Site-Randomized Controlled Trial of a Combined Cognitive Behavioral Therapy and a Medication Management Algorithm for Treatment of Depression among Youth living with HIV in the United States

Larry K. Brown[1], Miriam Chernoff [2], Betsy D. Kennard[3], Graham J. Emslie[3], David E. Shapiro[2], Kathryn Lypen[4], Sarah Buisson[4], Adriana Weinberg[5], Laura B. Whiteley[1], Shirley Traite[2], Chelsea Krotje[6], Lauren Harriff[6], and Ellen Townley[7] for the IMPAACT 2002 team

[1]Rhode Island Hospital; Alpert Medical School of Brown University, Providence, RI, USA, [2]Center for Biostatistics in AIDS Research, Harvard T.H. Chan School of Public Health, Boston, MA, USA, [3]University of Texas Southwestern Medical Center, Dallas, TX, USA, [4]FHI 360, Durham, NC USA, [5]University of Colorado Denver Anschutz Medical Center, Aurora, CO, USA, [6]Frontier Science Foundation, Amherst, NY, USA, [7]National Institute of Allergy and Infectious Diseases, National Institute of Health, Rockville, MD, USA

BACKGROUND

U.S. youth living with HIV (YLWH) have high rates of depression. Studies suggest that manualized, measurement-guided treatment is more efficacious than usual care. This study tests this treatment model for depression among U.S. YLWH, ages 12- 24 years in care at sites of the International Maternal Pediatric Adolescent AIDS Clinical Trials Network.

METHODS

Using restricted randomization, 14 participating sites were assigned to either a 24-week, combination cognitive behavioral therapy and medication management algorithm (COMB-R arm) tailored for YLWH or to Enhanced Standard of Care (ESC arm), which provided standard psychotherapy and medication management. Primary outcome measures included depressive symptoms evaluated using the 19-item Quick Inventory for Depression Symptomatology Self-Report (QIDS-SR) collected through audio computer-assisted interviews, HIV viral load, and CD4 count. Eligibility included diagnosis of nonpsychotic depression and current depressive symptoms (score ≥ 11 on clinician-rated QIDS-C). Arm comparisons used t-tests on site-level means. Sensitivity analyses were conducted with Wilcoxon rank sum tests.

TABLE 1. Site Demographic Characteristics at Baseline (N=13)

