PSIMA - PRELIMINARY RESULTS

PSILOCYBIN ASSISTED PSYCHOTHERAPY FOR METHAMPHETAMINE USE DISORDER: A PILOT STUDY

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EK was supported to complete this work by an NCCRED Clinical Research Scholarship

Early phase 1 and 2 trials of PAT for depression, Alcohol and Tobacco use

No effective pharmacotherapy and only mildly effective psychosocial treatments available for Methamphetamine use disorder

Strong rationale that the transdiagnostic benefits, potential role of increased psychological flexibility, 'pro social effects' and increased sense of 'connection' may be of benefit in treating MAUD

Brett, J., Knock, E., Todd Korthuis, P., Liknaitzky, P., Murnane, K., Nicholas, C R., Patterson, J., Stauffer, C. (2023). Exploring psilocybin-assisted psychotherapy in the treatment of methamphetamine use disorder. *Front Psychiatry 14: 1123424* https://doi.org/10.3389/fpsyt.2023.1123424

TGA rescheduling of psilocybin for Treatment resistant depression & MDMA for PTSD in Aus

FDA did NOT approve MDMA for PTSD citing a number of issues including trial design, unclear role of psychotherapy & ethical concerns

METHOD

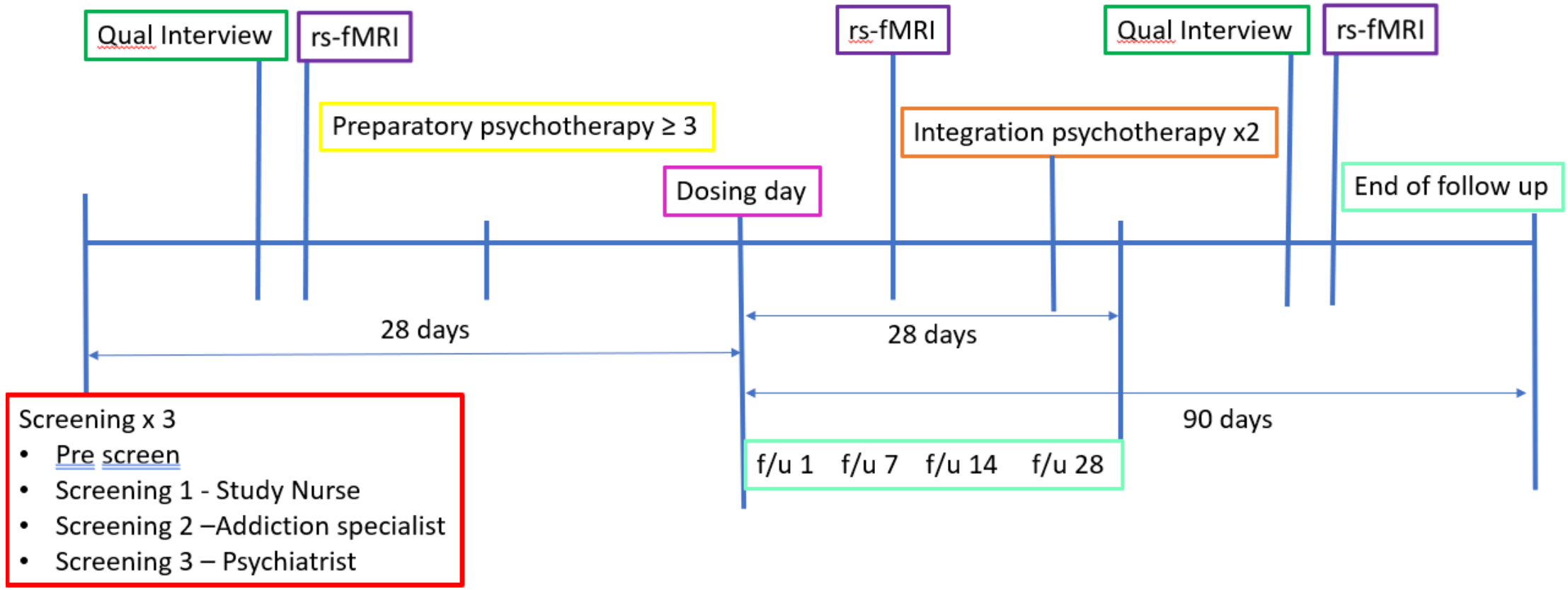
- Open label, single arm design
- 15 Participants
- Primary Objectives
  - Safety and Feasibility of PAT delivered in an outpatient setting to adults with MA use disorder
- Secondary Objectives
  - MA use via TLFB
  - Craving –Visual Analogue Craving Scale
  - Depression Anxiety & Stress - DASS21
  - Wellbeing –Warwick Edinburgh Mental Wellbeing Scale

Inclusion Criteria

- Over 25 years old
- Meet criteria for MAUD (positive UDS at screening)
- < 16 days use per month→ Criteria removed (no max days use/month) after 5 participants
- Safe home environment and Support person available for evening post dose administration.

Exclusion Criteria

- Personal or 1st/2nd degree relative with psychosis bipolar or schizophrenia


Qual Interview
rs-fMRI
Preparatory psychotherapy ≥ 3
Dosing day
rs-fMRI
Integration psychotherapy x2
Qual Interview
rs-fMRI
End of follow up
28 days
28 days
90 days
f/u 1 f/u 7 f/u 14 f/u 28
Screening x 3
• Pre screen
• Screening 1 - Study Nurse
• Screening 2 –Addiction specialist
• Screening 3 – Psychiatrist

Age (Years): Median (range)	42 (32-61)
Gender	
Male (n(%))	12(80)
Female	3(20)
Sexual orientation	
Gay or Lesbian	6(40)
Heterosexual	6(40)
Other	3(20)
Education level	
University undergraduate degree	5(33)
University postgraduate degree	6(40)
Technical/trade/vocational certificate or diploma	4(27)
Employment Status	
Full time paid	9(60)
Part time paid	2(13)
Unemployed	4(27)
Housing	
Own home	7(47)
Rental (Public or private)	8(53)

Methamphetamine Use	
Age at first use (median (IQR)) (years)	32 (38-28.5)
Days use of previous 28 (median, IQR)	12 (7-16)
Primary route of administration	
Smoke	10 (67)
Inject	2 (13)
Both	3 (20)
Psychiatric history	
Concomitant psychiatric medication	7(47)
Previous diagnosis of ADHD	4(40)
Previous diagnosis of Depression	4(40)
Previous diagnosis of Anxiety	4(40)
Previous diagnosis of PTSD or complex trauma	3(20)
Stanford Expectations of Treatment Scale (SETS)	
Positive expectancy (Max=6) (Mean, SD)	5 (1.13)
Negative expectancy (Max=6) (Mean, SD)	3 (1.21)

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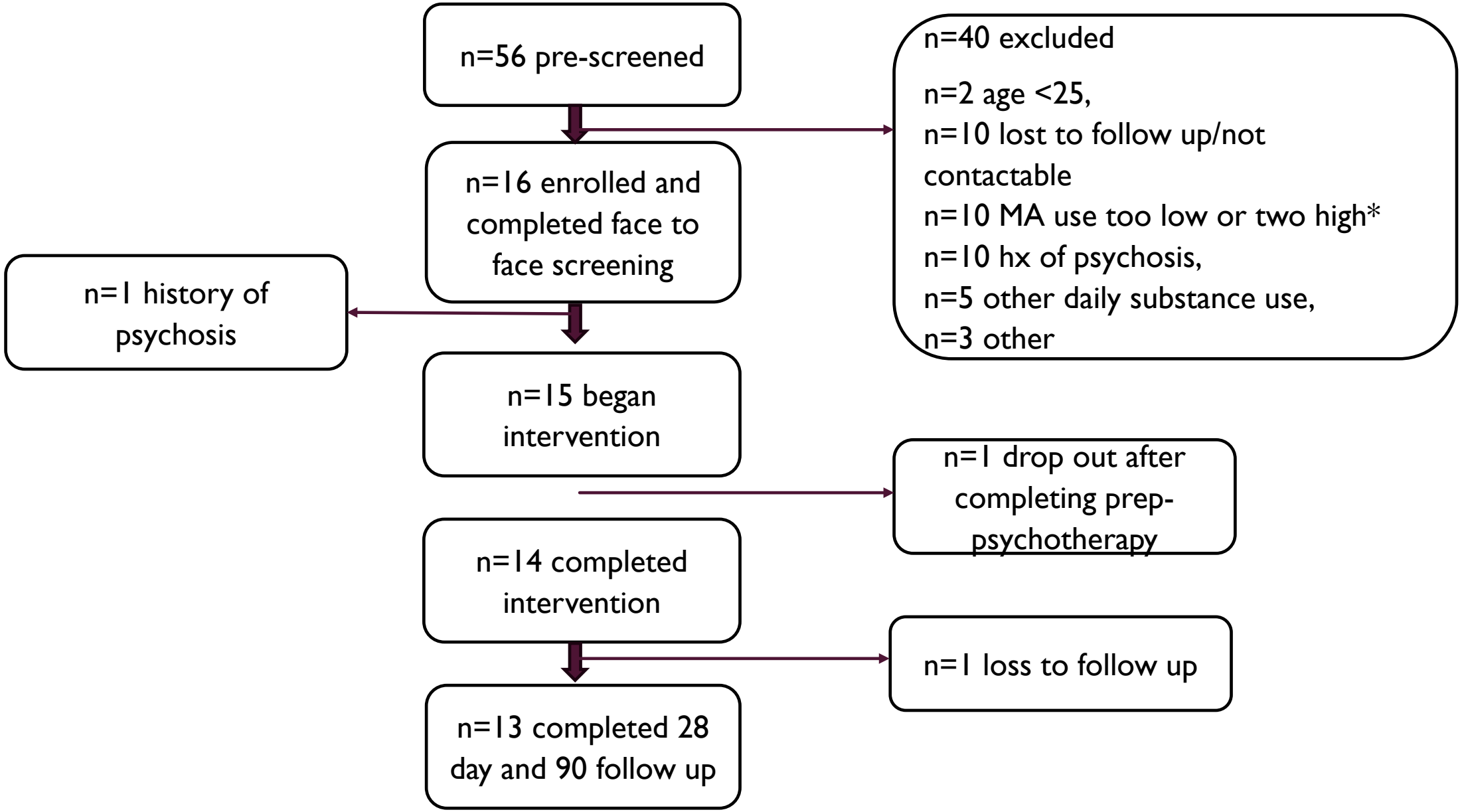
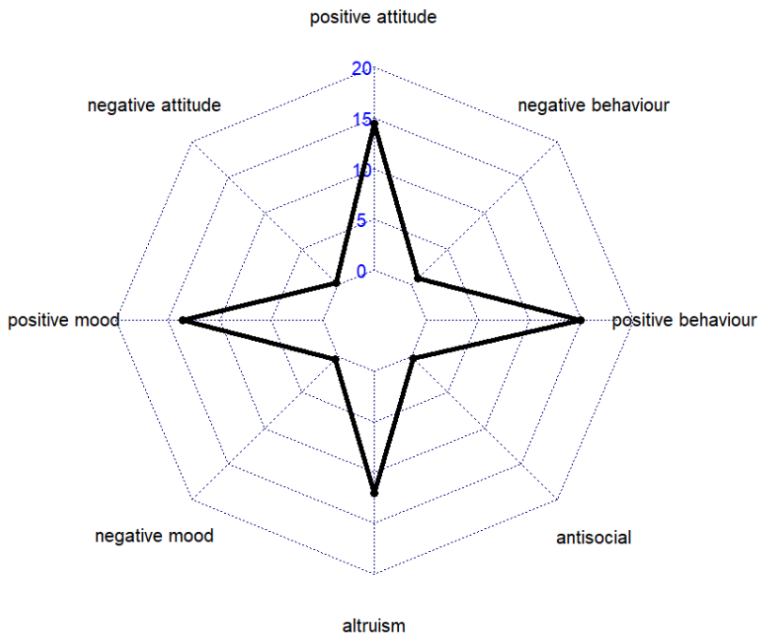

