

# Remote Clinical Assessments: A Powerful Tool For Psychiatric Drug Trials

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## INTRODUCTION

Recent technological advances as well as increased availability and affordability of high-speed connections have made videoconferencing (VC) a viable option for interacting with patients remotely. As a tool in clinical research, VC makes it possible to use Remote Centralized Raters to improve the efficiency of psychiatric trials. The use of Remote Centralized Raters to administer primary outcome measures of a trial reduces variability by significantly decreasing the number of raters involved (e.g., 8-10 vs. 60-75 raters). Remote Centralized Raters can be rigorously trained and calibrated to a degree not logistically feasible with a larger group of raters at geographically diverse study sites. The separation of Remote Centralized Raters from the study site also eliminates the pressure to enroll patients or inflate baseline scores to qualify subjects. Remote Centralized Raters are also blinded to study visit number, which reduces expectancy bias. VC has a long history in clinical care and has recently been used in several clinical trials. Concerns regarding the feasibility of using VC and Remote Centralized Raters, problems with subject acceptance, and negative effects on outcome reliability have simply not been substantiated. This year, MedAvante is supporting its first ongoing trial in Russia. In the United States and globally, MedAvante has conducted over 15 clinical trials using VC and Remote Centralized Raters, and has completed over 45,000 scale administrations. After five years, MedAvante has clearly demonstrated that the vast majority of subjects are comfortable with VC assessments, reliability of psychiatric ratings across Remote Centralized Raters is very high, and assessments conducted via VC by Remote Centralized Raters maintain the high level of validity needed for signal detection.

## Patient Acceptance and Feasibility

### Primary Care Patients in Psychiatric Clinical Trials: A Pilot Study Using Video Conferencing<sup>1</sup>

J.B.W. Williams, A.Ellis, A.Middleton, K.A. Kobak

**Methods:** 45 patients at two primary care clinics screening positive for major depression, panic, or generalized anxiety were enrolled and given a diagnostic interview via VC. They were provided treatment as usual and interviewed weekly by VC with a symptom severity scale.

**Results:** 36 (80%) of the patients completed the six-week study. 94% reported they would participate again, 96% felt comfortable communicating via VC in general, and 94% said they were able to satisfactorily communicate their feelings via VC.

Patients with depression or anxiety agreed to be interviewed by VC, felt comfortable with VC, and reported that they could satisfactorily communicate their feelings via VC.

## Reliability of Outcomes

### Development and Reliability of a Structured Interview Guide for the Montgomery-Asberg Depression Rating Scale (SIGMA)<sup>2</sup>

J.B.W. Williams and K.A. Kobak

**Methods:** 51 participants with a mood disorder diagnosed according to DSM-IV criteria were included. 162 test-retest interviews were conducted, each patient was interviewed twice, once by each rater. Of the 81 pairs of interviews, 30 pairs were done using two face-to-face interviews, 30 pairs were done using one face-to-face and one VC interview, and 21 pairs were done using one face-to-face and one telephone interview.

**Results:** The intraclass correlation (ICC) for total score between raters conducting MADRS interviews using the SIGMA was  $r=0.93$  across all 3 methods. There was no statistically significant difference between the correlations of pairs of SIGMAs administered in different ways (face-to-face, VC, telephone interview). There was no significant difference between the mean MADRS scores obtained by the first interviewer and the second interviewer. See Table 1.

The reliability of remote administration of the MADRS using the SIGMA, by both telephone and videoconference is equivalent to face-to-face interviews.

**Table 1** Intraclass Correlations Between Raters on individual items of the Montgomery-Asberg Depression Ratings Scale, by Mode of Administration

	All modes of administration <sup>b</sup> (n=81)	Intraclass correlation <sup>a</sup>		
		Telephone v. face-to-face (n=21)	Video v. face-to-face (n=30)	Face-to-face v. face-to-face (n=30)
Apparent sadness	0.82	0.80	0.80	0.84
Reported sadness	0.93	0.84	0.84	0.86
Inner tension	0.75	0.80	0.72	0.75
Reduced sleep	0.86	0.77	0.86	0.94
Reduced appetite	0.85	0.83	0.86	0.87
Concentration difficulties	0.85	0.68	0.85	0.95
Lassitude	0.74	0.67	0.72	0.82
Inability to feel	0.79	0.86	0.79	0.76
Pessimistic thoughts	0.71	0.61	0.69	0.78
Suicidal thoughts	0.89	0.92	0.86	0.93
Total	0.93	0.90	0.95	0.93

a. All correlations significant at  $P < 0.001$ .  
b. Independent interviews, six raters.