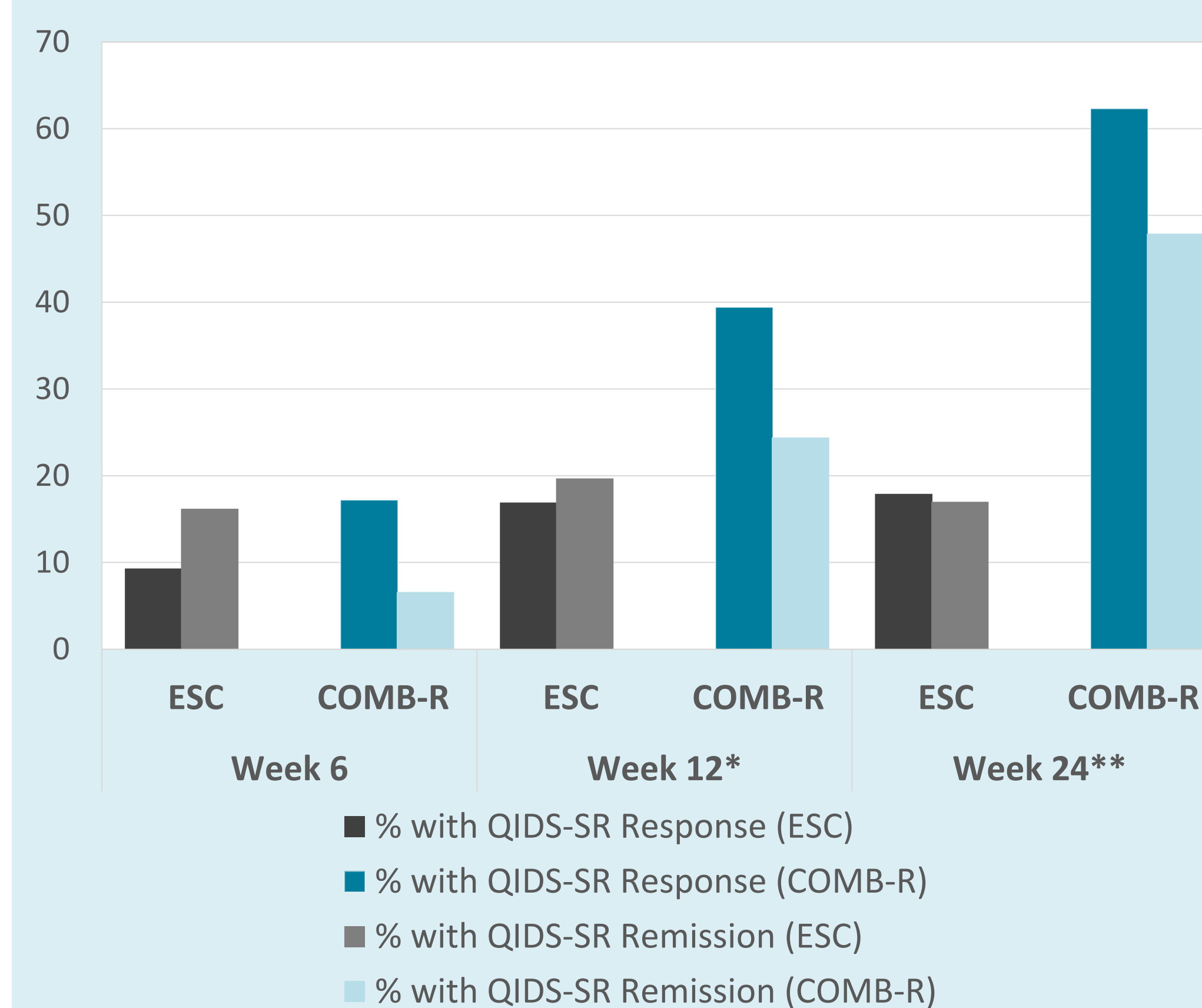| Site-Level Characteristic (% or mean)	Mean Across Sites
% Male	44.7
Age at Entry (years)	21.41
% Black	60.7
% Perinatal Transmission	52.9
% with Severe Depression (QIDS-SR)	46.6
HIV viral load (log10 copies/ml)	2.18
% with Viral Load Suppression	57.5
CD4+ count (cells/uL)	693
% on Psychiatric Medications	48.3

RESULTS

Six COMB-R (one site withdrew) and seven ESC sites enrolled 156 YLWH, with a median of 13 per site (range 2-16). At baseline there were no significant differences between arms on demographic factors, severity of depression, or HIV status (see Table 1 for sample characteristics).

At Week 24, youth at the COMB-R sites, compared to ESC sites (See Figures 1 and 2):
- Reported fewer depressive symptoms, (mean QIDS-SR score 6.7 vs. 10.6, difference -3.9, 95% CI -6.8, -0.9, p=0.01),
- Greater proportion with a treatment response (more than 50% reduction in QIDS-SR score from entry; 62.3% vs. 17.9%, p<0.001),
- Greater proportion in remission (QIDS-SR score less than or equal 5; 47.9% vs.17.0%, p=0.01).

The site mean viral load and CD4 level were not significantly different between arms at Week 24 (Figure 3). The proportions of participants with psychiatric hospitalization or suicide attempt were not significantly different between arms. Non-parametric sensitivity analyses largely confirmed these findings (data not shown).

FIGURE 1. Response and Remission over 24 Weeks

- % with QIDS-SR Response (ESC)
- % with QIDS-SR Response (COMB-R)
- % with QIDS-SR Remission (ESC)
- % with QIDS-SR Remission (COMB-R)

