

IMPAACT 2002

Combined Cognitive Behavioral Therapy and a Medication Management Algorithm for Treatment of Depression among Youth Living with HIV in the United States

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CC Meeting*

Participating Sites

- CRS 5114, Bronx-Lebanon Hospital Center
- CRS 5055, Children's Diagnostic and Treatment Center
- CRS 5030, Emory University School of Medicine
- CRS 5052, The University of Colorado
- CRS 6501, St Jude Children's Research Hospital
- CRS 5040, Stony Brook University Medical Center
- CRS 5013, Jacobi Medical Center Bronx
- CRS 5048, The University of Southern California LA
- CRS 3801, Texas Children's Hospital
- CRS 5092, Johns Hopkins University School of Medicine
- CRS 5083, Rush University Medical Center
- CRS 5112, David Geffen School of Medicine at UCLA
- CRS 4601, UCSD

Background and Rationale

- Medication algorithms and cognitive behavioral therapy (CBT) are effective for the treatment of depression.
- IMPAACT 2002 builds on a combined CBT and medication algorithm (COMB) found efficacious in ATN 080:
 - Test the “core components” of COMB with all essential elements of collaborative, stepped care but is adapted for easy dissemination (COMB-R).
 - Examine the impact of COMB-R on biological and medical adherence outcomes with a larger sample with greater power to detect impacts.
 - Examine moderators of COMB-R impact, such as gender and initial level of depression.

(APA) APA. *Practice Guideline for the Treatment of Patients with Major Depressive Disorder, Third Edition*. 2010.

Kennard, B., Brown, L., Hawkins, L., Risi, A., Radcliffe, J., Emslie, G., ... the Adolescent Trials Network for HIV/AIDS Interventions, S. (2014). Development and Implementation of Health and Wellness CBT for Individuals with Depression and HIV. *Cognitive and Behavioral Practice*, 21(2), 237–246. <http://doi.org/10.1016/j.cbpra.2013.07.003>

Study Objectives

Primary Objectives - To evaluate whether:

- Cognitive Behavioral Therapy and Medication Management Algorithm (COMB-R) is associated with improved depression outcomes at 24 weeks, compared to Standard Care.
- COMB-R is associated with improved biological measures of health over 24 weeks (CD4 cell numbers and copies of HIV RNA in plasma) compared to Standard Care.

Secondary Objectives - Examine:

- Adherence for HIV and depression treatment.
- Maintenance of depression impact at 48 weeks.
- Moderators of impact: demographic, behavioral, and biological factors
- Behavioral risk outcomes (alcohol/drug use; sex-risk behaviors)
- Use of therapy and medication at all sites.
- Adverse Events - psychological hospitalizations and suicide attempts

Study Schema

Design: Multi-site, two-arm, cluster-randomized study

Study Population: HIV-infected youth, ages 12 to 24 years, diagnosed with nonpsychotic depression (structured clinician rating)

- Prior or current treatment is not an exclusion criteria.

Sample Size: 13 US sites were randomized, to enroll 156 participants

Study Intervention: Sites assigned to COMB-R or Enhanced Standard Care (ESC)

Study Duration: Accrual will be approximately 24 months. Participants will complete assessments to 48 weeks.

Enhanced Standard of Care: Online training in depression assessment/monitoring, supportive psychotherapy, and use of antidepressants.

Health and Wellness CBT Content

(tailored for relevant issues: stigma, trauma, medical care)

	Treatment Stage	Frequency	Month
I.	Motivation to engage; psychoeducation	Weekly	1
II.	Reduce symptoms with core skills; identify strengths	Weekly	2
III.	Wellness skills—relapse prevention	Every other week	3, 4
IV.	Consolidate gains	Monthly	5, 6

Medication Algorithm

- Framework, not “restrictive,” not a specific medication
- Strategy based on measured care/patient response

Stage	Treatment	Medication Options
Stage 0	No medication	N/A
Stage 1	SSRI Mono Therapy	Increase dose, or augment partial responses (e.g. lithium, bupropion)
Stage 2	2 nd SSRI	Increase dose, or augment partial responses
Stage 3	Non-SSRI	Increase dose, or augment partial responses
Stage 4	Combination Treatment	Two antidepressants or antidepressant plus lithium

IMPAACT 2002: Key Milestones

- **August 2016:** Protocol Version 1.0 released to sites
- **November 2016:** Sites randomized to ESC or COMB-R arm
- **December 2016:**
 - Protocol-specific online training completed
 - Training material (slides and video) posted to website
 - Study opened to accrual
- **January-April 2017:** 12 out of 13 sites were activated to initiate study implementation
- **March 2017:** First participant enrolled

Enrollment & Implementation Update

- 45 potential participants contacted and approached for eligibility determination
 - ~ 25% did not consent to formal screening
 - ~ 30% not eligible (generally because symptoms too mild)
- Total accrual of 19 participants as of 21 May 2017
 - COMB-R: n=8
 - ESC: n=11

Each site is expected to enroll approximately 12 participants

- Implementation
 - Monthly Monitoring Calls with H&W CBT Therapists & Site Prescribers
 - FAQ list being constructed

Implementation Issues

- **Randomization by site unusual IMPAACT and required:**
 - Similar COMB-R and ESC consent forms to reduce perceived difference in “burden” by condition
 - Pre-study surveys of patient characteristics & volume
 - Random selection of “blocks” of patients, rather than approaching patients when convenient
- **Two stage consent process**
 - Screening (one hour mental health evaluation)
 - Enrollment
- **At COMB-R sites - Depression self-report score shared with site clinician and Protocol team in timely fashion.**
- **At COMB-R sites- challenging to have part-time and busy clinicians available for monthly supervision calls.**



Questions?