitive Processing Therapy

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- CPT welcomes the somatic experience
- Provides structure for approaching extremely distressing emotional content
- And yet, works quickly
- 12 sessions of content
- Begins with Trauma Impact Statement – beliefs of why and how the trauma occurred and impacts the person
- Tools to work with emotions and thoughts

Cognitive Processing Therapy

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- Five major themes of beliefs introduced as catalysts for processing
  - Safety
  - Power/Control
  - Trust
  - Intimacy
  - Esteem
- Using tools to work with beliefs, completes with a new Trauma Impact Statement

Mechanisms specific to healing trauma

- Non-avoidance – emotional, behavioural and experiential
- Meaning-making – cognitive flexibility
- Safe and trusted relationship – longitudinal studies
  - Less negative social support, less PTSD
  - Over time, PTSD can erode social support

Why combine CPT with MDMA?

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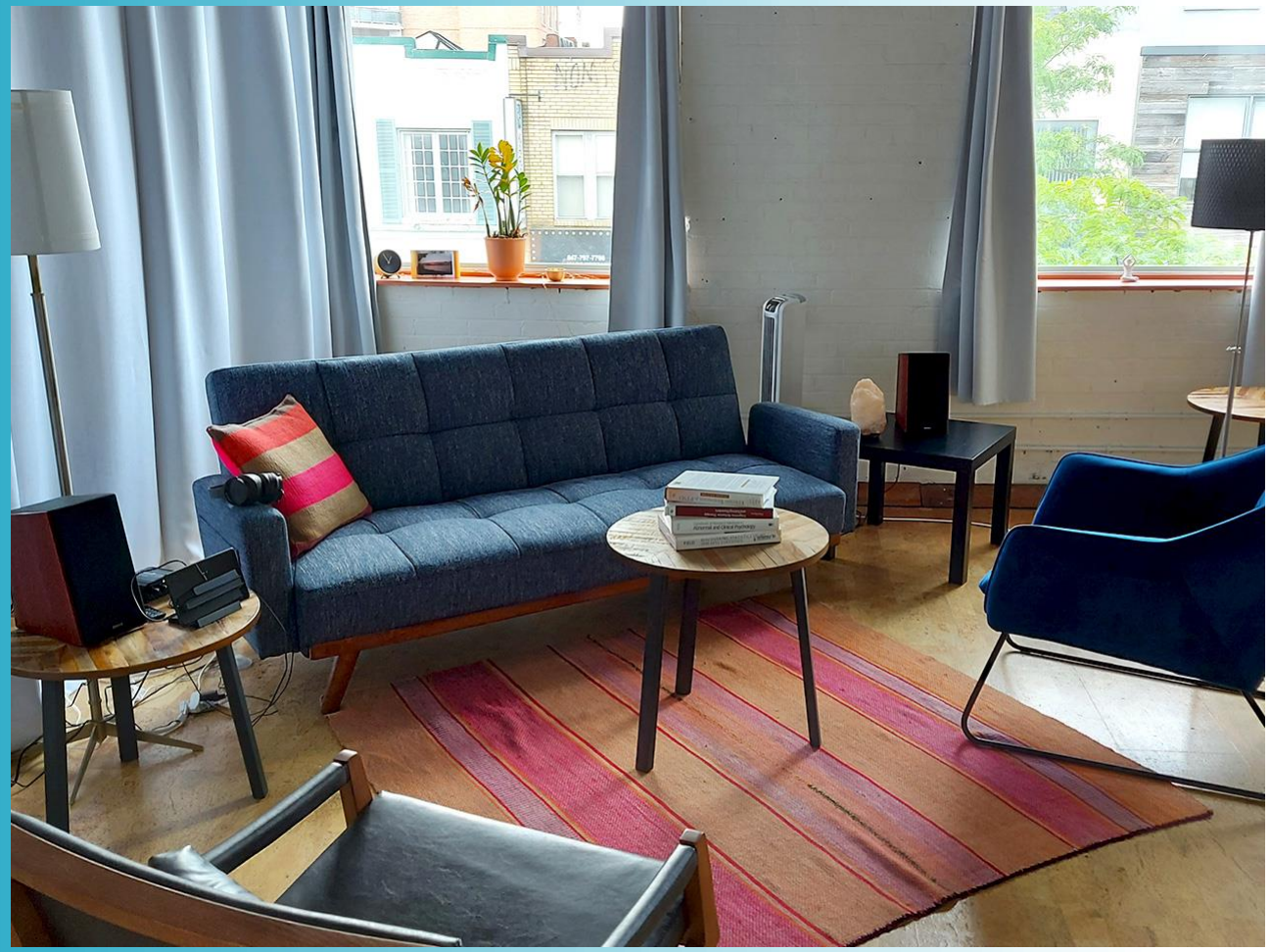
- CPT is a widely disseminated treatment in North America, and in some locations in Europe
- It has been tested and adapted across different cultures and contexts, including variations with no written assignments, conducted by peers, and with variable length (+/- sessions depending on response) (Bass et al., 2022; Galovski et al., 2016; Resick et al., 2021)
- It has been identified as one of the PTSD treatments with the best evidence across multiple treatment guidelines (e.g., APA, ISTSS)
- In trials, up to 60% of folks who receive the treatment no longer meet criteria for PTSD at follow-up (e.g., Schnurr et al., 2022)