* Mean difference between ESC and COMB-R sites for QIDS-SR Response at Week 12 (p = 0.06)
** Mean difference between ESC and COMB-R sites was statistically significant for QIDS-SR Response (p < 0.001) and Remission (p = 0.01) at Week 24
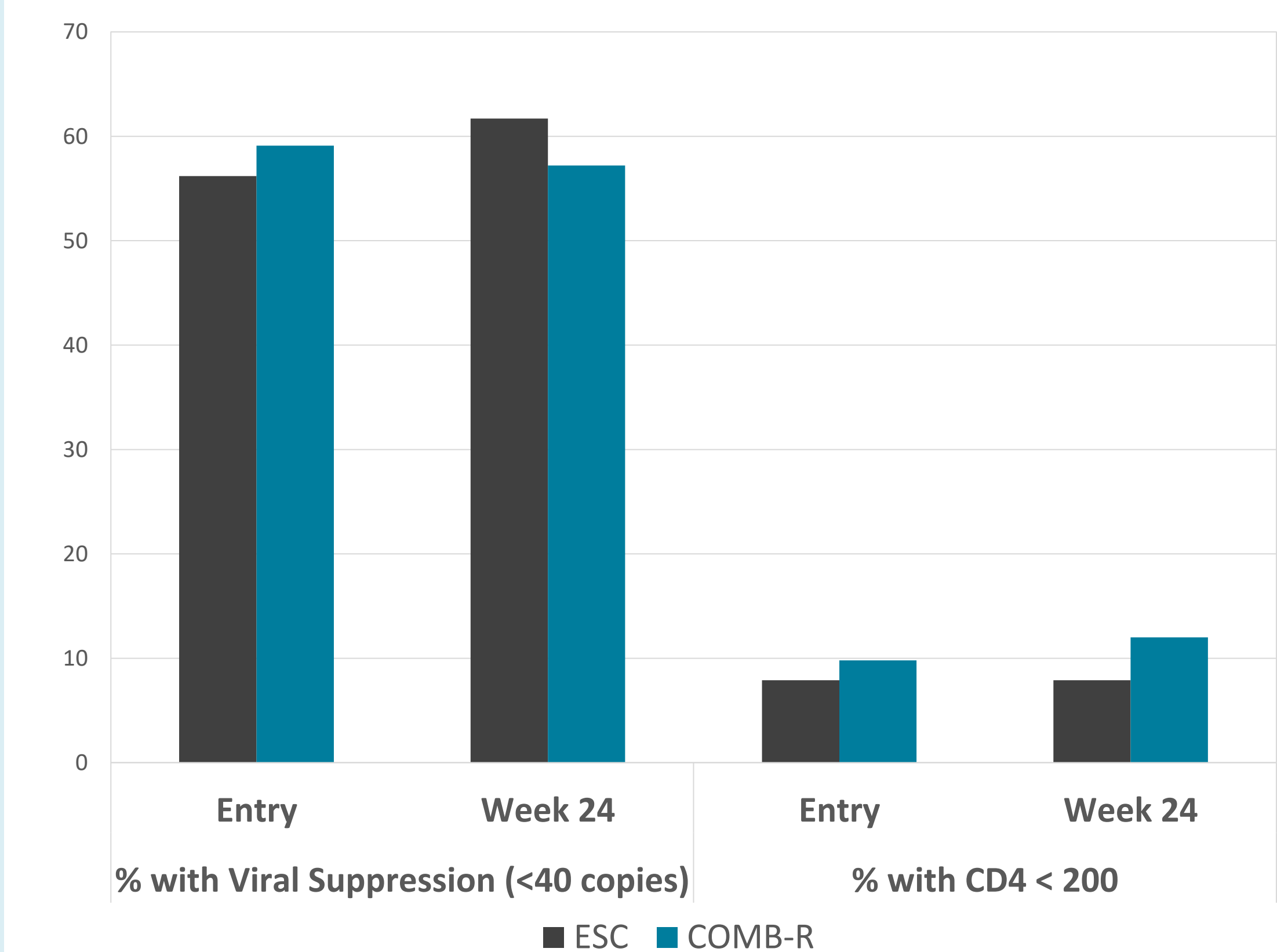
FIGURE 2. QIDS-SR Over 24 Weeks
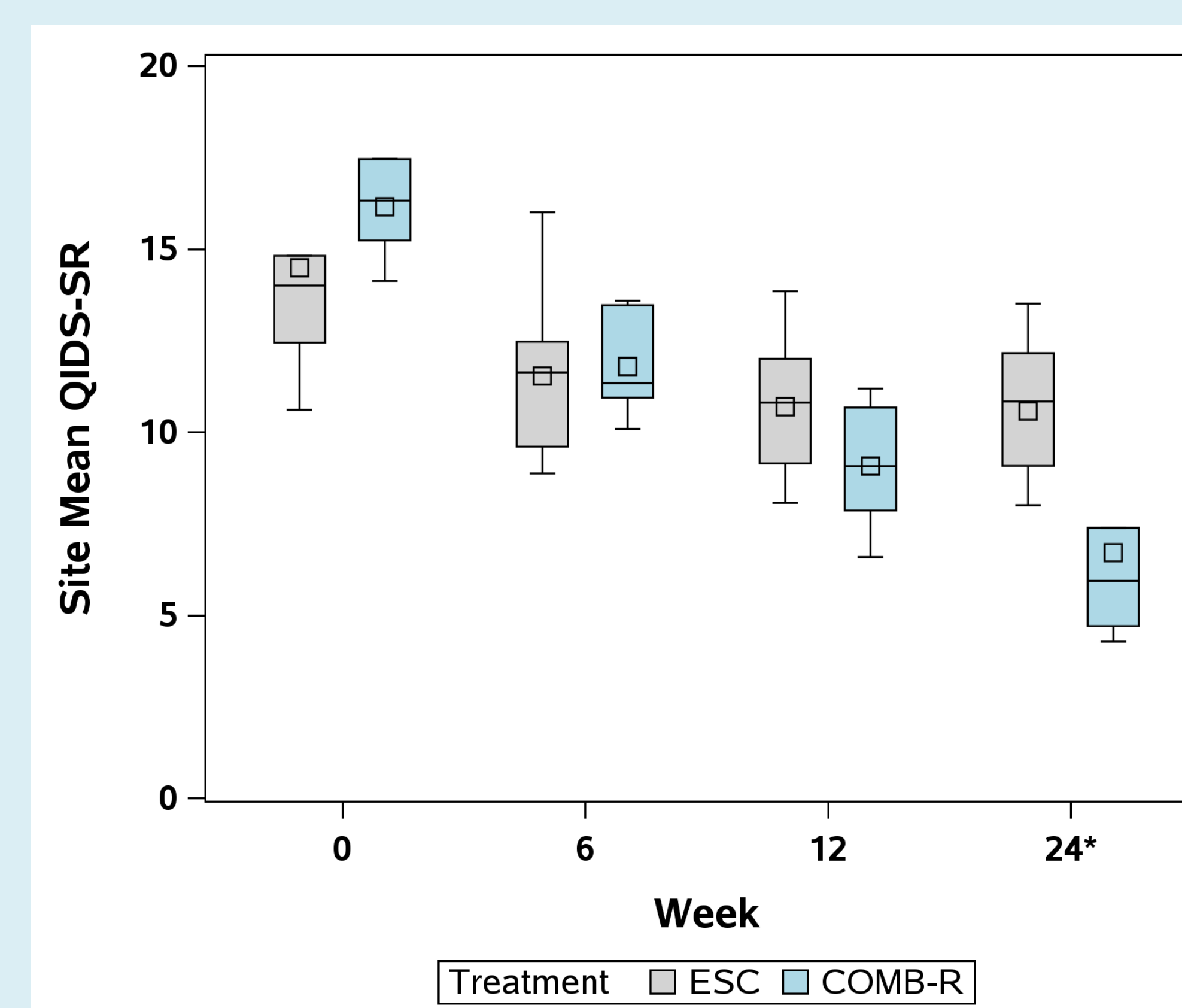
* Mean difference between ESC and COMB-R sites was statistically significant for QIDS-SR at Week 24 (p = 0.01)

Note: Box plots represent median, mean (square) and interquartile ranges for site means.

FIGURE 3. Viral Suppression and CD4 at Entry and Week 24 (COMB-R vs. ESC)

ESC   COMB-R

CONCLUSIONS

A 24-week manualized, measurement-guided psychotherapy and medication management algorithm tailored for YLWH was more effective in reducing depressive symptoms than standard care at HIV care clinics.