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## Metropolitan Atlanta Community Adolescent Rapid Testing Initiative: The Impact of Motivational Interviewing and Intensive Case Management on the Psychosocial and Clinical Care Outcomes of Adolescents and Young Adults with HIV

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### Abstract

Early diagnosis and treatment are critical to preventing HIV-related complications and transmission for adolescents and young adults with HIV (AYAWH). The Metropolitan Atlanta Community Adolescent Rapid Testing Initiative (MACARTI) was a single center, prospective, nonrandomized, interventional control group study incorporating motivational interviewing (MI) psychotherapy strategies with community outreach, HIV testing, and intensive case management (CM). This sub-study of MACARTI examined how the MI and CM components influenced psychological distress, proactive coping, HIV/AIDS stress, and HIV stigma in association with HIV disease markers (HIV viral load [VL] and CD4<sup>+</sup> T-cell [CD4<sup>+</sup>] counts). Ninety-eight AYAWH ( $M_{age} = 21.5 \pm 1.8$ , range 18–24) were allocated to either the standard of care (n=49) or MACARTI (n=49) arms and results were compared between these two groups. Baseline and follow-up surveys measured psychological distress, proactive coping, HIV/AIDS stress, and HIV stigma. MACARTI arm assignment was associated with statistically significant reductions in psychological distress ( $p=0.016$ ), HIV/AIDS stress ( $p=0.023$ ), and the use of more reflective coping ( $p=0.016$ ) and strategic planning strategies ( $p=0.001$ ) during the first six months. These results did not remain significant at one-year follow-up but may still provide support for the integration of psychotherapy strategies into HIV identification, linkage, and retention efforts in the future.

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## Keywords

HIV; motivational interviewing; psychological distress; linkage and retention

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The United States (U.S.) HIV epidemic disproportionately affects adolescents and young adults ages 13 to 24 (Centers for Disease Control and Prevention [CDC], 2018a). Adolescents and young adults with HIV (AYAWH) made up 21% of new diagnoses in the U.S. in 2017 (CDC, 2018b) and are the least likely age group to connect to care and attain viral suppression. As such, novel strategies intended to identify, link, and retain AYAWH in medical care are critically needed. Psychological distress and HIV-related stress are linked with numerous barriers to receiving timely medical care and reduced quality of life for people living with HIV (Pakenham & Rinaldis, 2002). Furthermore, HIV stigma is associated with poor linkage, retention, and engagement in care, reduced adherence, decreased HIV testing and condom usage, and loneliness (Mahajan et al., 2008; Dowson, Kober, Perry, Fisher, & Richardson, 2012; Smit et al., 2012; Hubach et al., 2015; Eaton et al., 2015). These findings highlight the need for HIV care identification, linkage, and retention approaches to attend to behavioral health factors in order to optimize clinical outcomes, including strategies that increase proactive coping behaviors and reduce psychological distress, HIV/AIDS stress, and HIV stigma.

The Metropolitan Atlanta Community Adolescent Rapid Testing Initiative (MACARTI) was a pilot single center, prospective non-randomized interventional study of AYAWH that began with a formative phase comprised of conducting focus groups of youth with and without HIV and engagement in ethnographic studies in order to understand testing preferences and discover non-traditional testing venues. MACARTI was developed to identify AYAWH early, link and retain them in HIV care, and increase their adherence to medical treatment by simultaneously addressing developmental, social, psychological, and economic barriers to care. MACARTI exemplifies this multilevel approach by combining non-traditional venue HIV testing, brief psychotherapy informed by motivational interviewing (MI) strategies, and strengths-based case management services (CM).