Why combine CPT with MDMA?

- Not everyone benefits, however
- Therefore worth exploring amplifiers of treatment
- If works, could be an easily disseminable combination intervention given the large number of providers who are already trained in CPT

CPT + MDMA Approach

- Create a safe and predictable framework
  - Safety being key for individuals with PTSD – helps the individual then be able to assert effective control
- Skills and tools
- Allow for whatever experience comes up in the MDMA sessions
- Integrate through the use of the skills and tools after
- Creating a scaffold to tether experience to



What does an MDMA session look like?

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- Maximizing time spent “inside”
  - Eyeshades and headphones
- Allowing for whatever cognitive, emotional and somatic material arises
- Supporting non-avoidance of embodied and experiential learning

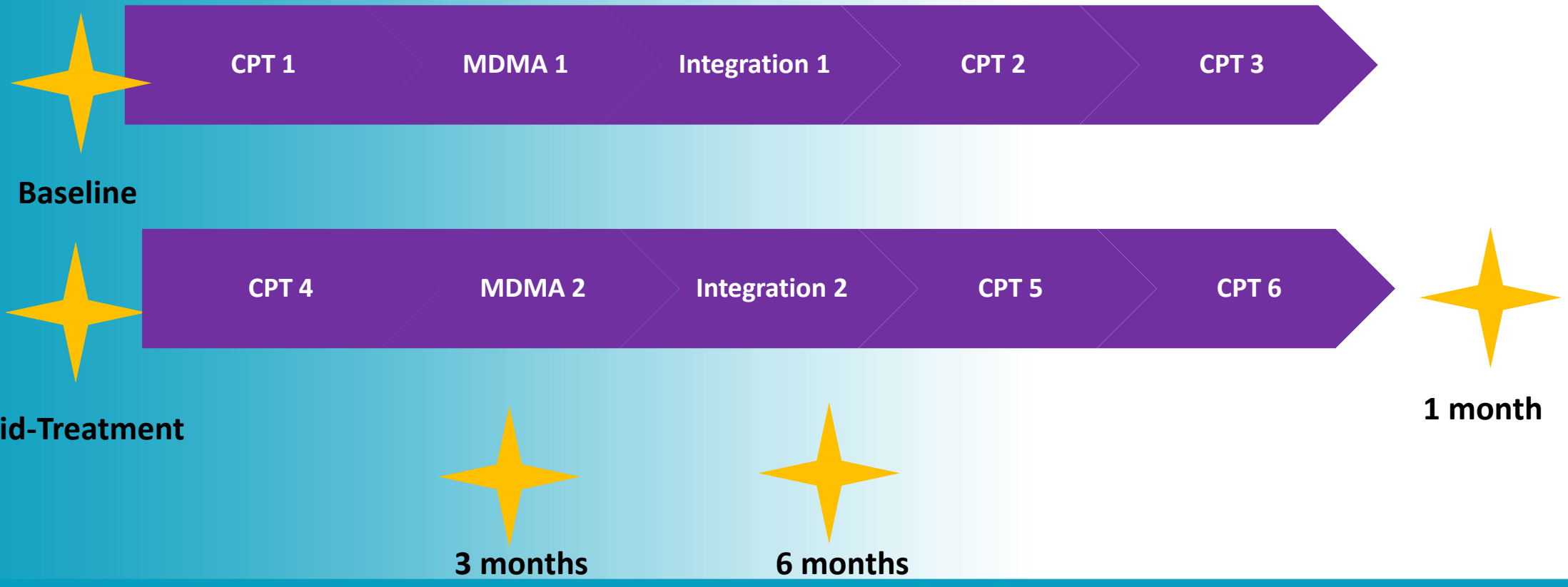
Study Design - Sample

- 10 individuals – community sample in downtown Toronto
- Any individual with PTSD diagnosis – range from just meeting criteria to very severe, no exclusion for personality features
- Could have substance use disorders, but with ability to abstain for the active portion of treatment (e.g., no physiological withdrawal)
- Diverse sample – gender diversity, 60% BIPOC

Study Design

- Entire treatment complete in seven weeks
- 2 MDMA sessions
  - 80mg + 40mg first session
  - 120mg + 40mg second session
- Condensed CPT delivery schedule – 12 sessions of content over 6 sessions
- Primary and secondary therapist model
  - Primary therapist in all sessions
  - Secondary therapist in initial meet and greet, MDMA sessions, and next day integration sessions

Protocol Flow



Preliminary Results – Self-Reported PTSD Outcomes

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Outcome Measure	Pre-Treatment Mean (SD)	Post-Treatment Mean (SD)	Test Statistic	N	Hedge's *g* Pre to Post
CPT+MDMA					
PCL	51.50 (11.02)	32.00 (15.80)	$t(9) = 3.23$, $p = 0.01$	10/10	**0.94**

Forthcoming Results

- CAPS-5
- Secondary measures – depression, social support, posttraumatic growth, posttraumatic cognitions
- Perceptions of the treatment and experience
- Long-term outcomes

