

Interactive Voice Response System for Patient Reported Changes in Mood State Using Outbound Call Prompting

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Abstract

Background: The Profile of Mood States (POMS)^I has been widely used in a variety of clinical trials to identify and quantify affective states^{II}. Despite its use, little research has examined the POMS as administered via Interactive Voice Response (IVR). We examined the psychometric properties of the IVR POMS and compliance associated with an outbound calling procedure.

Methods: Thirty-one healthy normal subjects from a phase IV trial completed the IVR POMS daily. Outpatient POMS ratings were completed daily following a random call to the subject between 9am to 7pm. Inpatient POMS ratings were completed at three equally spaced time intervals throughout the day.

Results: Raw scores were analyzed from the two weeks prior to inpatient (pre-inpatient), the two weeks inpatient, and the two weeks immediately following inpatient (post-inpatient). Total Mood Disturbance (TMD) score, Tension-Anxiety (T-A), Depression-Dejection (D-D), and Anger-Hostility (A-H) subscale scores were averaged for each subject as well. Although there was some suggestion for more symptom endorsement during the inpatient period, one-way ANOVA's showed no significant differences among the POMS scores when compared across the three time periods, suggesting relatively stable mood across in/outpatient status, as well as the relative utility of once daily versus multiple administrations. Although completion rates from pre-inpatient (80%) to post-inpatient (65%) showed a significant decrease ($t = -3.23$ $p < .003$), this decrease did not appear to be related to POMS total or subscale scores as a median split resulting in "high" vs. "low" compliance groups showed no significant differences in TMD or subscale scores for either pre or post-inpatient conditions.

Conclusions: IVR administration of the POMS is an effective data collection method for inpatient and outpatient trials. Daily administration is as efficient as three times, suggesting that subjects accurately summate their mood state over 24 hours. Compliance with the IVR POMS appears to wane over time for reasons unrelated to mood states suggesting the need for additional prompting as the trial progresses.

Introduction

- The Profile of Mood States (POMS) consists of a list of 65 adjectives rated individually on a 5-point scale: not at all, a little, moderately, quite a bit, and extremely.
- The validity of the POMS has been well-established through previous publications, particularly in studying mood variations in normal adult populations and non-psychotic subjects.
- Interactive Voice Response (IVR) technology, accessed via telephone networks and using touch-tone keypad selection, enhances assessment methodology by increasing efficiency of data collection and minimizing patient completion errors.
- An IVR version of the POMS has not been previously published.

Objective

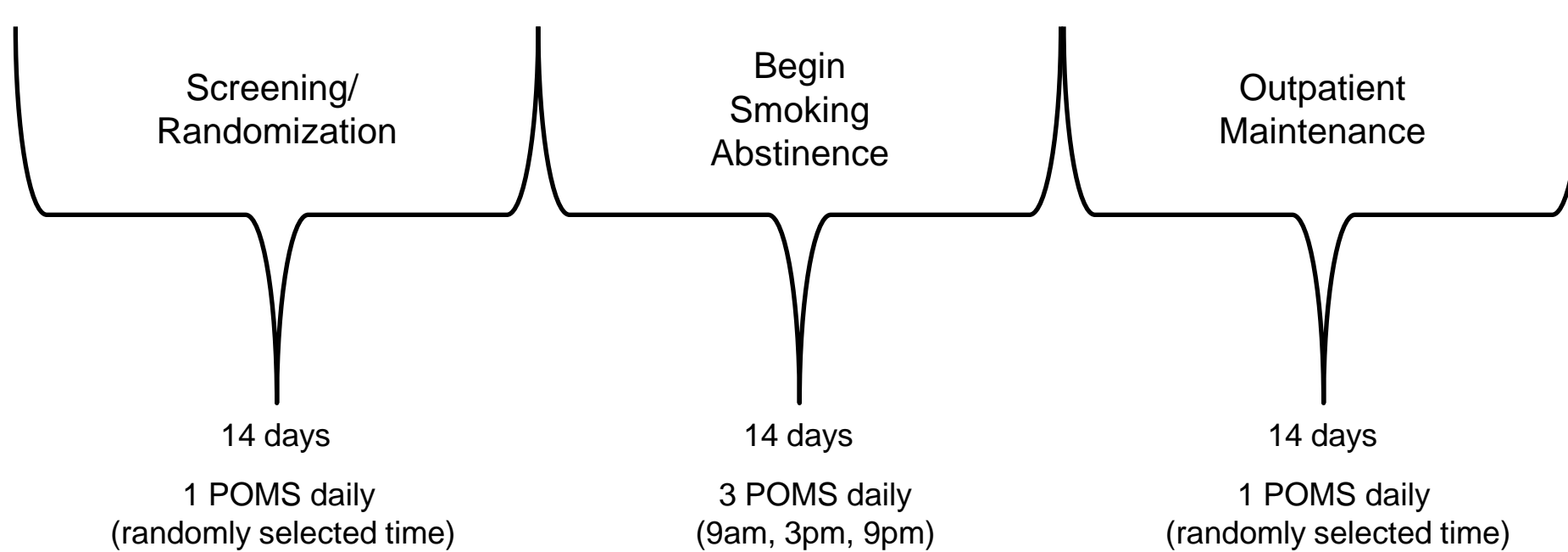
- The objective of this study was to examine the psychometric properties of the IVR POMS and compliance associated with an outbound calling procedure.

