Siefried et al - NABU

Supplementary Table 2 - Schedule of Assessments

Study day	**0**[a]	**1**[b]	**7**	**14**	**21**	**28**	**35**	**42**	**49**	**56**	**63**	**70**	**77**	**84**	**112**
Protocol window - days	-14	0	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3
Study Week	0	0	1	2	3	4	5	6	7	8	9	10	11	12	16
Assessments															
Pre-screening	•														
Informed consent	•														
Demographics, medical history	•														
Confirm eligibility	•	•													
Prior concomitant medication	•														
Medical review	•													•	
Weight		•	•	•	•	•	•	•	•	•	•	•	•	•	
Concomitant medication	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Concomitant psychosocial care	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Investigational Product															
Study medication dispensed		•	•		•		•		•		•		•		
Medication pack returned for pill count			•		•		•		•		•		•	•	
Safety															
Adverse events		•	•	•	•	•	•	•	•	•	•	•	•	•	•
Blood pressure, pulse, temperature	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
C-SSRS Lifetime/Recent		•													
C-SSRS Since Last Visit						•				•				•	•
Pathology															
hCG[±]	•					•				•				•	
UDS POC all substances	•														
UDS POC opioids		•[d]				•				•				•	
UDS POC MA		•	•	•	•	•	•	•	•	•	•	•	•	•	
Liver function tests	•														
Questionnaires															
TLFB (alcohol, MA, opioids, cigarettes/nicotine)	•	•[d]				•				•				•	•
SURGE	•	•				•				•				•	•
Daily methamphetamine use[c]		•	•	•	•	•	•	•	•	•	•	•	•	•	
Daily adherence[c]		•	•	•	•	•	•	•	•	•	•	•	•	•	
SMAQ			•	•	•	•	•	•	•	•	•	•	•	•	
WURS		•													
ESSI		•													
Promis-29		•												•	
DASS-21		•												•	
CVAS		•												•	
AWQ		•												•	
TSQM v. II														•	
Optional Interview															
Qualitative interview														←→	

Siefried et al - NABU

Supplementary Table 2 - Schedule of Assessments

a	= screening	b	= baseline (Day 1, first dose of study investigational product)
•	= study activity	c	= daily smartphone EMA (self-report)
↔	= study activity conducted any time on indicated days inclusive	±	= people of childbearing potential only
	= post-primary endpoint (taper-down and follow-up periods)	d	= TLFB, UDS POC (opioids) must be repeated on day of first dose if screening and baseline visits not combined
AWQ	Amphetamine Withdrawal Questionnaire	Promis-29	Patient-Reported Outcomes Measurement Information System-29
C-SSRS	Columbia Suicide Severity Rating Scale	SMAQ	Simplified Medication Adherence Questionnaire
CVAS	Craving Visual Analogue Scale	SURGE	Substance Use Recovery Goals and Expectations
DASS-21	Depression Anxiety Stress Scales	TLFB	Timeline Follow-Back
ESSI	ENRICHD Social Support Inventory	TSQM	Treatment Satisfaction Questionnaire for Medication
hCG	Human chorionic gonadotropin (urine)	UDS POC	Urine drug screen – point of care
		WURS	Wender Utah Rating Scale

Siefried KJ, *et al. BMJ Open* 2025; 15:e092032. doi: 10.1136/bmjopen-2024-092032