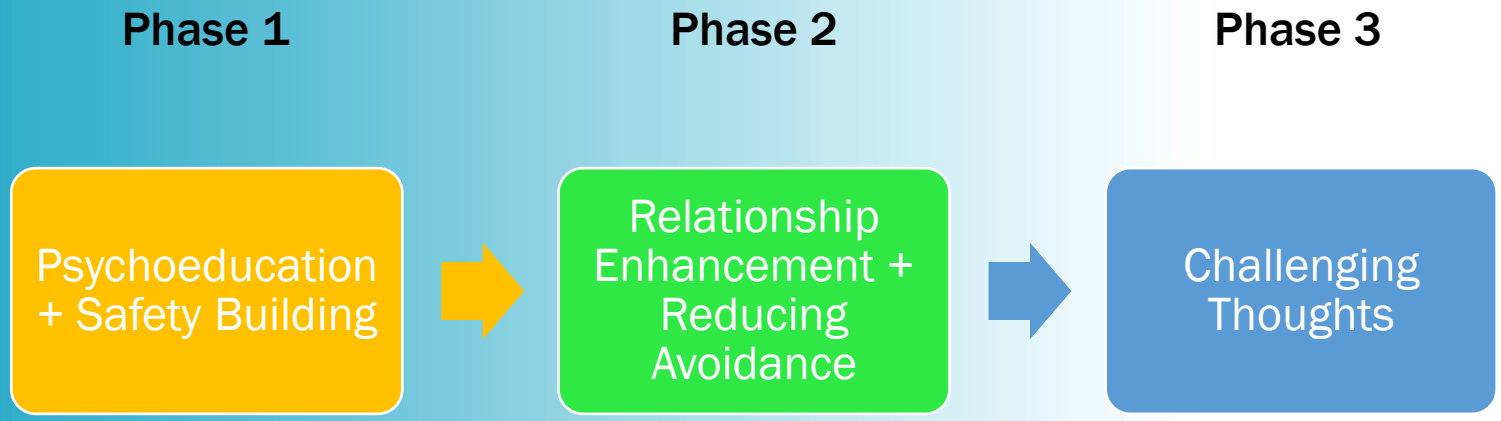
Discussion

- Thus far, can see was feasible and acceptable
- Pushed the bounds with condensed dosing, reduced therapist time (with primary/secondary model), two MDMA sessions
- No SAEs
- Anecdotally, participants expressing satisfaction and gratitude, desire to continue their own independent healing journeys
- Spontaneous reports of appreciating the structure
- We will see what the final results yield, but signs point to being another potentially