n=56 pre-screened
n=40 excluded
n=2 age <25,
n=10 lost to follow up/not contactable
n=10 MA use too low or two high*
n=10 hx of psychosis,
n=5 other daily substance use,
n=3 other
n=16 enrolled and completed face to face screening
n=1 history of psychosis
n=15 began intervention
n=1 drop out after completing prep-psychotherapy
n=14 completed intervention
n=1 loss to follow up
n=13 completed 28 day and 90 follow up

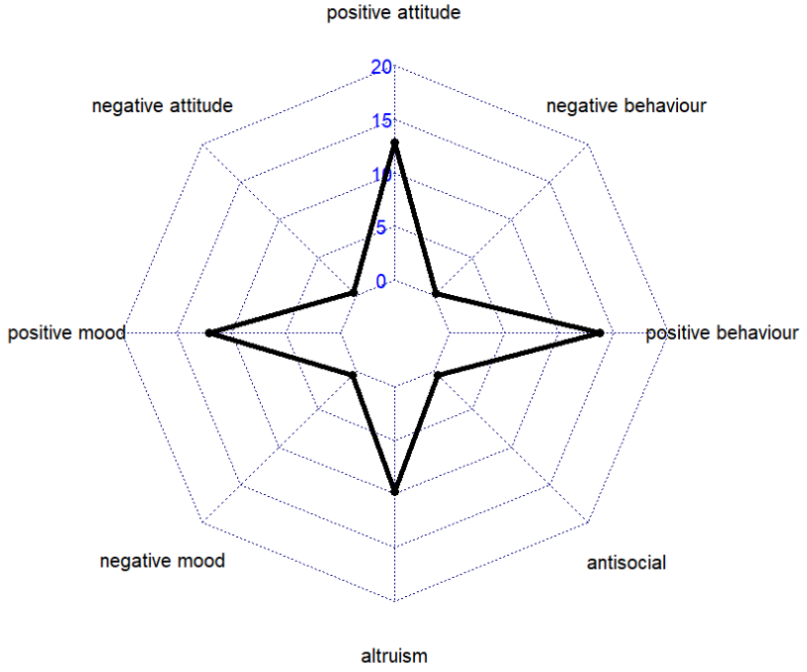
SAFETY

- No serious adverse events
- 18 adverse events not related to the study drug, all of which resolved
- 7 adverse events possibly or probably related to the study drug.
  - 1 x GI –Nausea
  - 5 x Nervous system –Headache, Noise sensitivity
  - 1 x Hypertension
- Blood pressure monitoring at hourly intervals
- Risk of psychosis: No evidence of change in presentation that may indicate risk of emerging psychosis

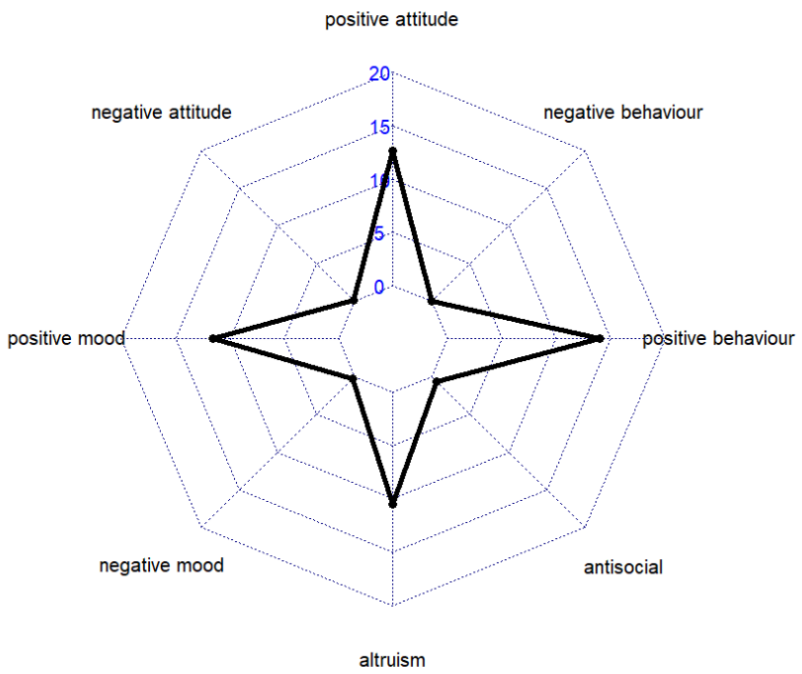
PERSISTING EFFECTS QUESTIONNAIRE (PEQ)



Day 7



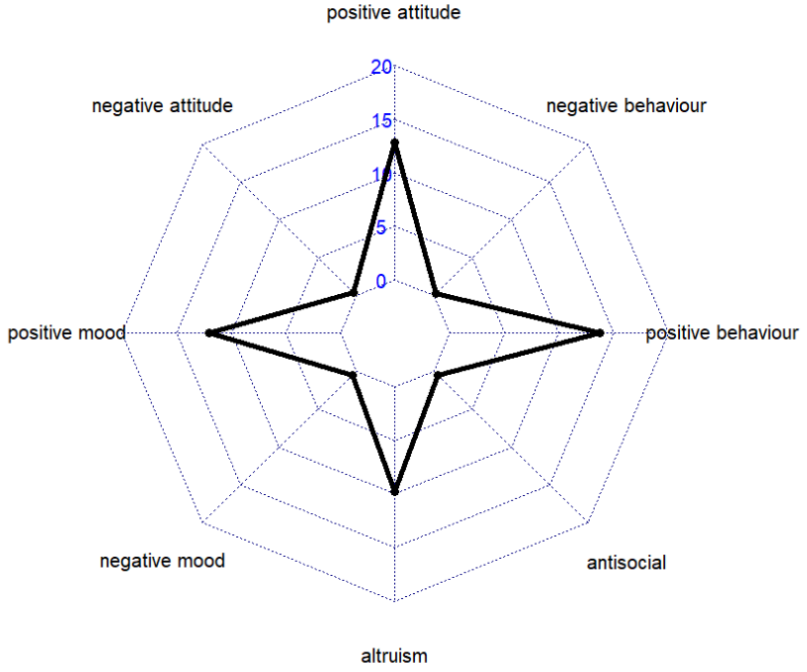
Day 28



Day 90

PERSISTING EFFECTS QUESTIONNAIRE (PEQ)