MI, an evidence-based, person-centered psychotherapy approach that promotes behavior change by resolving ambivalence and strengthening intrinsic motivation, has been shown to enhance positive health-related behavioral change (Hill & Kavookjian, 2012; Konkle-Parker, Erlen, Dubbert, & May, 2012). Based on the transtheoretical model (Prochaska & DiClemente, 1992), MI encourages collaboration, evocation, and autonomy. MI principles include expressing empathy, developing discrepancy, rolling with resistance, and supporting self-efficacy (Miller & Rollnick, 2013). MI is a brief, yet flexible approach that can be delivered in about two to four sessions by providers within a multidisciplinary team and tailored to the needs of diverse populations (Hetema, Steele, & Miller, 2005; Parsons, Golub, Rosof, & Holder, 2007). Brief MI interventions targeting HIV risk behaviors in AYAWH have been shown to improve motivation, depression, and viral loads (Naar-King et al., 2009, 2010). CM services also have been found to increase engagement and retention of ethnic minority AYAWH in care; particularly those that aided in clinic/provider access, housing

assistance, food insecurity, and navigating a complex health system (Johnson et al., 2003; Wohl et al., 2011).

Given the importance of attending to psychological and psychosocial factors in enhancing HIV-associated outcomes, this study aimed to explore how MACARTI influenced associations between psychological distress, proactive coping, HIV/AIDS stress, HIV stigma, and medical outcomes in AYAWH. It was hypothesized that the brief MI-informed therapy and CM components of MACARTI would reduce psychological distress, HIV/AIDS stress, HIV stigma, and support proactive coping. Additionally, it was hypothesized that psychological distress, HIV/AIDS stress, and HIV stigma would be positively associated with viral load and negatively associated with CD4+ count, each of which are key HIV medical outcomes.

## Methods

### Participants

The study included 98 participants. Eligibility requirements for all subjects included being: (1) 18 to 24 years of age; (2) newly diagnosed with HIV (never tested positive for HIV prior to the start of the study); (3) treatment naive (never received HIV medical care); and (4) a first-time enrollee in care at this HIV care clinic. New HIV diagnoses were later confirmed through the various county health departments. Screening and enrollment began in December 2012 and ended in January 2016. During Phase 1 of MACARTI, focus groups comprised of HIV positive and at-risk adolescents and young adults were used to identify the non-traditional HIV testing venues used to recruit MACARTI participants. Although this method more efficiently identified and linked AYAWH to HIV care (Camacho et al., 2017; Murray et al., 2018), a primary aim of the overall study, it prohibited the randomization of the two study arms as the SOC participants were referred differently (from community HIV volunteer organizations).

### Study Procedures

Participants were enrolled in the Standard of Care (SOC) or MACARTI intervention arm (49 in each arm; see Table 1 for demographics). SOC participants were enrolled via traditional referrals from community HIV volunteer organizations and received HIV care in accordance with established practice standards. Of the 62 SOC participants recruited via flyers and in-person solicitation after presenting for enrollment at the clinic, 49 were new to HIV care and subsequently enrolled. Following linkage and engagement in HIV care, SOC participants were given access to standard CM (referrals to housing, food assistance, and transportation) and/or psychotherapy services in a co-located mental health clinic, though their participation was self-initiated or by referral following engagement in care.

MACARTI participants were enrolled via the non-traditional HIV testing venues identified in the first phase and were recruited by study staff following rapid initial HIV testing in these settings (e.g., clubs, bars, libraries). Prior to testing, participants received brief MI-focused intervention to plan for test results. Participants testing negative were provided education on HIV prevention strategies while participants testing positive were offered

emotional support, CM, and accelerated enrollment assistance linking them to HIV care. Once linked, they received upfront MI-informed counseling sessions and intensive case management services. Of 435 total participants tested, 49 received a positive HIV test result and were assigned to the MACARTI arm.