Subjects

- 87 subjects (32 females and 55 males) were selected for this analysis.
- Subjects were between 18 and 75 years of age. Females average age=34.9 years (range= 20-72), Males average age=34.5 years (range=19-60).
- Subjects were current cigarette smokers scoring >5 on the Fagerström Test for Nicotine Dependence.
- Subjects had no current or past history of major Axis I or II disorder as determined by the Structured Clinical Interview for DSM-IV (SCID). The SCID-I and SCID-II were both performed. Furthermore, for inclusion, subjects needed to score a 0 on items 1 and 2 (Apparent and Reported Sadness, respectively) on the Montgomery-Åsberg Depression Rating Scale^{III} (MADRS).
- Subjects had no current or past history of suicidal ideation or suicidal behavior as determined by the Columbia Suicide Severity Rating Scale (C-SSRS)^{IV}.
- All assessments were administered by experienced, trained staff.

Methods and Design

- Study enrollment was part of a single-site, 1:1 randomized, double-blind, placebo-controlled study with a 12-week treatment period for smoking cessation. The design included a two-week outpatient baseline period, two weeks of inpatient treatment, and outpatient treatment for the remaining weeks.
- Subjects were enrolled in sequential cohorts of 15-20 every four weeks.
- Subjects completed the IVR POMS in both outpatient and inpatient phases of the study.
- As outpatients, subjects completed the IVR POMS once daily. Each subject provided a personal contact telephone number for the IVR system to initiate outbound calls. These automated calls served as a prompt for subjects to complete their daily IVR POMS, and were randomly generated between 9am and 9pm to collect diverse sampling of their mood data. Subjects could not complete their IVR POMS prior to this outbound call. Furthermore, to increase compliance, automated “reminder” calls were made to subjects who did not complete their IVR POMS within one hour of receiving their initial automated telephone call.
- As inpatients, IVR POMS were completed three times daily, at equally spaced, fixed intervals.
- As illustrated in the figure below, data analysis for this research was restricted to two weeks before inpatient, two weeks inpatient, and two weeks immediately following inpatient.