Day 7



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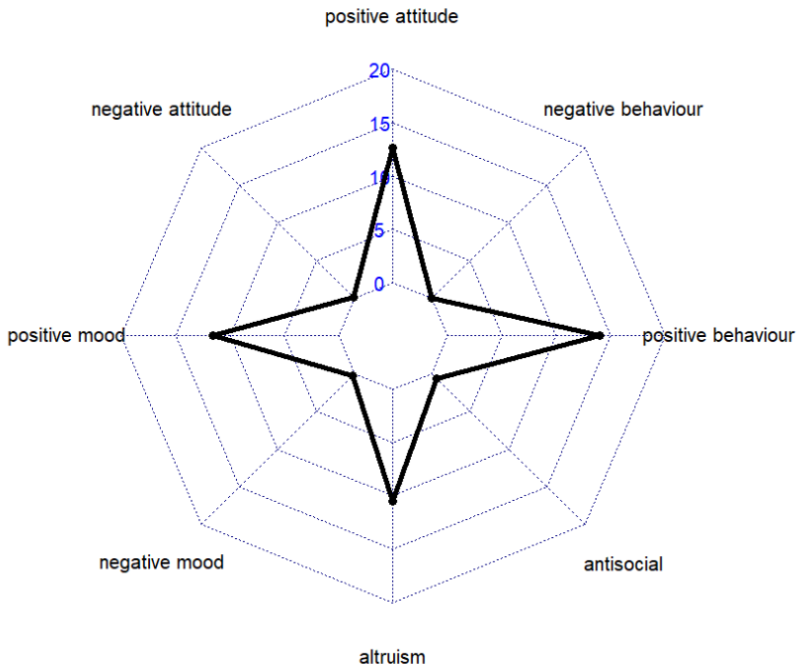
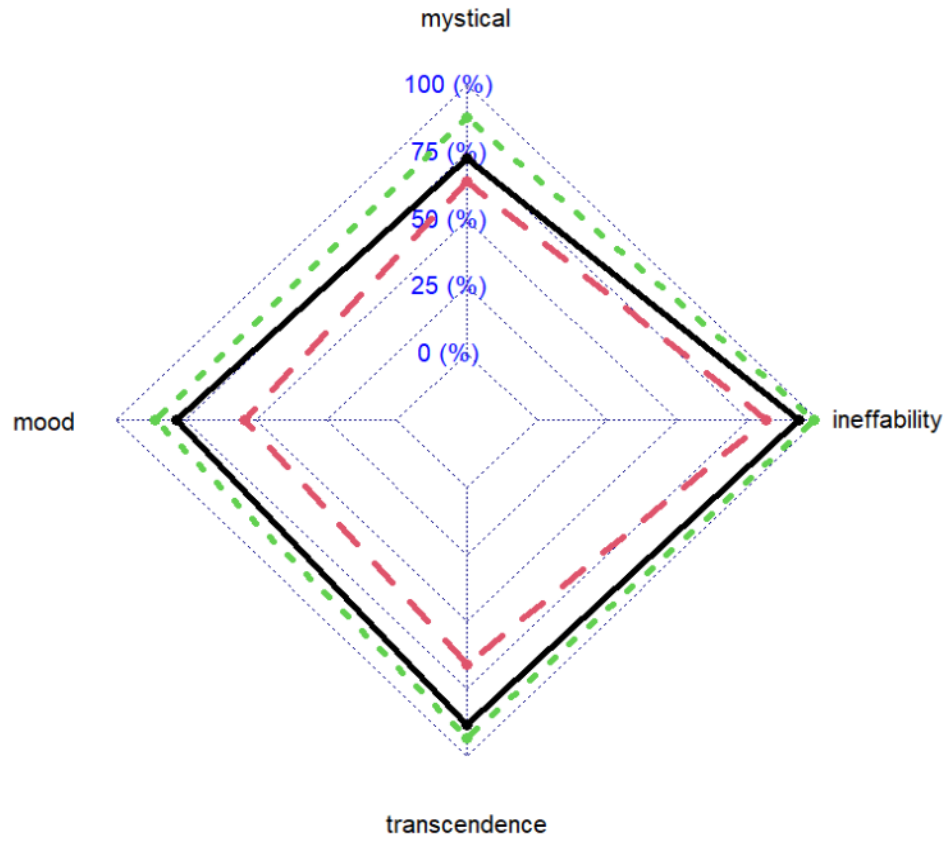


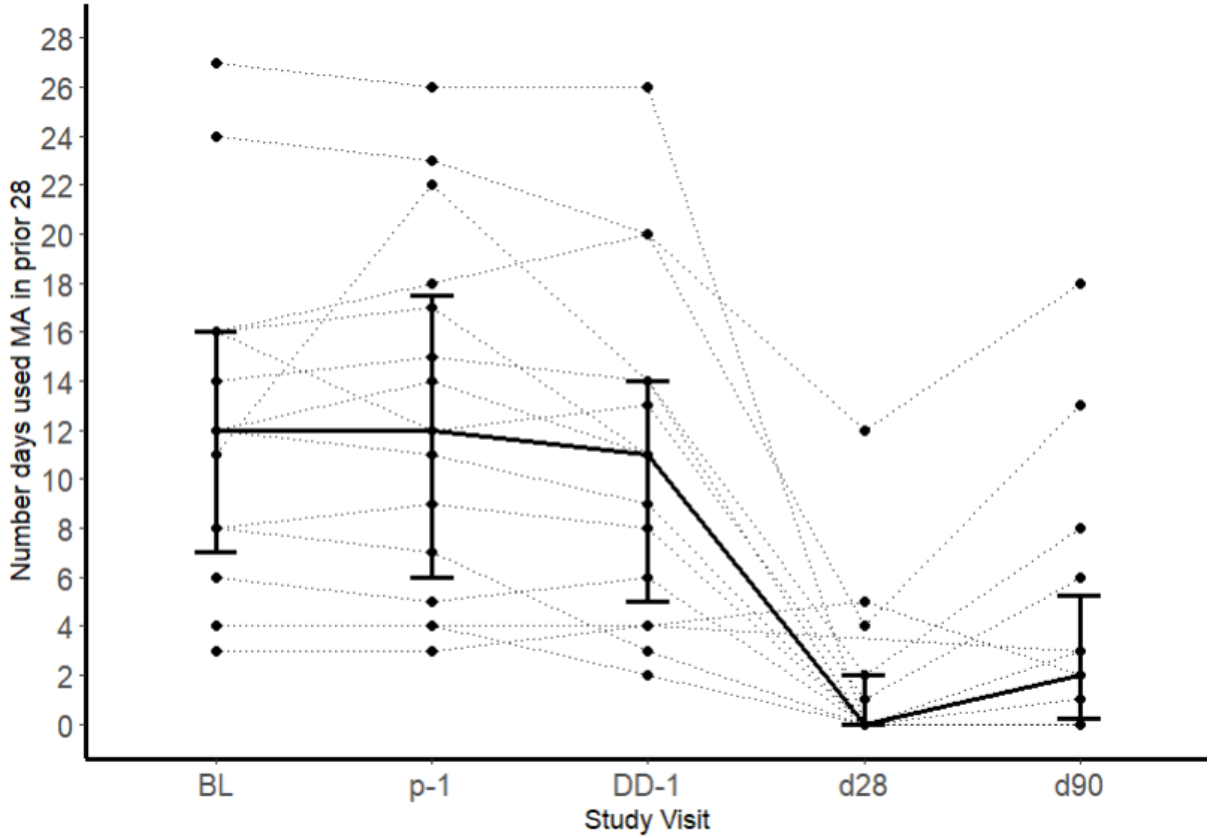
Day 90

ACUTE DOSE EFFECTS –MYSTICAL EXPERIENCES QUESTIONNAIRE

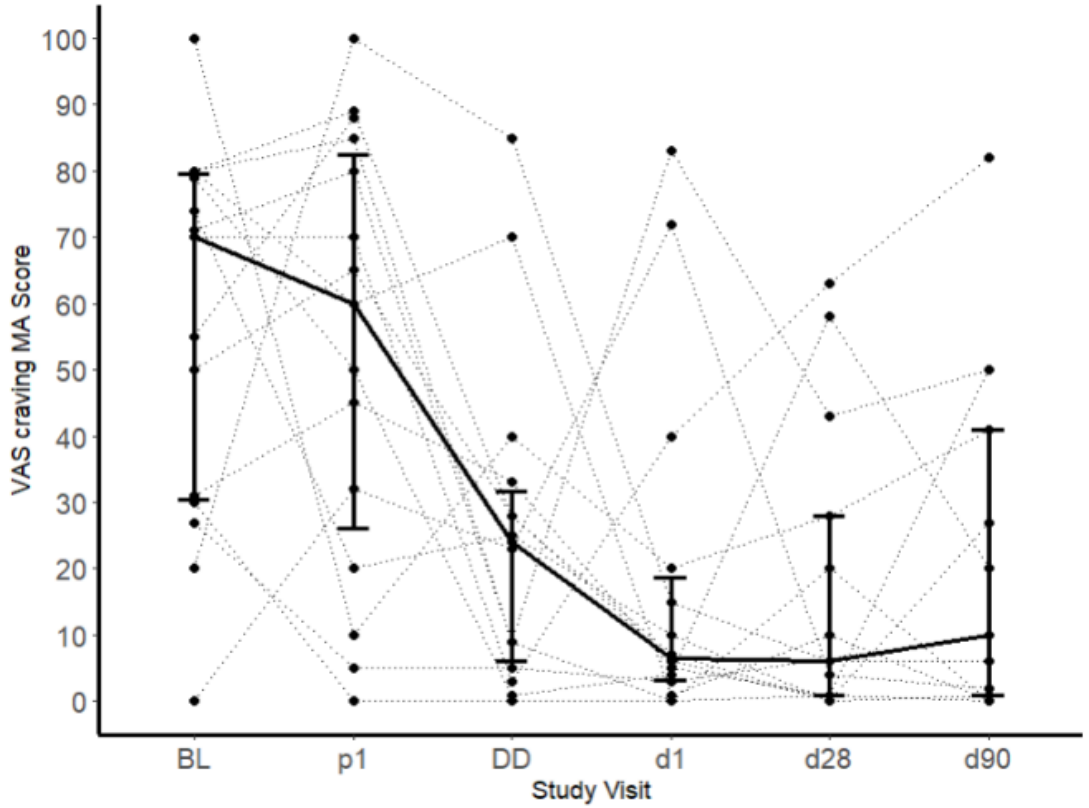
- Measures the intensity of the mystical experience
- 11 participants (79%) experienced a ‘complete mystical experience’
- Defined by >=60% of maximum total score in each subdomain



