## An exploratory analysis of actigraphy and sleep diaries in a methamphetamine withdrawal clinical trial

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**Introduction and Aims:** Sleep disturbance, common during methamphetamine (MA) use and withdrawal, has to date only been assessed by questionnaires in this population. Actigraphy is a well-established, non-invasive measure of the sleep-wake cycle, and has demonstrated comparable accuracy to gold-standard polysomnographic sleep studies. This is the first study to investigate the feasibility and utility of using actigraphy and sleep diaries to investigate sleep during MA withdrawal.

**Design and Methods:** We conducted an open-label single-arm trial to investigate safety and feasibility of a 5-day tapering-dose regimen of lisdexamfetamine for the treatment of MA withdrawal. Participants were inpatients for 7 days; continuously wore an actigraph (Philips Actiwatch 2), completed a modified Consensus Sleep Diary (CSD) each morning, and were interviewed.

**Results:** 10 participants (median age 37 years, 90% male) enrolled. Participants interviewed (n=8) reported the actigraph was not difficult or distracting to wear nor was completion of the daily sleep diary onerous. No participant removed the device prematurely. Actigraphic average sleep duration was 646 minutes, sleep onset latency 20 minutes, and wake after sleep onset (WASO) 78 minutes. Sleep diaries under-reported sleep compared with actigraphy (sleep duration 141 minutes (p=0.005) less; WASO 45 minutes (p<0.001) less). Mean sleep efficiency was 83.9% by actigraphy, however participants rated their overall sleep quality at 4.7 on a nine-point scale by CSD.

**Discussions and Conclusions:** Continuous actigraphy is feasible to measure sleep-wake cycles in people withdrawing from MA, with high accuracy and low participant burden. We found differences in self-reported and actigraphic sleep, requiring further exploration.

**Implications for Translational Research:** Accurate sleep measurement is essential to better understand stimulant use and withdrawal, and has the potential to be used as an efficacy outcome in future trials and clinical practice in inpatient and outpatient settings.

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