

# POS6 Med-4: A COMPARISON OF THE CRAVING PROFILE OF A NOVEL NICOTINE REPLACEMENT THERAPY VS NICOTINE PATCH DURING THE FIRST TWO WEEKS OF A QUIT ATTEMPT: A NON-INFERIORITY STUDY



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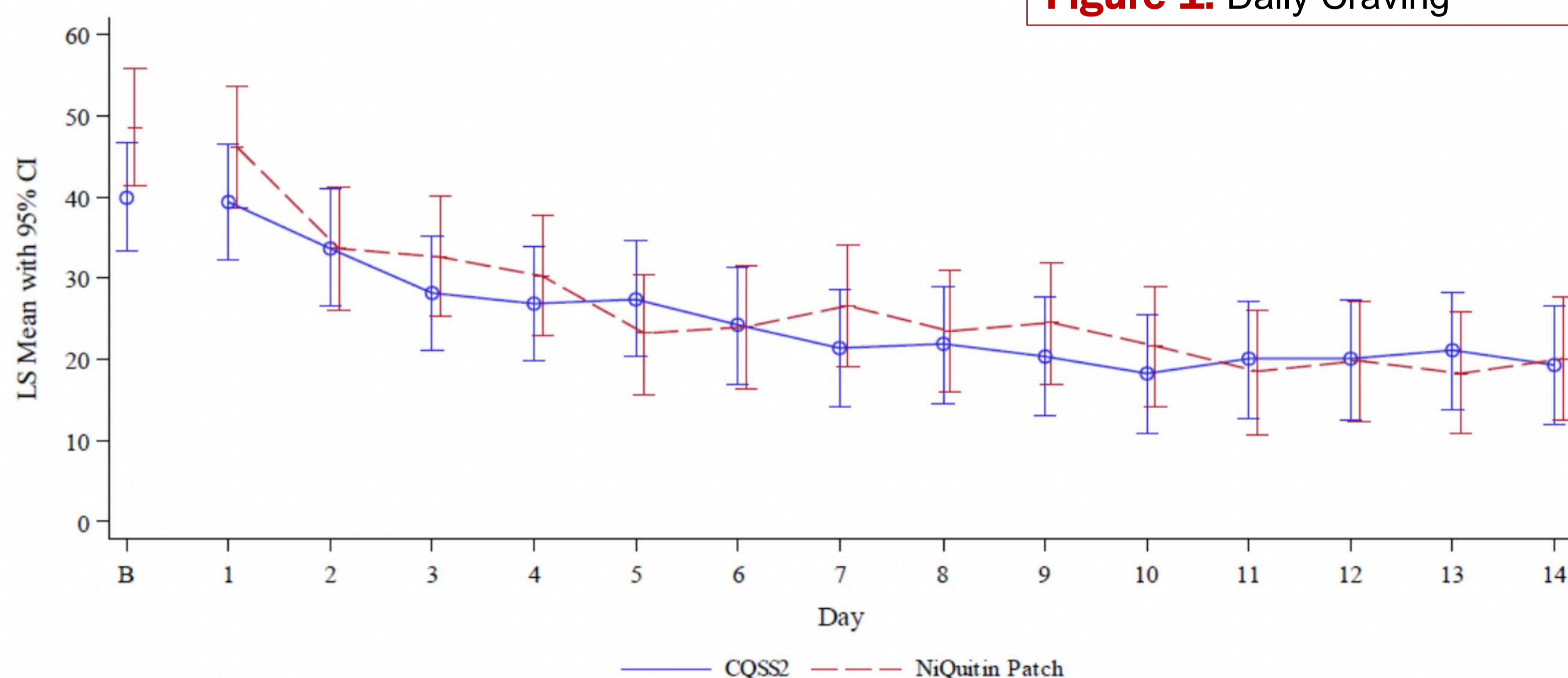
## Introduction:

- Smokers report that craving is a key barrier to cessation
- As such, one evaluation of novel treatments is whether they can attenuate the craving experienced during quitting
- The Chrono Quit Smoking Solution (CQSS2) is a wearable drug delivery product that transdermally delivers metered pulses of nicotine (~21 mg daily)
- Here we report the results from a Phase 2, two-arm, open-label non-inferiority study designed to assess the craving profile of the CQSS2 vs nicotine patch (21mg/24-hrs) during the first two weeks of a quit attempt