METHAMPHETAMINE USE



CRAVING



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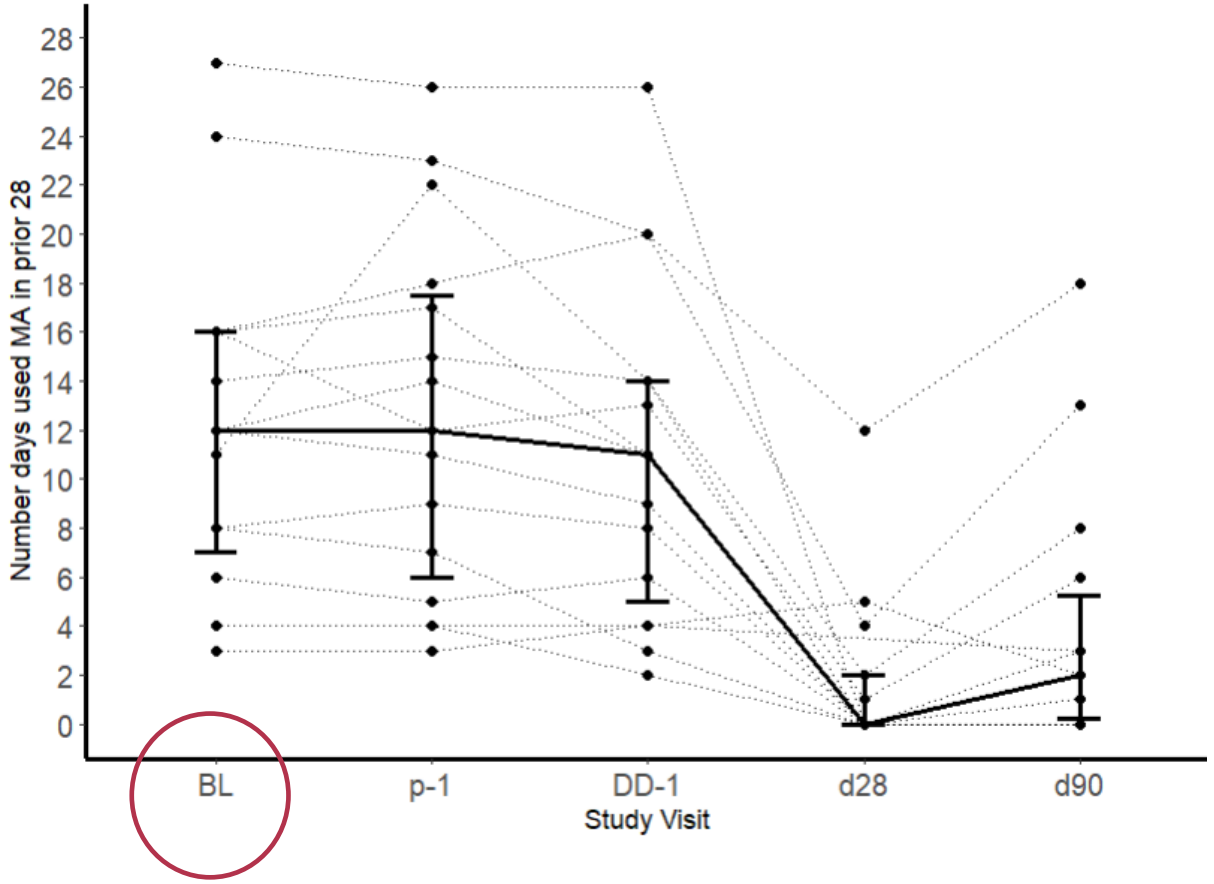

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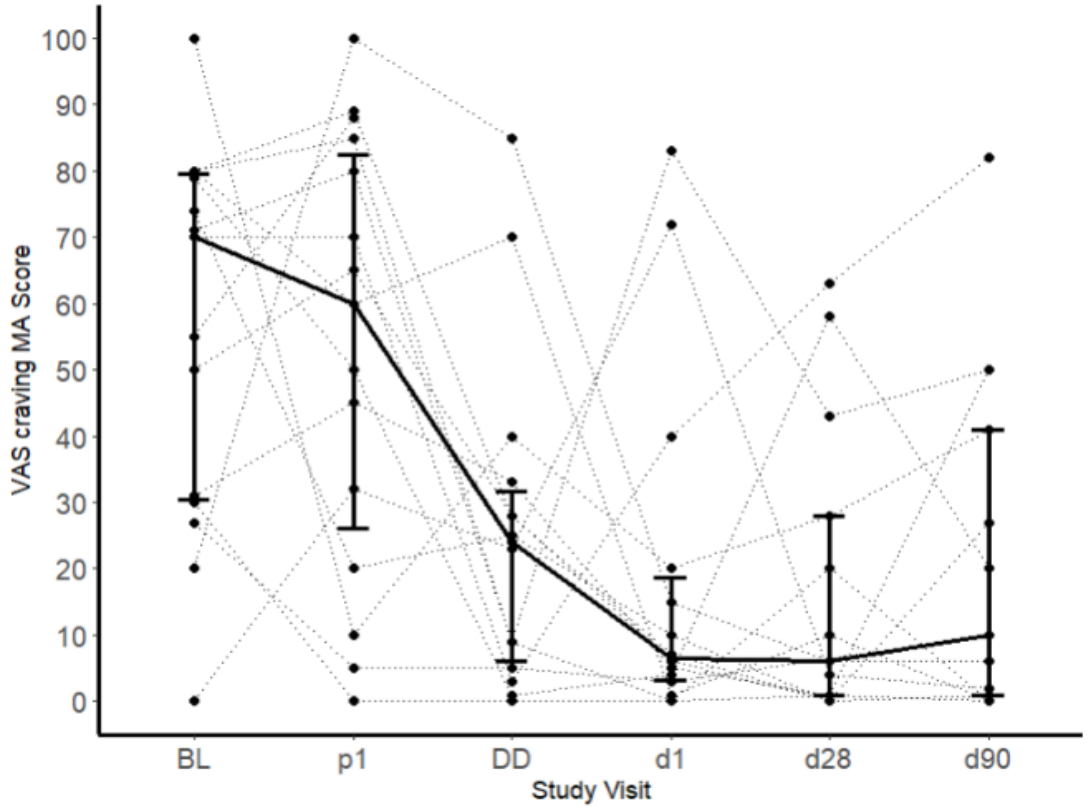

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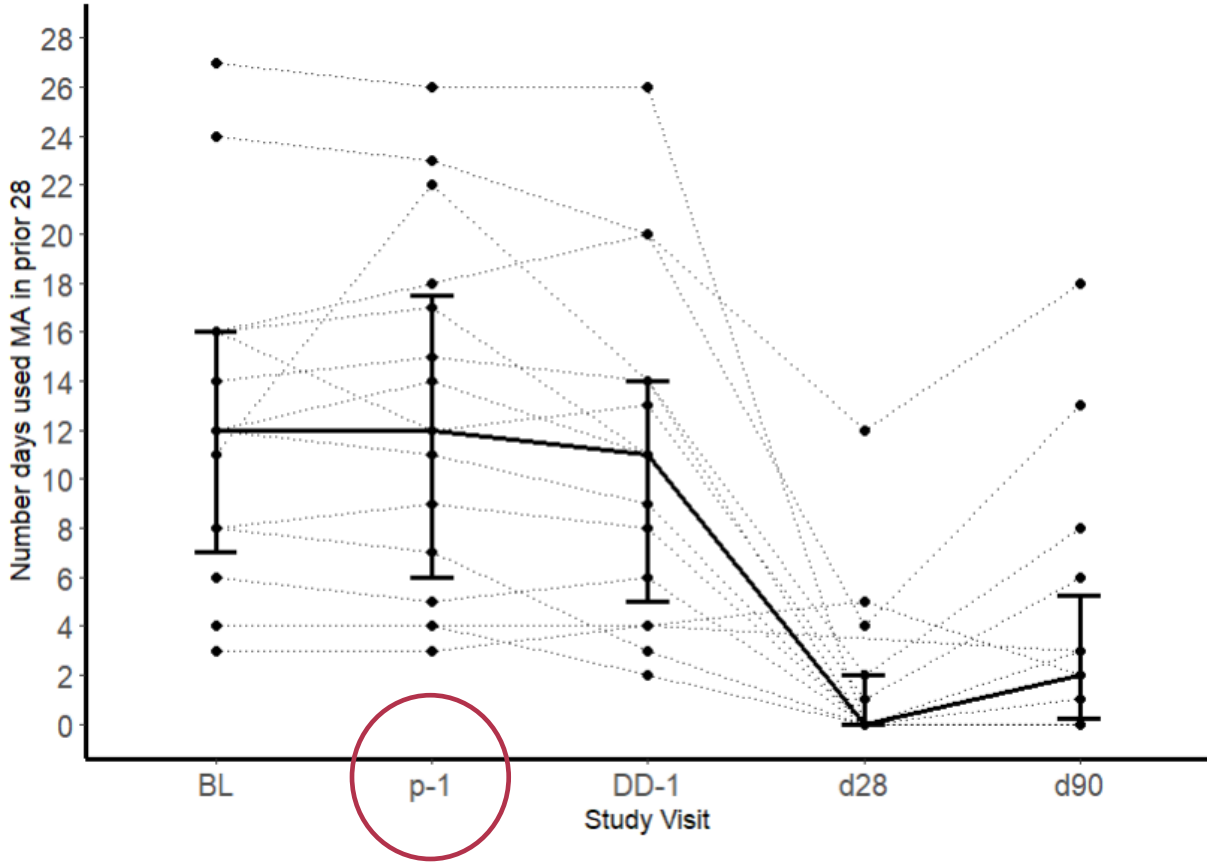

