

Pharmacological validation of NeuroKit A portable central nervous system (CNS) test battery with sensitivity and reproducibility comparable to NeuroCart

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Introduction

- NeuroKit is a portable equivalent to NeuroCart, a well-established and validated central nervous system (CNS) test battery to quantify pharmacodynamic (PD) effects in early-phase clinical CNS drug development.
- NeuroKit incorporates CNS domains previously demonstrated to be most sensitive to a wide range of mechanisms of action in early phase clinical trials.

Assessment	CNS domain/function
Saccadic peak velocity (SPV)	arousal, vigilance, alertness
Smooth pursuit eye movement	visuomotor coordination
Adaptive tracking	sustained attention, visuomotor coordination, fine motor skills
Body sway	motor coordination, postural stability
Visual analogue scales (VAS)	subjective drug effects
N-back	working memory
Finger tapping	motor function

Objective

Pharmacological validation of NeuroKit against NeuroCart — assessing its sensitivity and reproducibility in capturing PD effects — using three established CNS-penetrant compounds with distinct mechanisms of action.

Design

- Randomized, double-blind, double-dummy, placebo-controlled, 4-period crossover study.



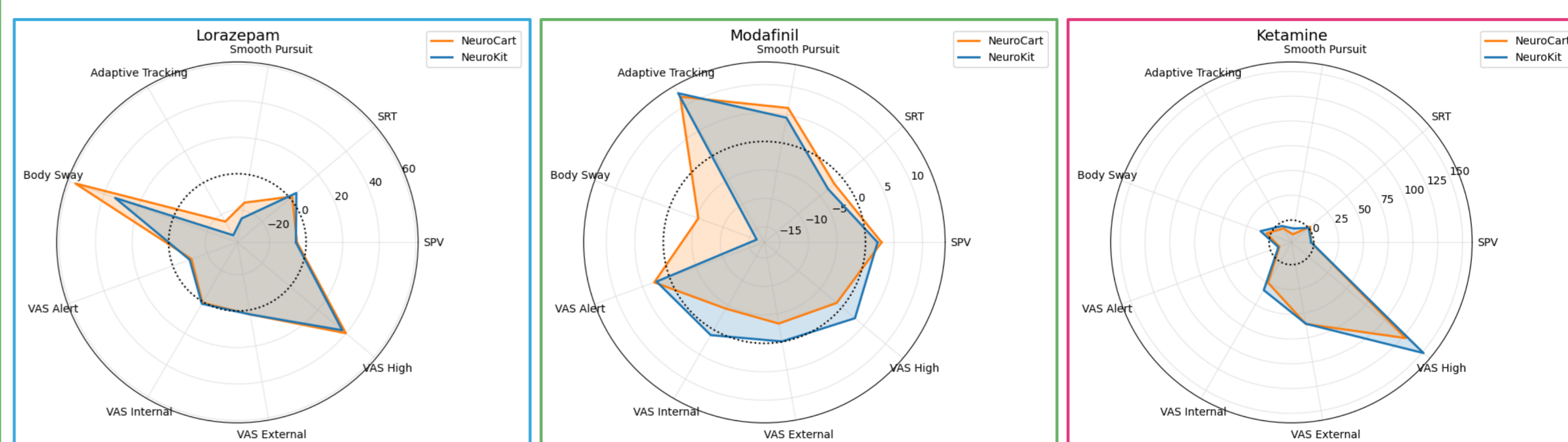
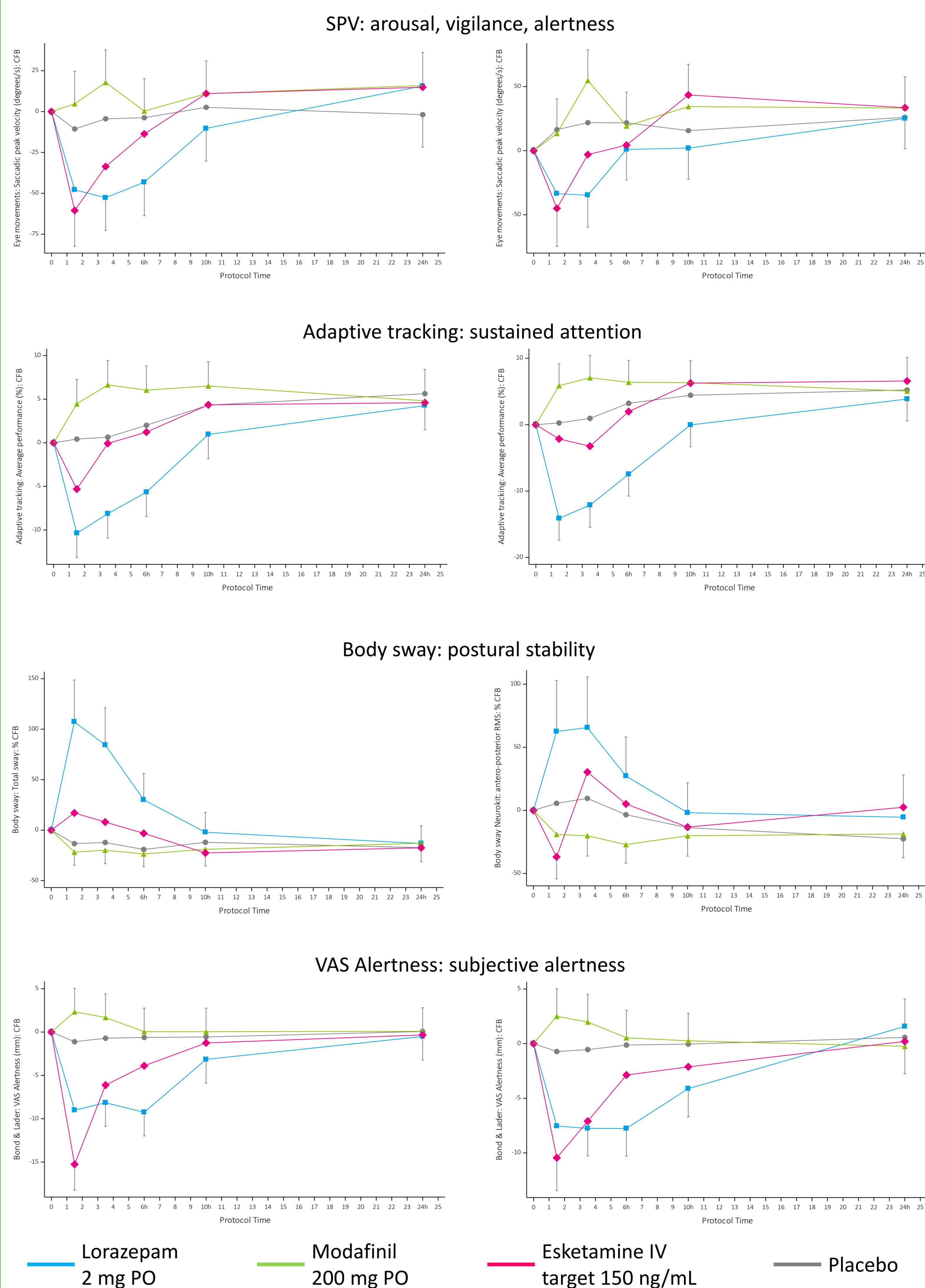
- 16 healthy male and female participants.
- Participants performed NeuroKit and NeuroCart predose, and at 5 counterbalanced postdose timepoints per treatment period.
- PD endpoints were analysed using linear mixed-effects models. Least-squares means and Minimal Detectable Effects (MDE) compared sensitivity between methods. Reproducibility assessed via F-tests for inter- and intra-participant variance.

Conclusion

- NeuroKit detected mechanism-specific CNS effects for lorazepam, modafinil and S-ketamine, comparable to PD profiles previously established using NeuroCart.
- NeuroKit demonstrated comparable sensitivity and reproducibility to NeuroCart.
- These findings support NeuroKit as a portable, validated tool in early-phase clinical studies with CNS-active compounds, facilitating biomarker-driven early CNS drug development.

Treatment effects	Sensitivity	Reproducibility
NeuroKit detected treatment effects consistent with NeuroCart in 88% of endpoint-drug contrasts	NeuroKit MDE lower or equal in 55% of endpoints, including arousal, working memory, subjective effects and body sway	Inter- and intra-participant variance did not differ significantly

Results



CNS domain drug profiles are consistent across NeuroCart and NeuroKit