efficacious approach to working with MDMA with individuals with PTSD

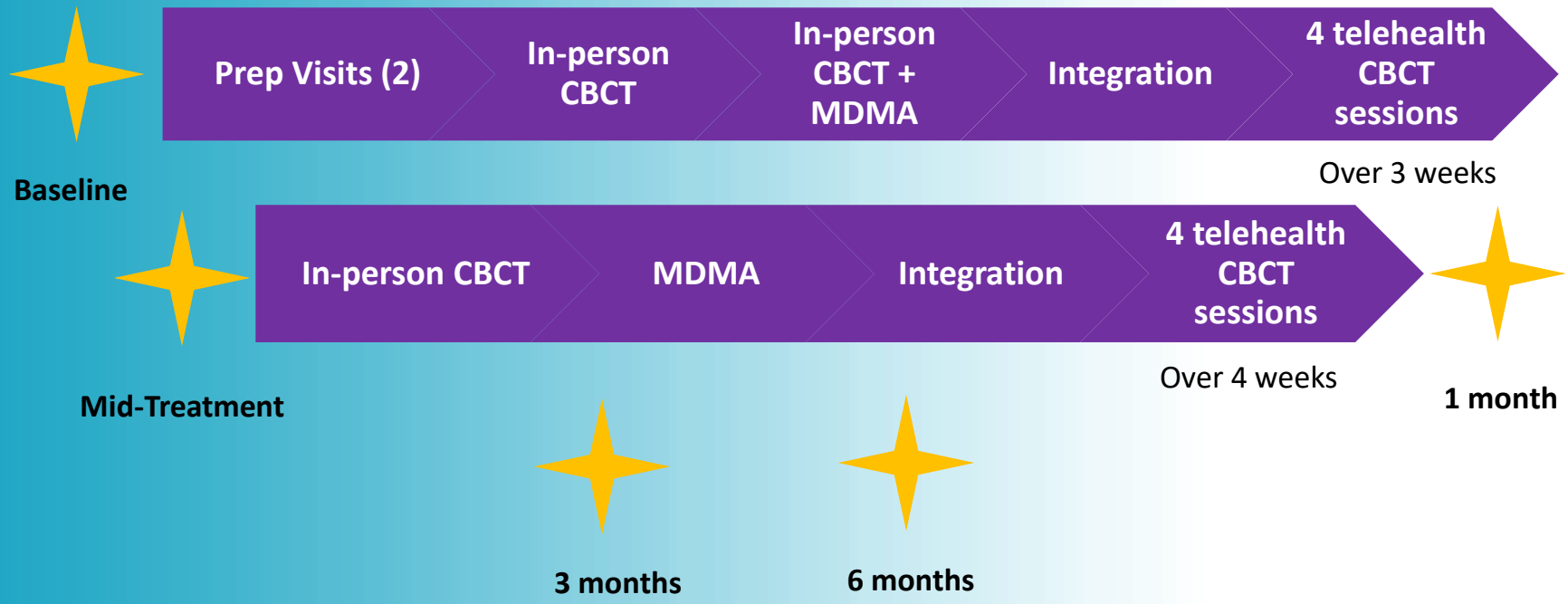
Benefit of adding to previously tested treatment - CBCT

- Cognitive Behavioral Conjoint Therapy for Posttraumatic Stress Disorder (CBCT for PTSD) (Monson & Fredman, 2012)
- CBCT for PTSD has shown:
  - decreases in PTSD symptoms
  - increases in relationship satisfaction
  - improved partner functioning in numerous trials (e.g., Monson et al., 2012; Schumm et al., 2013)