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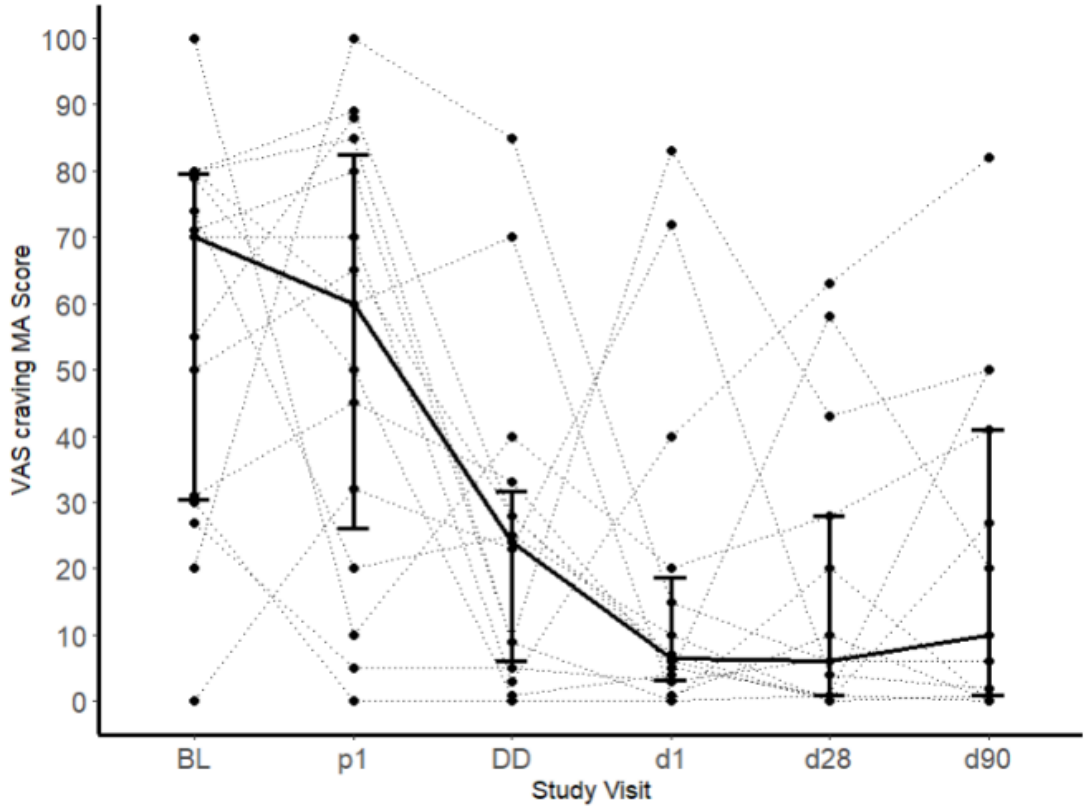

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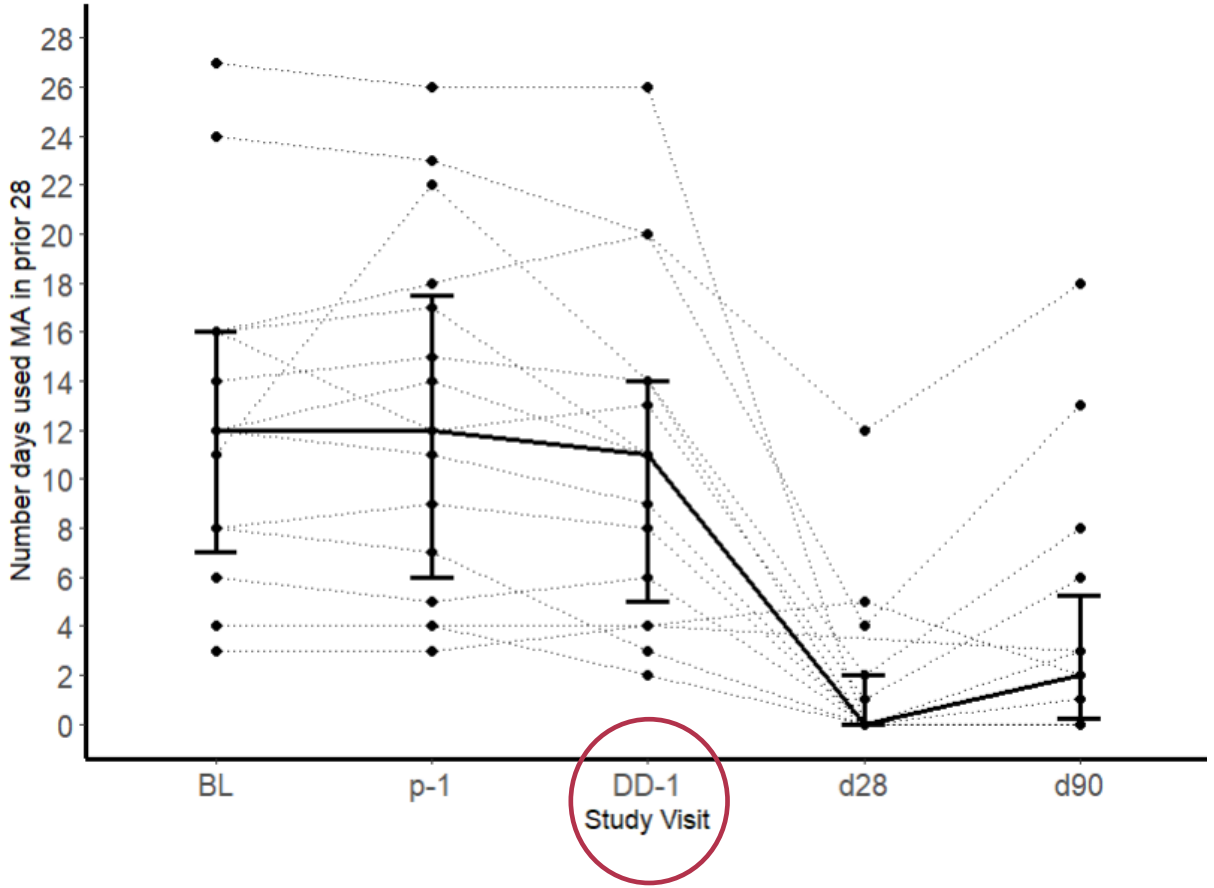

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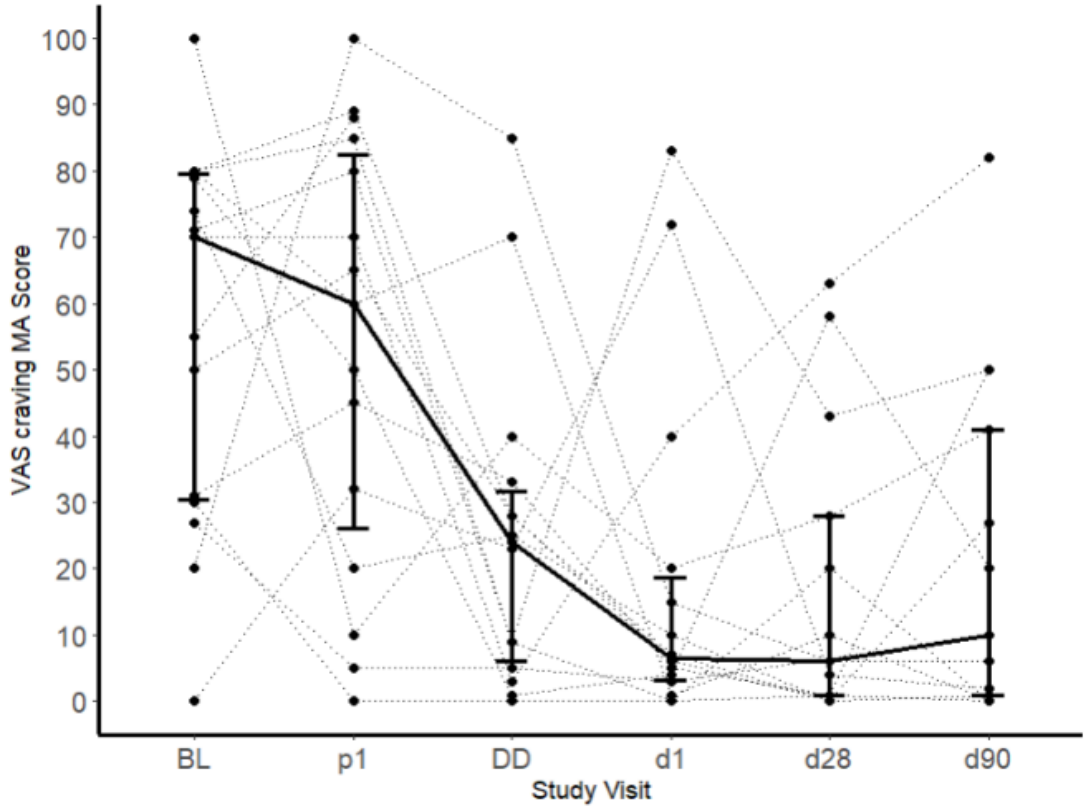