## Validity

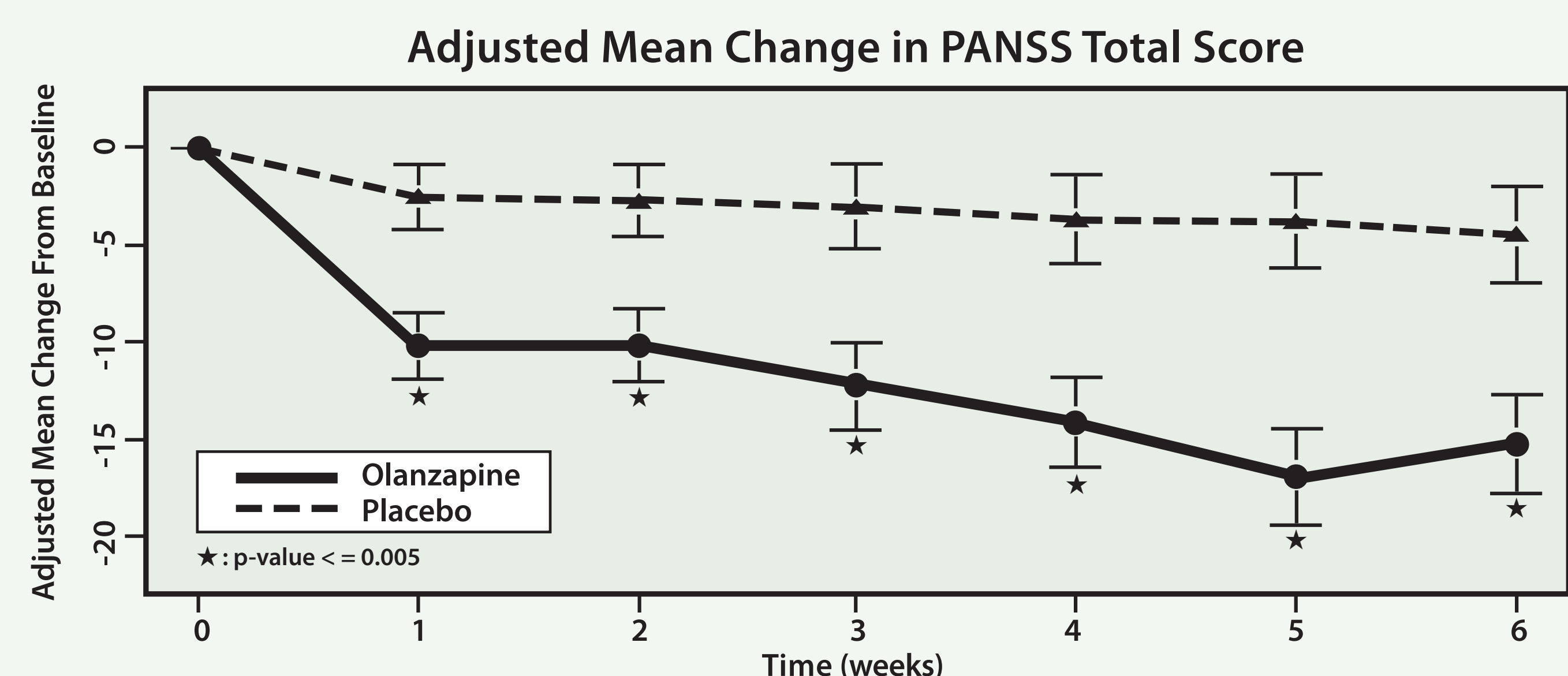
### Use of Remote Centralized Raters Via Live 2-Way Video in a Multicenter Clinical Trial for Schizophrenia<sup>2</sup>

J. Shen, K.A. Kobak, Y. Zhao, M. Alexander, J. Kane, MD

**Methods:** 313 patients from 32 sites, aged 18 to 65 years, with an acute exacerbation of schizophrenia were included and randomly assigned to 6 weeks' treatment with active comparator (olanzapine) or placebo. Subjects were evaluated weekly by a centralized rater using the PANSS. Overall, 1993 remote PANSS assessments were completed by centralized raters (n=18) during the study.

**Results:** A significant difference in changes from baseline in PANSS total score was found between active comparator and placebo starting at week 1, which continued throughout the study. See Figure 1.

The mean PANSS change was significantly different ( $p < .01$ ) between the active comparator (-15.2) and the placebo group (-4.4) for remotely administered assessments.



**FIGURE 1.** Adjusted Mean Change in PANSS total score by study week (analysis of covariance).

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#### References:

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