CBCT for PTSD



Protocol Flow



Therapy Room

Results – PTSD Outcomes

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Outcome Measures	Pre-Treatment Mean (SD)	Post-Treatment Mean (SD)	6-month Follow-up	N	Hedge's *g* Pre- to 6-months
MDMA+CBCT					
CAPS-5	42.00 (5.76)	16.33 (13.71)	16.17 (15.22)	6/6	**2.24**
PCL-Patient	61.50 (6.35)	20.17 (19.08)	20.00 (16.76)	6/6	**3.28**
PCL-Partner	52.00 (8.52)	18.00 (19.67)	13.50 (14.84)	6/6	**3.00**

Results – Relationship Satisfaction

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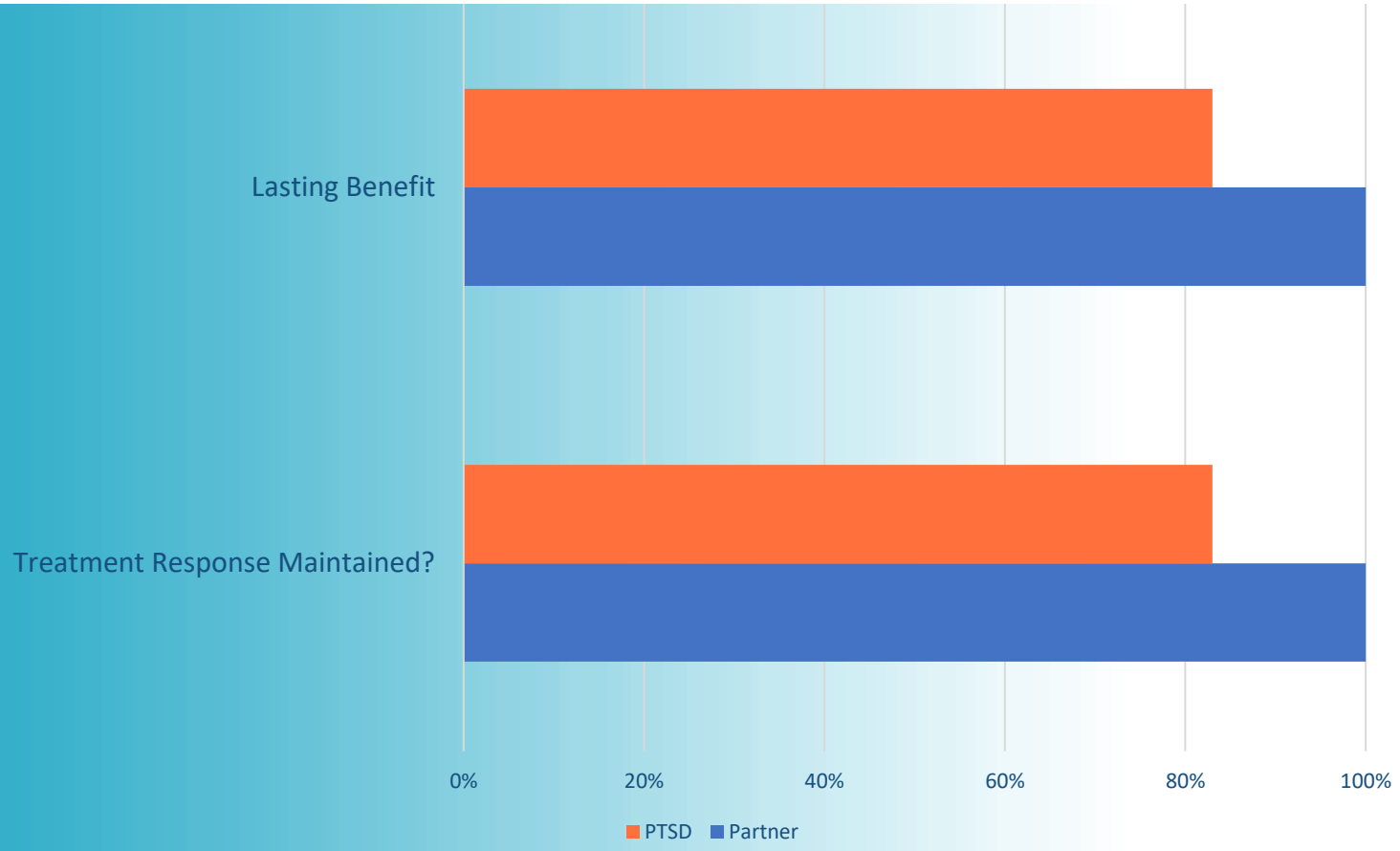
Outcome Measures	Pre-Treatment Mean (SD)	Post-Treatment Mean (SD)	6-month Follow-up	N	Hedge's *g* Pre- to 6-months
MDMA+CBCT					
CSI item - Patient	2.33 (0.58)	3.83 (1.47)	3.83 (0.75)	6	**2.13**
CSI item - Partner	2.67 (1.53)	3.83 (1.33)	4.33 (0.82)	6	**1.55**