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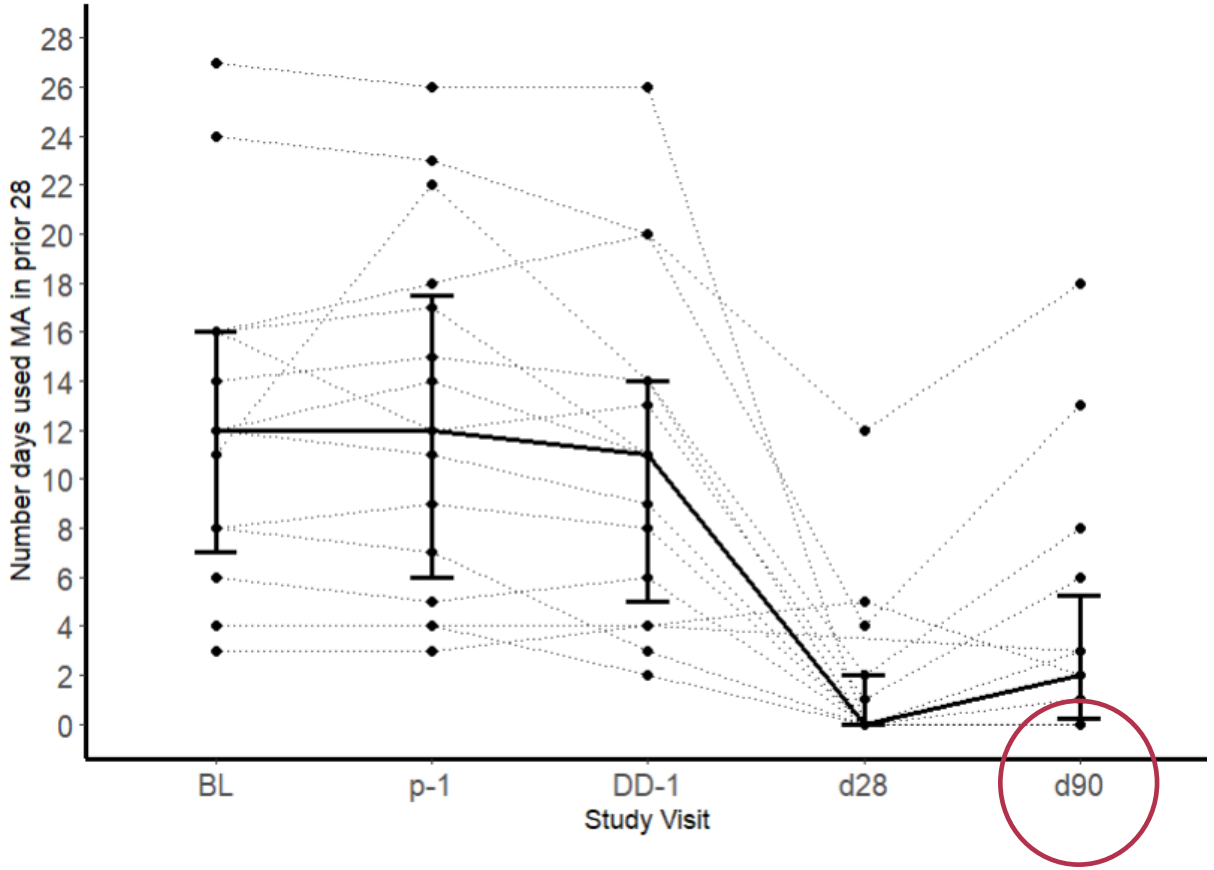

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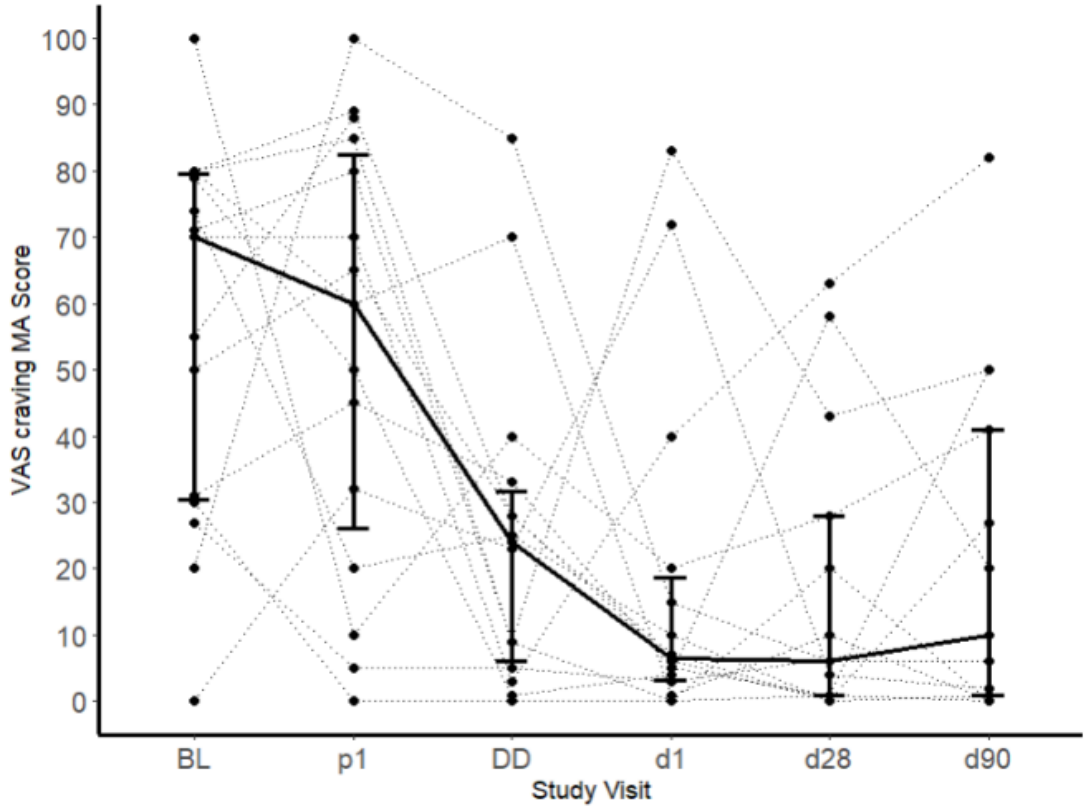

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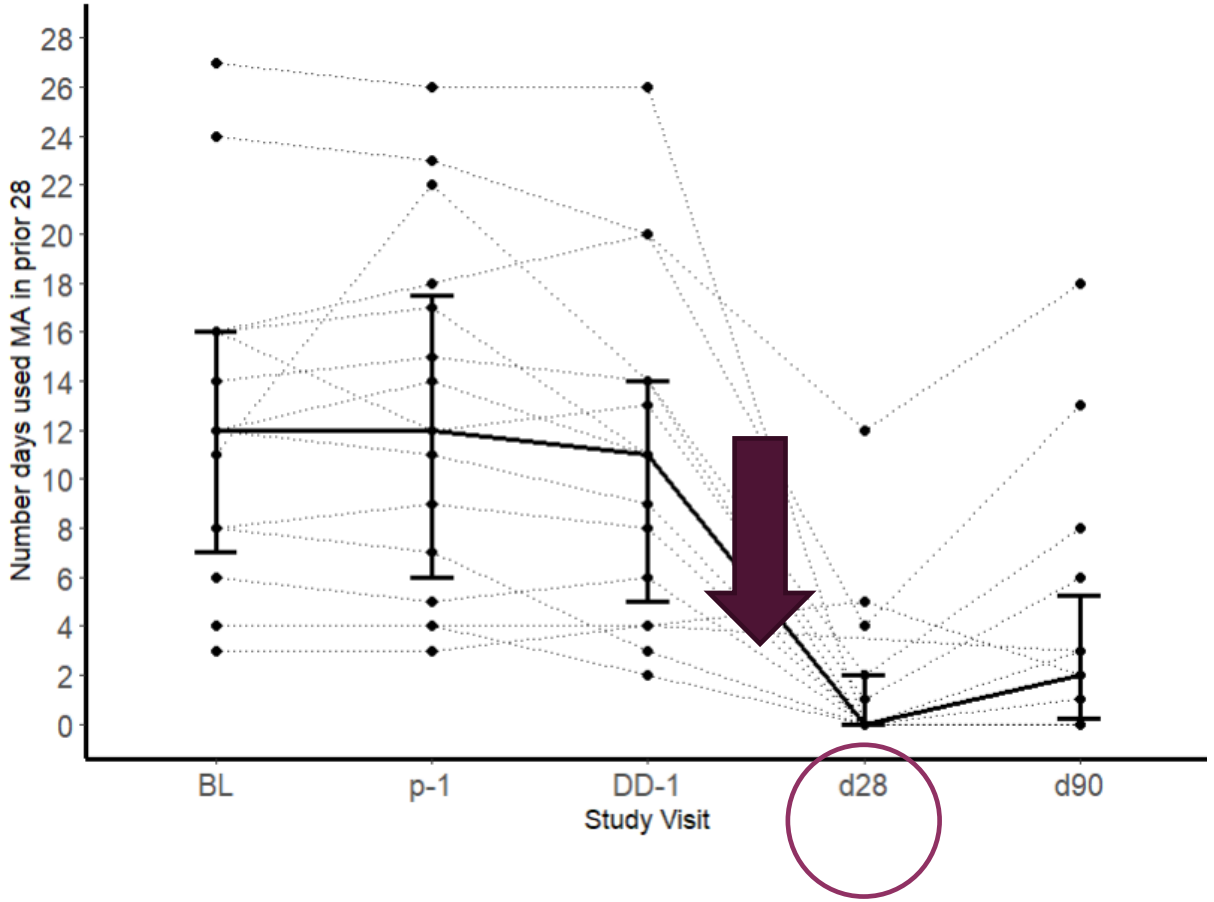