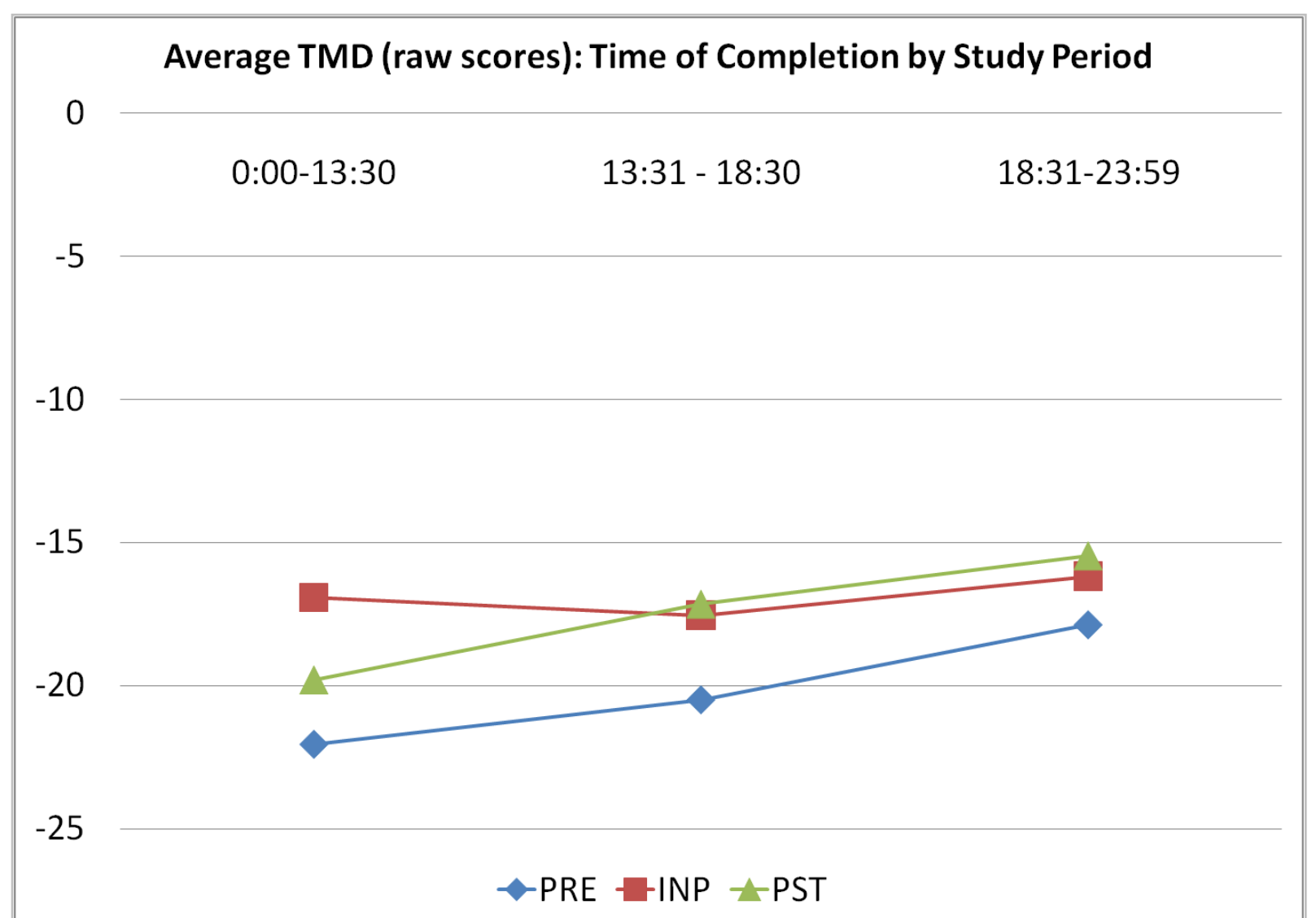
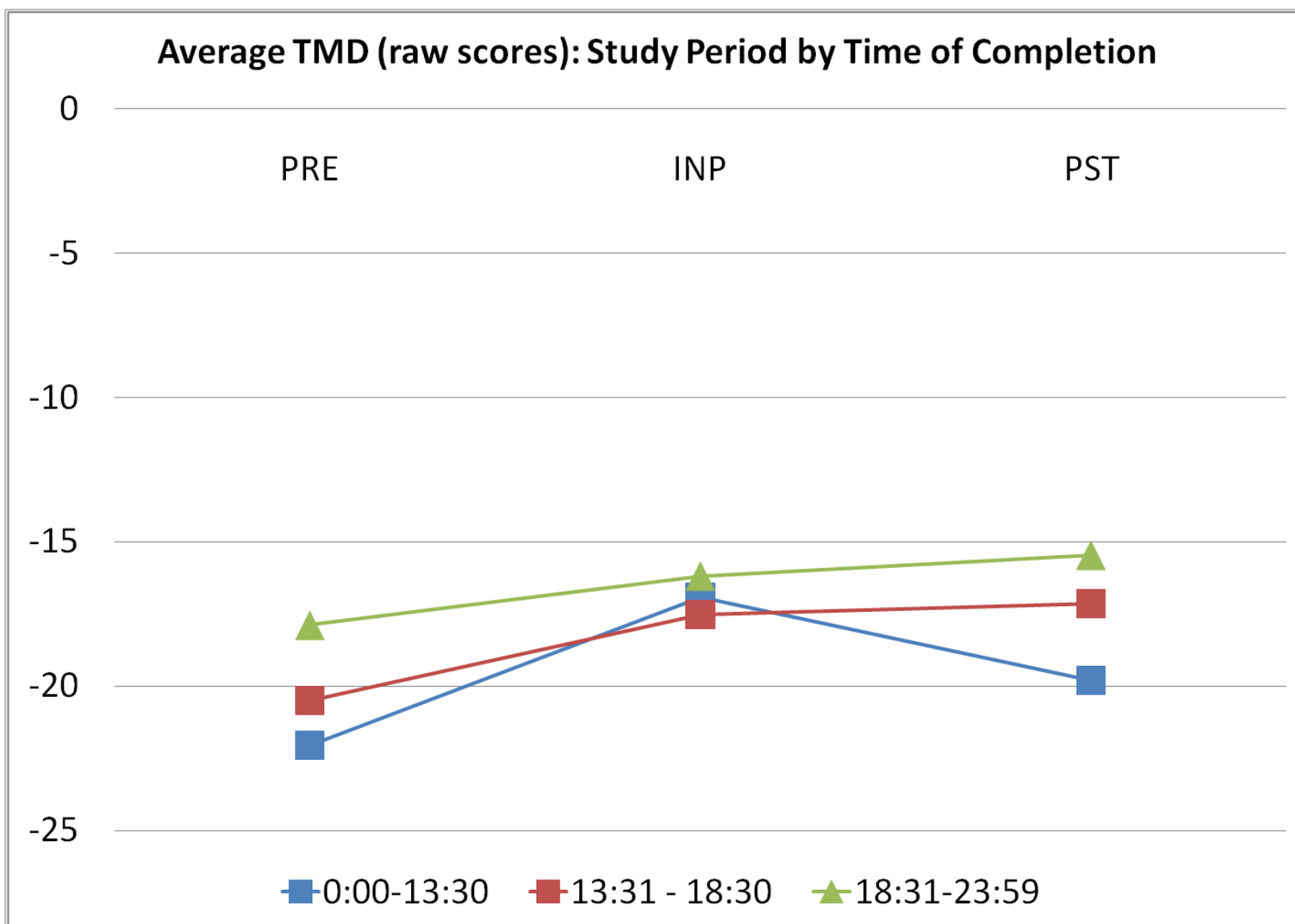
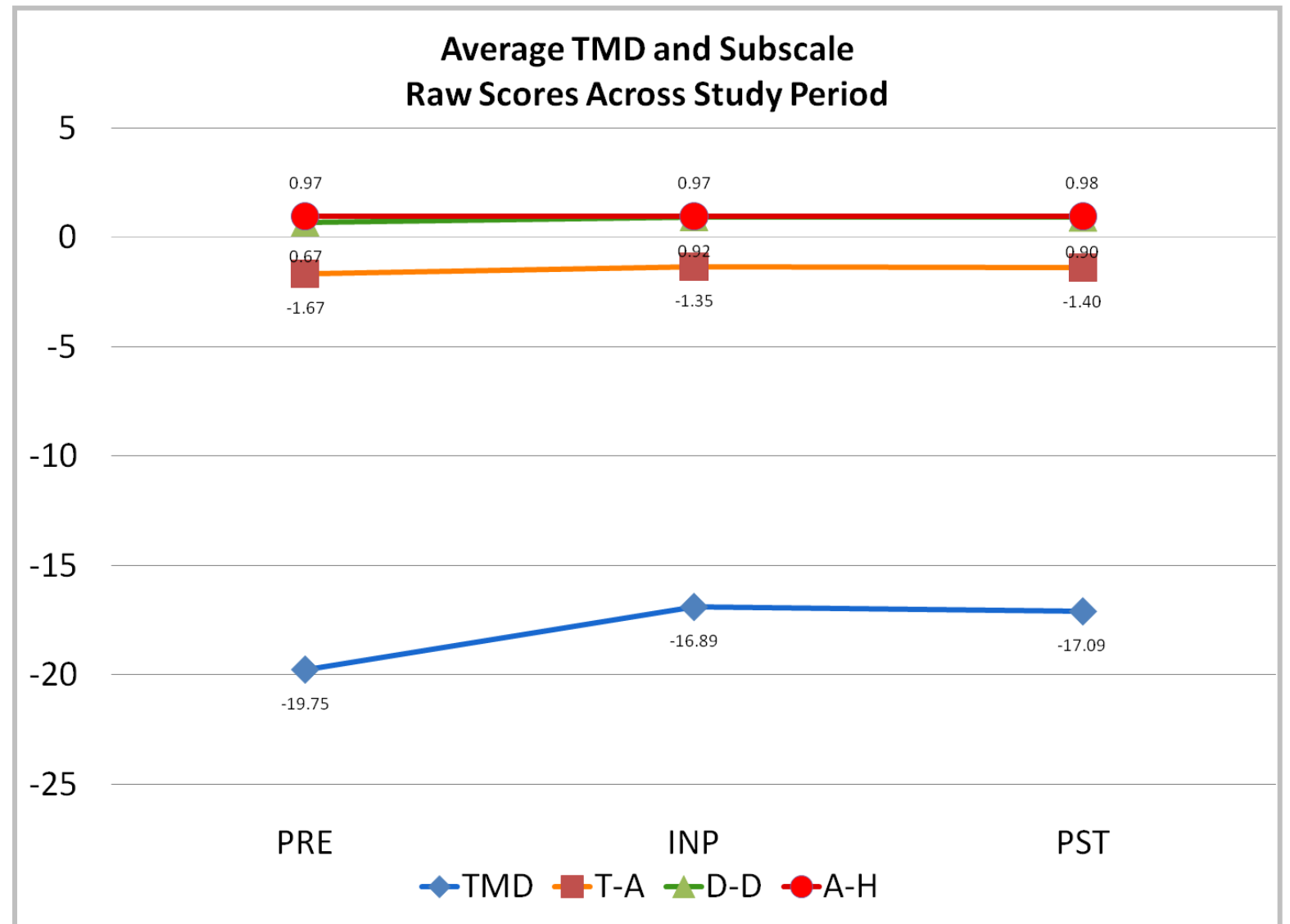
- The 65-item POMS was adapted to IVR. The system read each item aloud to the subject, and prompted a numeric response corresponding to the anchors descriptors. Subjects were allowed to change any responses by using the keypad to navigate through the items.
- At randomization, subjects were provided detailed written instructions for IVR completion of the POMS, and were also given an opportunity to practice before entering “live” data.
- POMS total score and subscale scores examined for this analysis were:
 - Total Mood Disturbance (TMD; all 65 items)
 - Three selected subscales:

Anger/Hostility (A-H)	Tension/Anxiety (T-A)	Depression/Dejection (D-D)
Angry	Tense	Unhappy
Peeved	Shaky	Sorry
Grouchy	On edge	Sad
Spiteful	Panicky	Blue
Annoyed	Relaxed	Hopeless
Resentful	Uneasy	Unworthy
Bitter	Restless	Discouraged
Ready to Fight	Nervous	Lonely
Rebellious	Anxious	Miserable
Deceived		Gloomy
Furious		Desperate
Bad-tempered		Helpless
		Worthless
		Terrified
		Guilty

- IVR POMS total and subscale scores were automatically computed in real time.
- A unique feature of the WCT IVR system was generating alerts via email directly to site staff when:
 - a) any subjects’ individual total or subscale score exceeded a pre-determined threshold and/or
 - b) the subject was not compliant in completing their POMS
- All incoming email alerts were reviewed within 48 hours (most were reviewed the next day), and action taken by site staff ranged from ongoing patient monitoring or brief contact with the subject, to psychiatric review by the PI or designee.

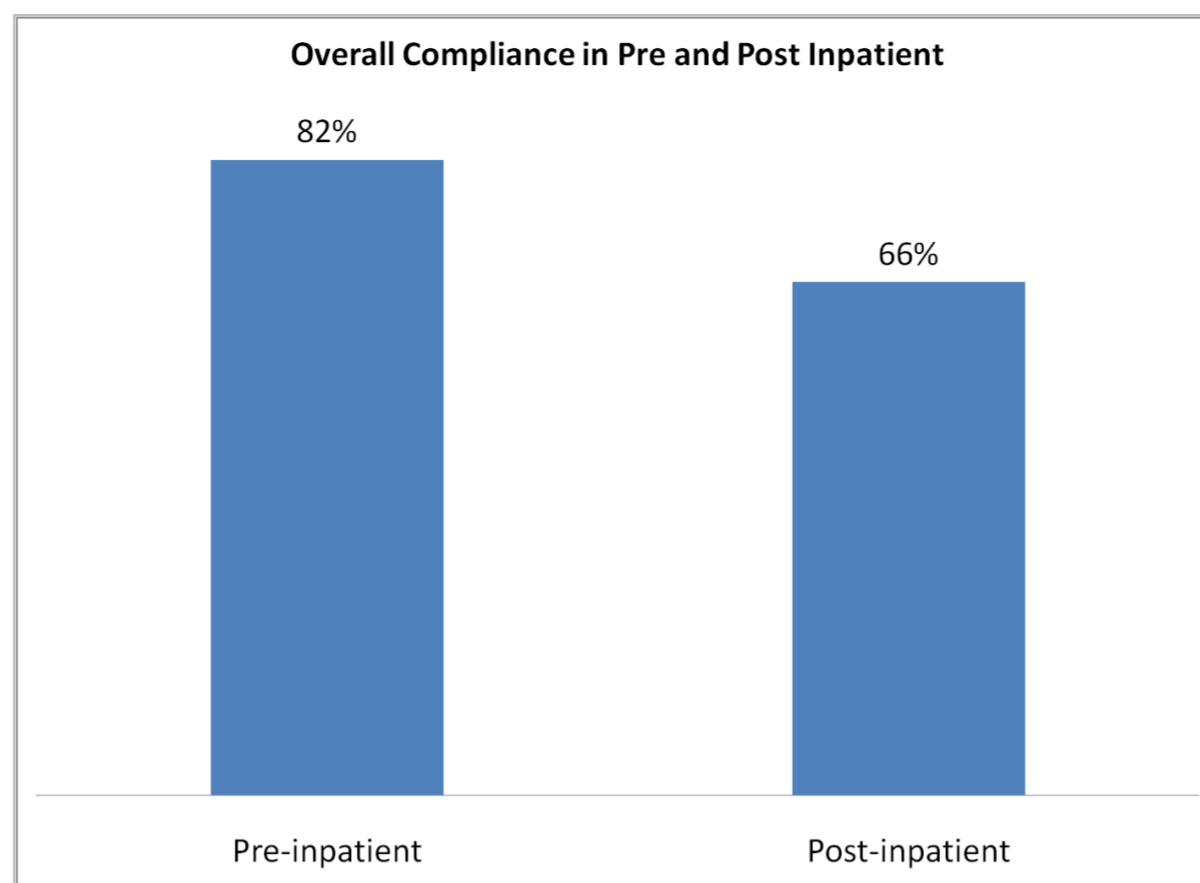
Results

- Total Mood Disturbance (TMD) score, Tension-Anxiety (T-A), Depression-Dejection (D-D), and Anger-Hostility (A-H) subscale scores were averaged for each subject. One-way ANOVA's showed no significant differences among the POMS scores when compared across the three time periods.