CSI item – "On the scale below, please circle the number that best indicates the degree of happiness, all things considered, of your relationship in the past week."

Range: 0 (Extremely Unhappy) to 6 (Perfect), 3 = Happy

Perceived Long-Term Treatment Benefits (6-Month Follow-Up)



Perceived Treatment Benefits

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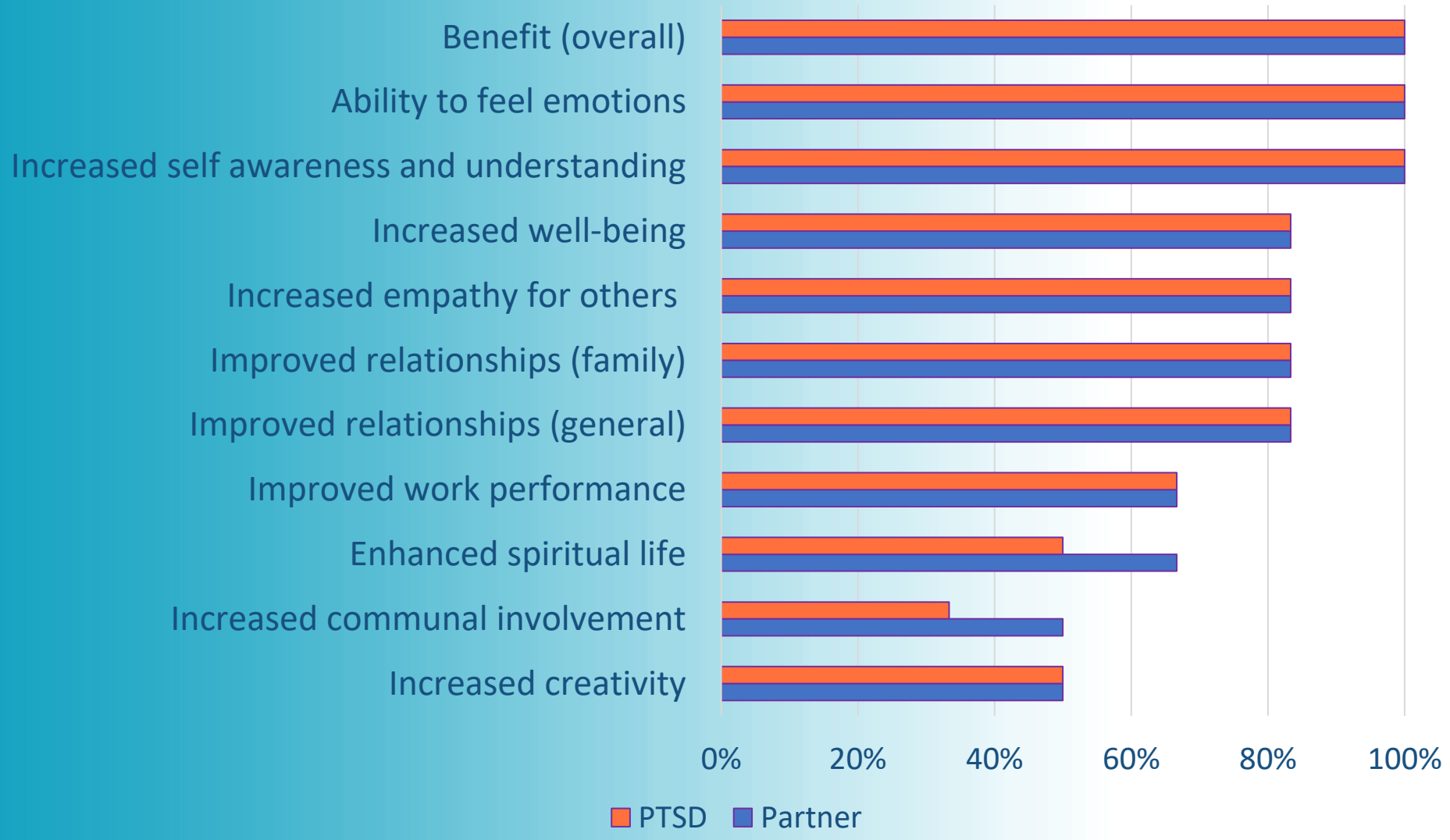
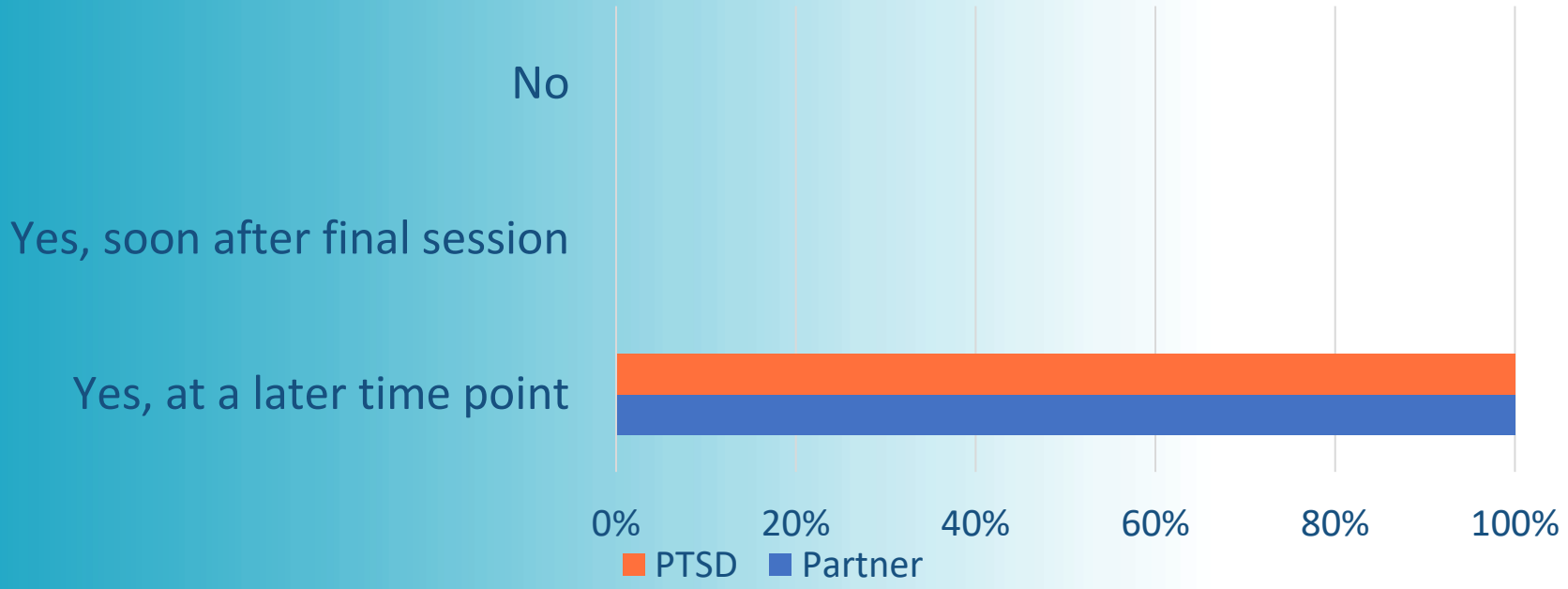