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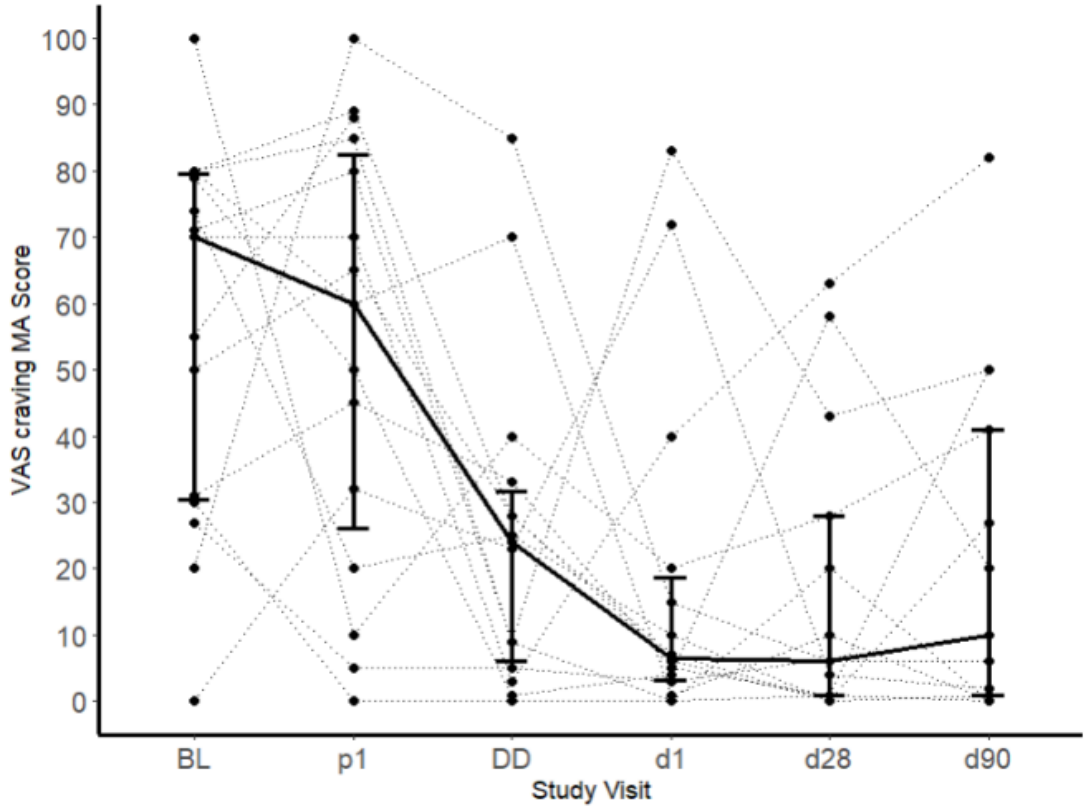

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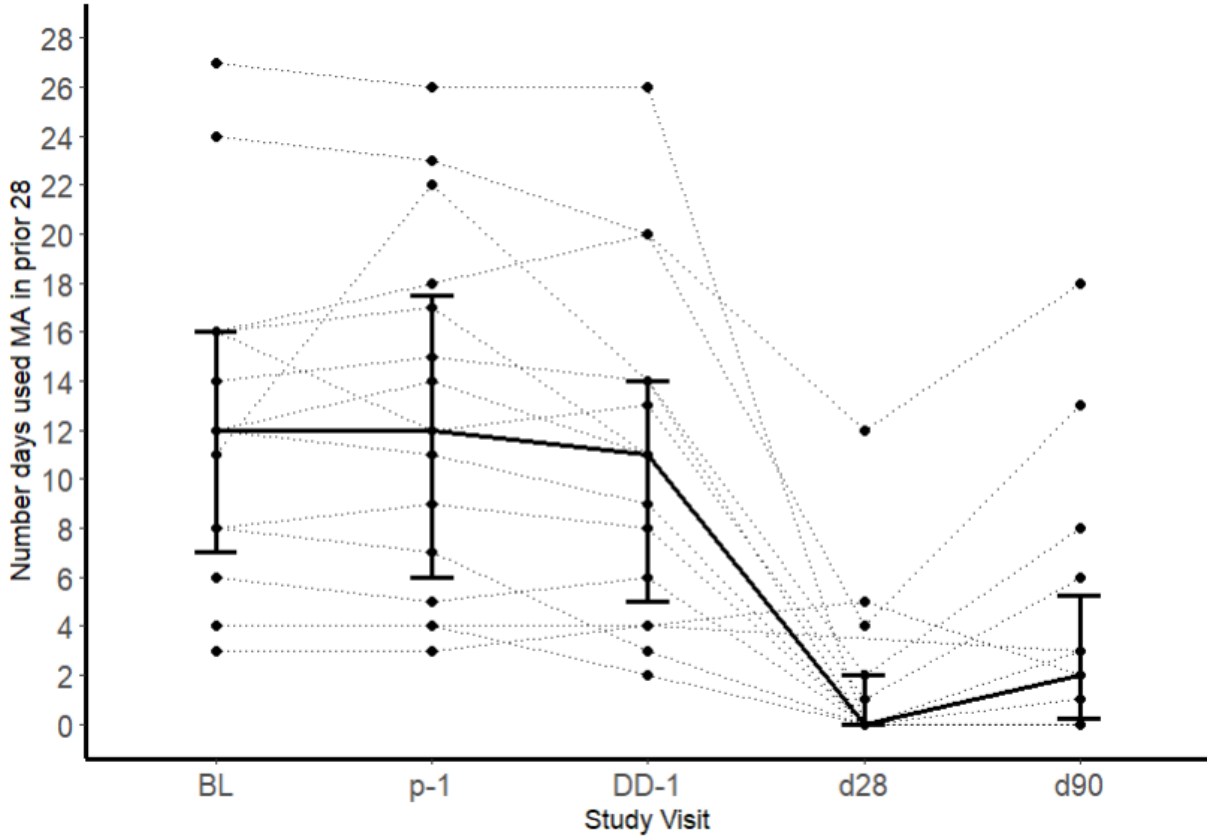

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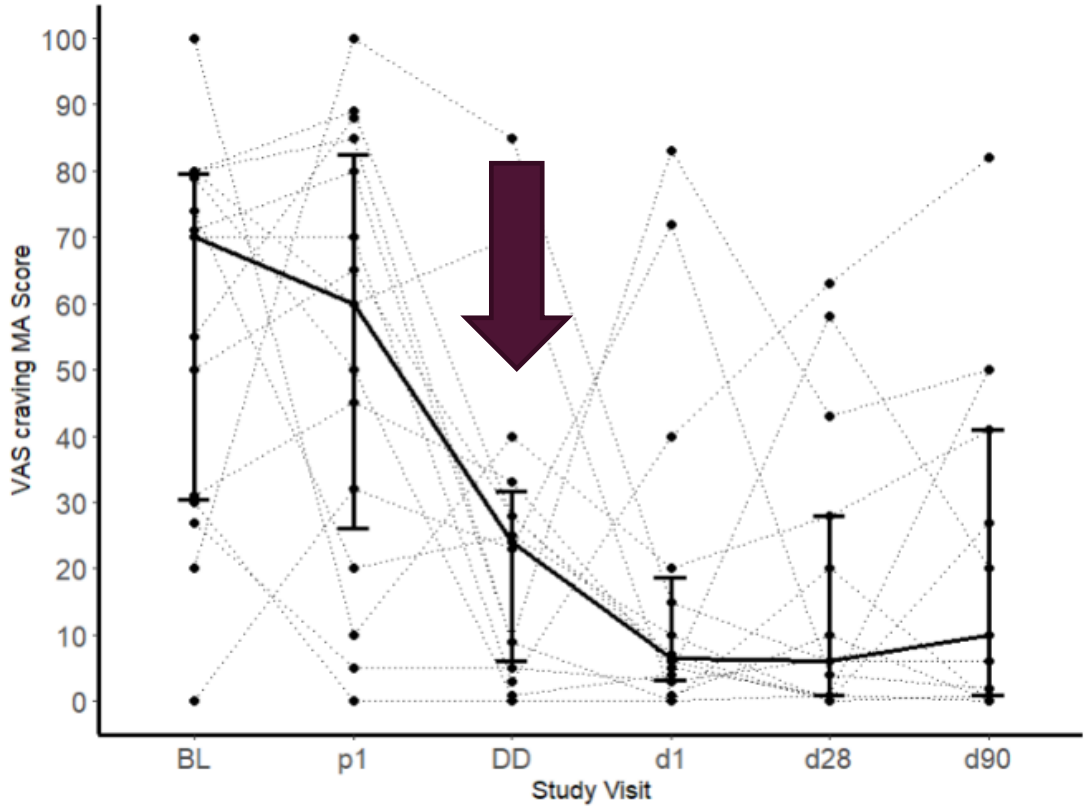
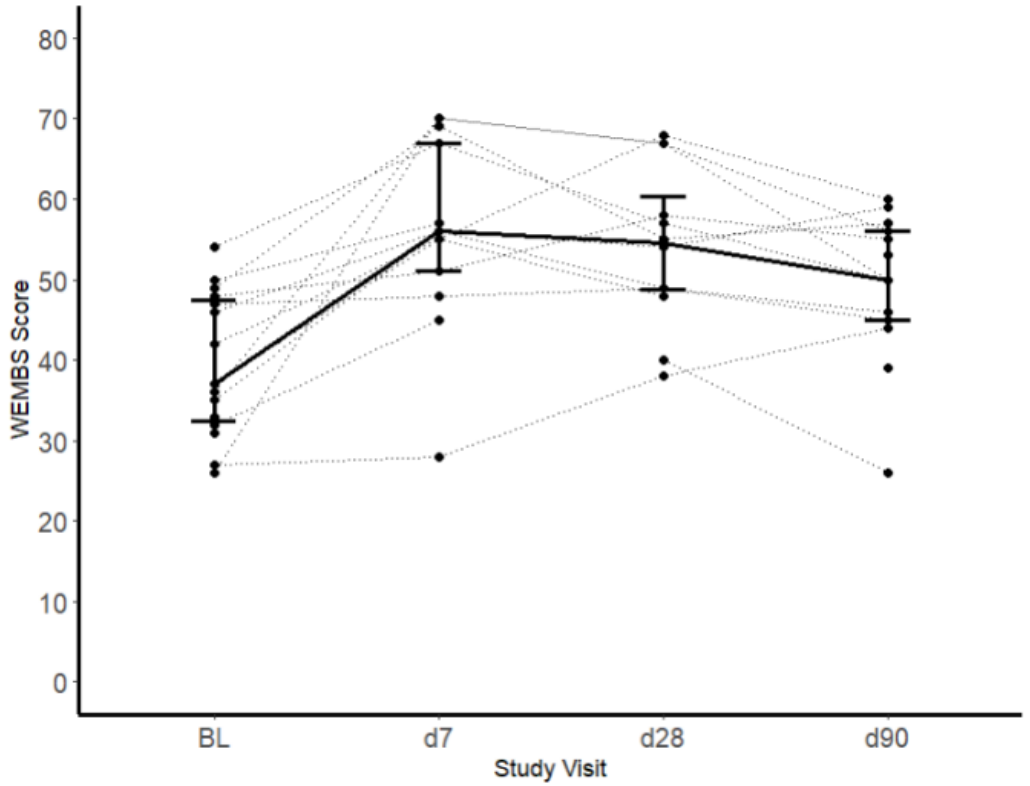
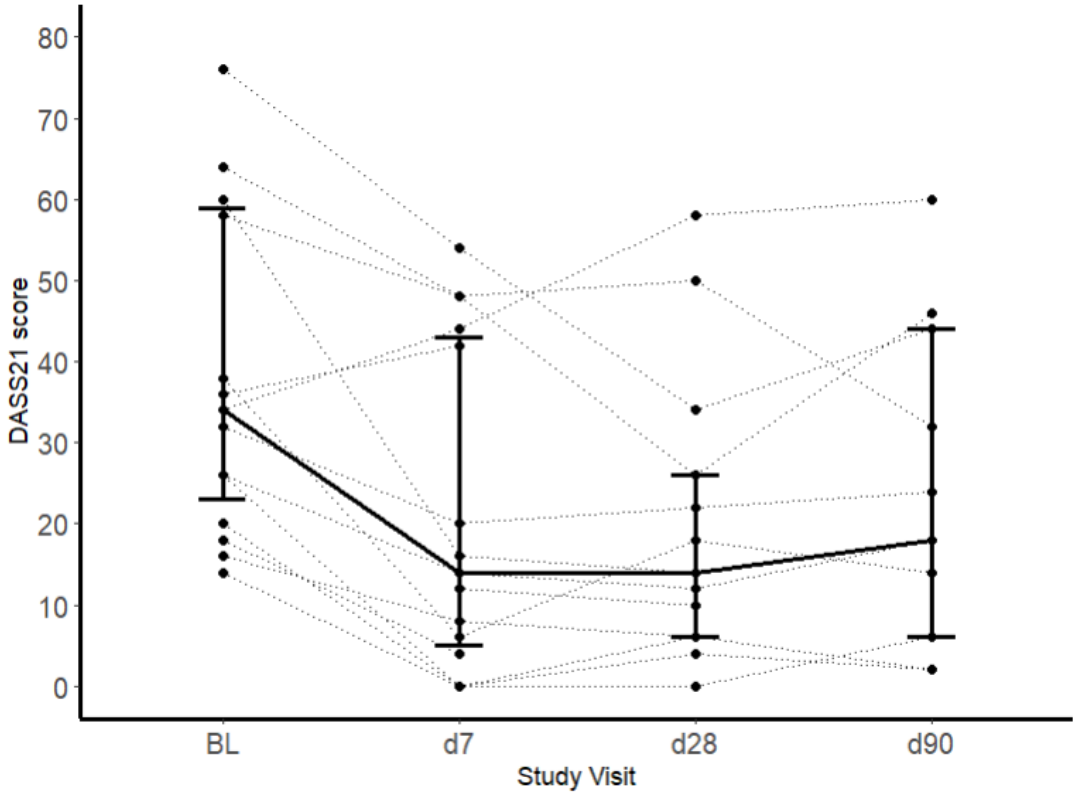