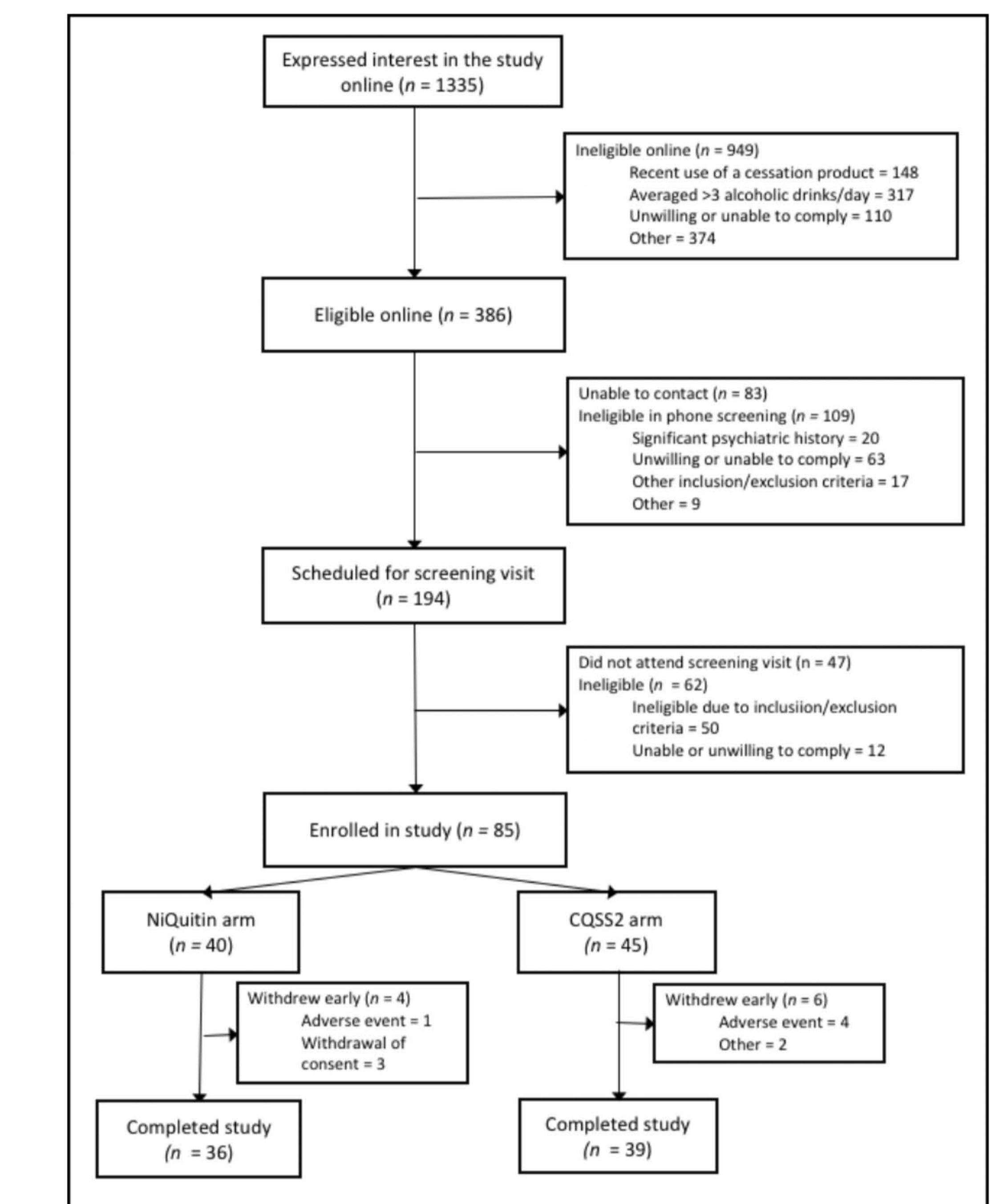
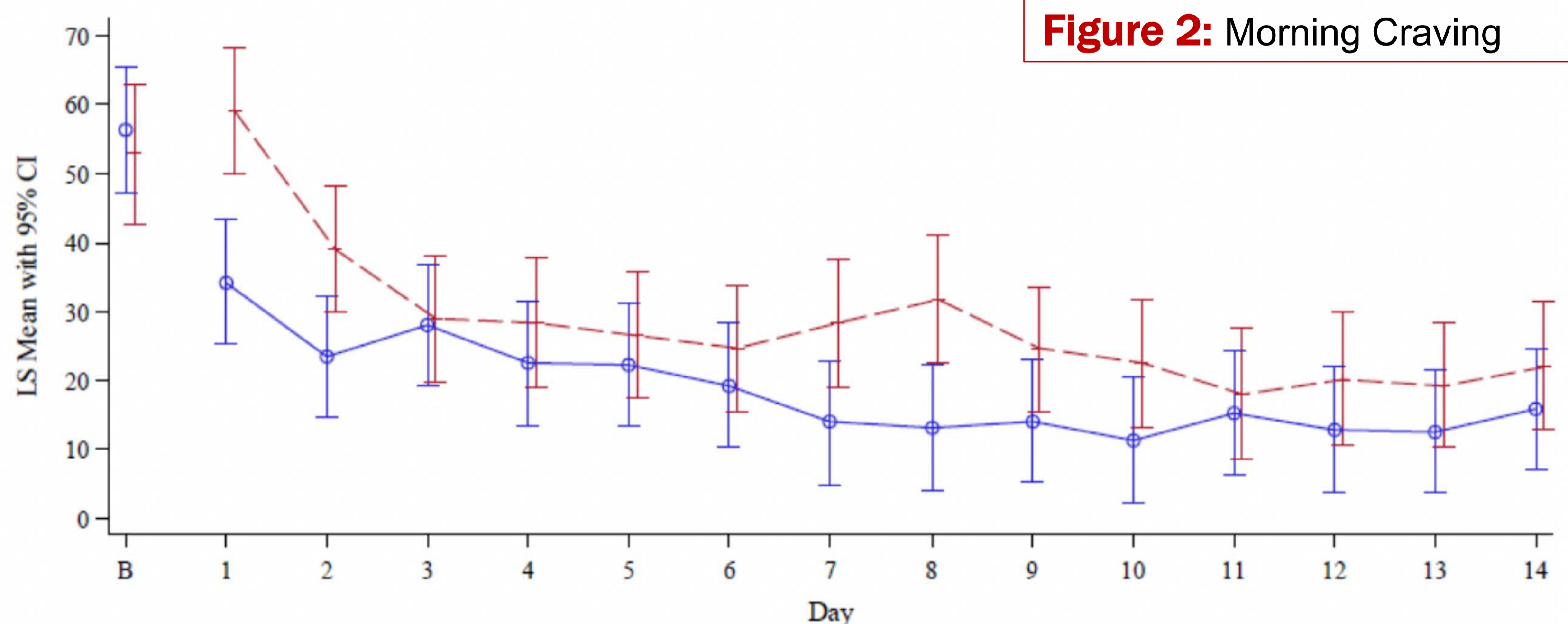
## Method:

- Interested quitters (n=85) were recruited using social and traditional media
- The first 40 participants received nicotine patch while the remaining 45 received the CQSS2
- Participants reported their craving and withdrawal symptoms in real-time during the four days leading up to, and 14 days after, an assigned quit day.
- Craving (assessed on a 101-point scale) and withdrawal (affect, concentration, and anhedonia) were assessed during ~4-5 randomly-timed assessments each day; symptoms were also assessed during daily morning and evening reports
- Based on a non-inferiority limit of 12.4 points, 36 participants per arm would afford >80% power for testing our primary hypothesis

**Figure 1:** Daily Craving



**Figure 2:** Morning Craving



## Results:

- Daily craving (Figure 1) and morning craving (Figure 2) followed the expected pattern, peaking soon after quit day and then gradually declining
- Consistent with the primary hypothesis, the CQSS2 was non-inferior to nicotine patch ( $p > .05$ )
- Withdrawal symptoms (negative affect, concentration, anhedonia) were consistent between groups ( $p > .05$ )

**Figures:** Daily Craving (Figure 1, above) and Morning Craving (Figure 2, below). Note: Craving scores from Day 1 through Day 14 were analysed using a mixed-effected model for repeated measures (MMRM) with baseline, treatment, day, treatment-by-day interaction, and baseline-by-day interaction

## Discussions:

- Craving and withdrawal symptoms experienced while wearing CQSS2 were comparable to those experienced by smokers using nicotine patch
- These results suggest that the CQSS2 may be an effective treatment for smokers wishing to quit
- These results support further clinical investigations with CQSS2 in managing cravings for smoking cessation

**Disclosure:** Stuart Ferguson has consulted for GlaxoSmithKline Consumer Healthcare and Chrono Therapeutics on matters relating to smoking cessation and has received researcher-initiated project grant funding (through the GRAND initiative), and travel funds, from Pfizer. He has also served on an advisory board for Johnson & Johnson. Patricia Oto, Melinda Morrell & Patrick Ruane are affiliated with Chrono Therapeutics Inc. This study was funded by Chrono Therapeutics Inc.