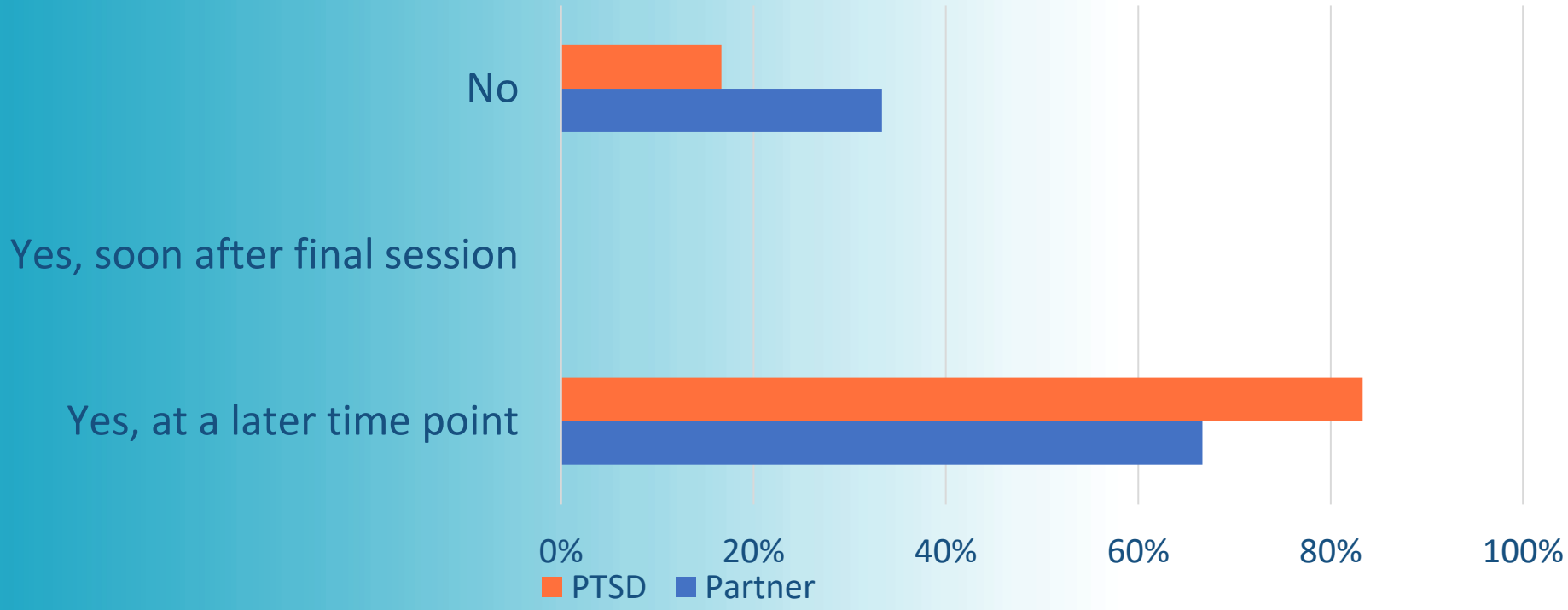


Interest in Additional Couples MDMA Therapy



Interest in Additional Individual MDMA Therapy Sessions?



Additional outcomes - Patient

- Improved/Increased:
  - Posttraumatic Growth
  - Dimensions of Relationship Quality: Support and Intimacy
  - Psychosocial functioning
  - Empathic concern

Additional outcomes - Partner

- Improved/Increased:
  - Posttraumatic Growth
  - Dimensions of Relationship Quality: Support, Conflict and Intimacy
- Decreased:
  - Behavioural accommodation

Current Couples Therapy Trial

- Large couples therapy for PTSD + MDMA trial – N = 30 dyads
- Currently enrolling
- CBCT vs CBCT + MDMA
- Crossover – can receive MDMA sessions

Thank you!

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Our participants

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