WELLBEING



DASS21



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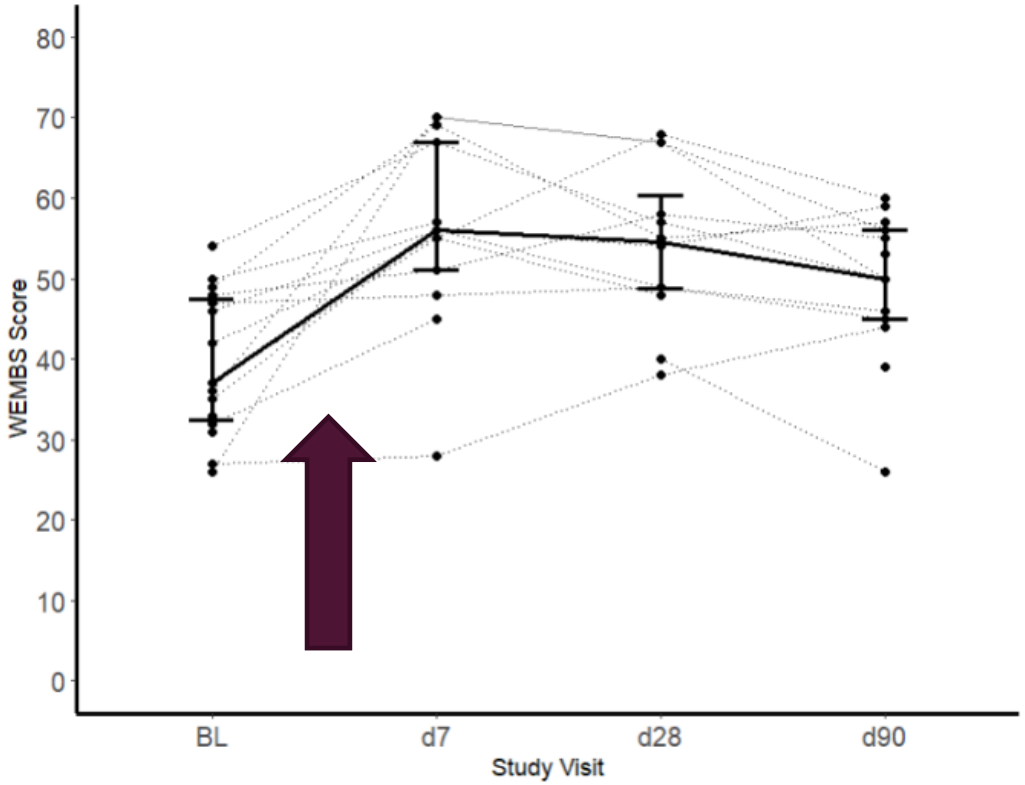

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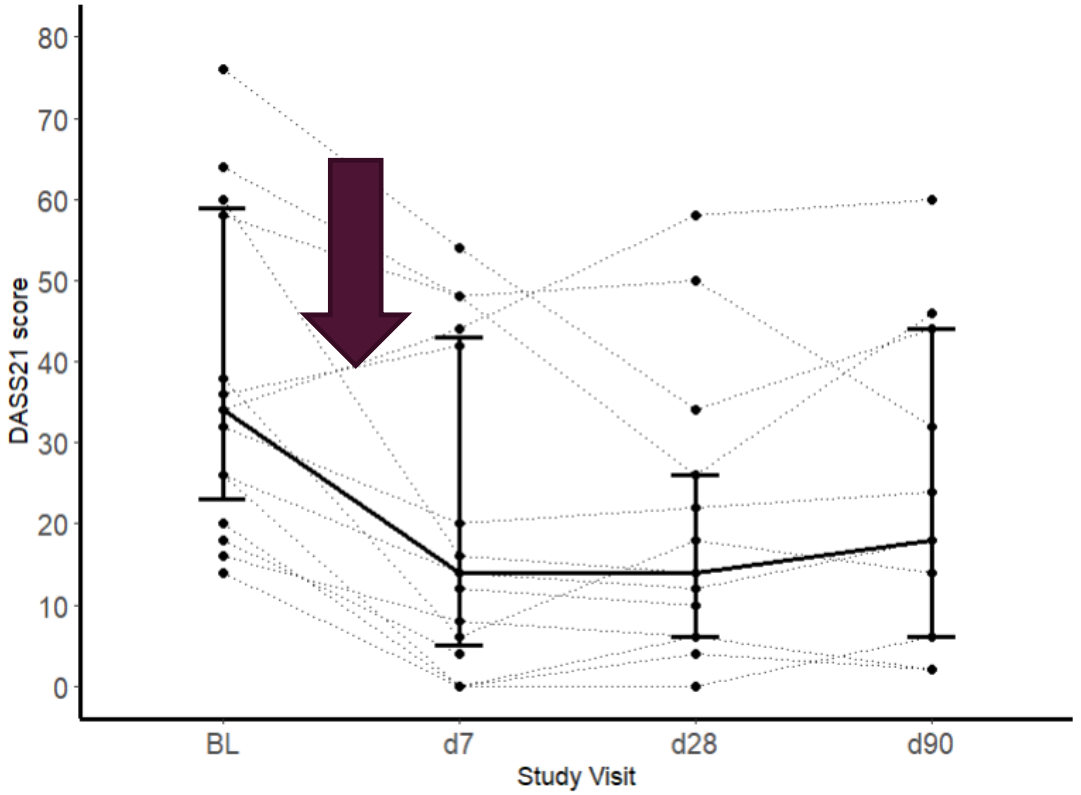

FINAL CONSIDERATIONS

- Good generalisability –but this can always be improved to ensure those with most need are included in research.
- Potential to include Inpatient detox in future models
- How to overcome challenges to participating for individuals with very limited social supports
- Small Sample size
- **Safe and feasible within a CMA using population**
- Further exploration of PAT for MAUD is warranted

Thank you