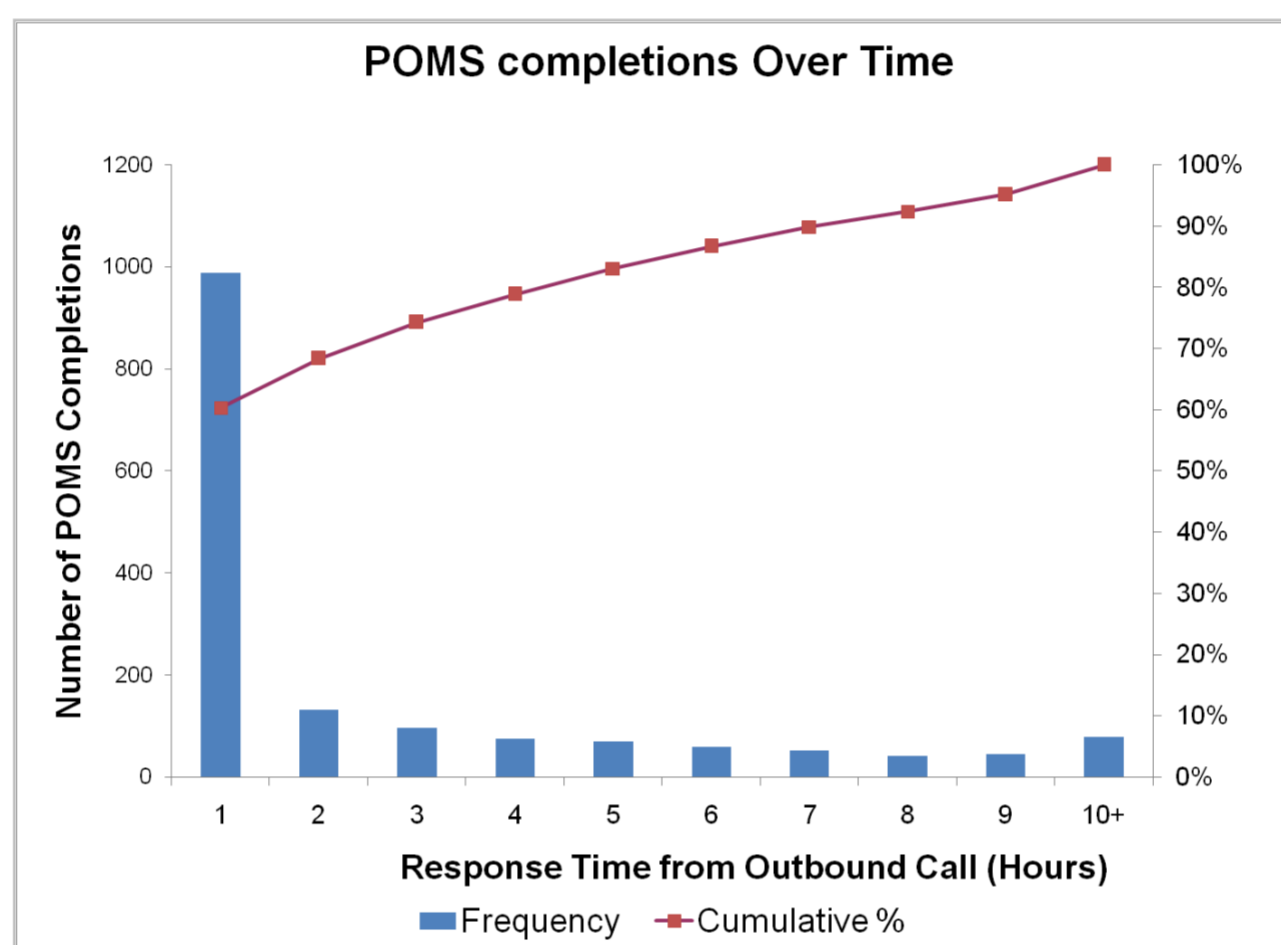


- TMD scores were grouped by study period (Pre-inpatient, Inpatient, and Post-Inpatient) and time of completion (0:00-13:30, 13:31-18:30, and 18:31-23:59). Averages of these groups were analyzed in comparison to one another.
- There were no statistical differences in either analysis across all groups. However, most groups showed more symptomology later in the day.

Results (cont)



- Overall compliance with IVR POMS was 82% and 66% in Pre-Inpatient and Post-Inpatient, respectively.
- Furthermore, of all POMS completions, the figure below shows that once the IVR makes contact, 60% (988 out of 1638) of subjects complete within 1 hour, 68% (132 out of 1838) within 2 hours, etc.



Conclusions

- IVR administration of the POMS is an effective data collection method for inpatient and outpatient clinical trials.
- IVR POMS shows relatively stable mood across in/outpatient status, as well as the relative utility of once daily versus multiple administrations. In other words, daily administration is as efficient as three times daily, suggesting that subjects accurately summate their mood state over 24 hours.
- Compliance with IVR POMS appears to decrease with time, but the cause of this decrease appears unrelated to POMS scores. This suggests the need for additional prompting as the trial progresses.

References

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