MACARTI participants received a minimum of five, 30–45 minute, MI informed therapy sessions administered by either a clinical social worker or psychology postdoctoral fellow under the supervision of a licensed psychologist. These sessions were provided prior to and concurrent with medical treatment and coincided with their enrollment, 30-day, 90-day, 6-months, and 12-month study visits. MACARTI sessions focused on helping participants adapt to the psychological sequela following a new HIV diagnosis, exploring ambivalence in making positive health behavior changes, developing a manageable and realistic plan that follow best practices for managing HIV medical care, and adopting a way of life to sustain positive, long-term health behaviors. The agenda for the sessions was set by participants based on current concerns and centered on skills practice in exploring ambivalence about treatment, improving communication, developing, assessing progress, and revising goals as needed, empowering participant's strategies for goal attainment, and reinforcing self-efficacy. MACARTI participants were encouraged to participate in additional sessions as needed as goals changed or were achieved. Approximately 10% of these participants elected for additional sessions. A detailed account of the MACARTI methodology is presented by Camacho-Gonzalez et al. (2017) and Murray et al. (2018).

The MACARTI outreach coordinator also served as a patient navigator, providing CM before, during, and between study visits. This coordinator maintained frequent contact through various outreach methods (phone calls, texts, in-person visits) and facilitated attendance to medical appointments, provided guidance on maneuvering through a complex health system, and connected them to services such as housing, transportation, health insurance programs, food assistance, etc.

At baseline, 1-, 3-, 6-, and 12-month time intervals, participants completed surveys via audio computer-assisted self-interviewing (ACASI) that included measures of psychological distress, proactive coping, HIV/AIDS stress, and HIV stigma. Researchers also collected viral load, CD4<sup>+</sup> T-cell count, and appointment attendance data from the medical record. The Emory University Institutional Review Board approved this protocol.

### Measures of Psychological and Psychosocial Variables

**Psychological Distress.**—The Kessler Psychological Distress Scale (K10) (Kessler et al., 2002) consists of 10 items, measuring frequency of symptoms of anxiety and depression on a five-point Likert scale ranging from 1 (*none of the time*) to 5 (*all of the time*), with higher scores reflecting greater perceived distress and severity of symptoms. A score of 20 or above is suggestive of the presence of a mental disorder (State of Victoria, Department of Human Services, 2002). The K10 has good internal consistency with a Cronbach's alpha of 0.93 (Kessler et al., 2003). The current sample's alpha was 0.93.

**Proactive Coping.**—The Proactive Coping Inventory (PCI) is a 55-item measure designed to assess diverse aspects of proactive coping and consists of seven subscales: proactive

coping, preventive coping, reflective coping, strategic planning, instrumental support seeking, emotional support seeking and avoidance coping. Coping behavior statements are rated on a four-point Likert scale ranging from 1 (not at all true) to 4 (completely true), with higher scores reflecting greater agreement with the coping behavior. The PCI and its subscales have high internal consistency (e.g., Cronbach alphas range from 0.71 to 0.85) (Greenglass, Schwarzer, Jakubiec, Fiksenbaum, & Taubert, 1999). The current sample's alphas ranged from 0.85 to 0.94.

**HIV/AIDS Stress.**—HIV/AIDS Stress Scale consists of 29 items on a five-point Likert scale ranging from 0 (*not at all*) to 4 (*extremely*) within the past month (Pakenham & Renaldis, 2002). Higher scores reflect greater HIV-related stress. The HIV/AIDS Stress Scale has high internal consistency and reliability ( $r = 0.85$ ) (Pakenham & Renaldis, 2002). The current sample's alpha was 0.92.

**Stigma.**—The 13-item HIV Stigma Scale (Sowell et al., 1997) assesses perceived HIV stigma using a four-point Likert scale ranging from 0 (*not at all*) to 4 (*often*) to rate the frequency of feeling stigmatized because of one's HIV status. Higher scores indicate higher perceptions of stigma and the scale contains three subscales: Distancing (form of social rejection), Blaming (conferring blame for contracting HIV), and Discrimination (mistreatment and prejudicial treatment by others) (Emlet, 2005). Cronbach's alphas for the HIV Stigma Scale ranged from 0.83 to 0.88 (Emlet, 2005). The current sample's alpha was 0.96

### Statistical Analyses

Statistical analyses were performed using SAS v.9.4 (Cary, NC) and CRAN R v.3.3 (Vienna, Austria), and significance was evaluated two-sided at the 0.05 level. Demographic, drug use, sexual history, and clinical characteristics were summarized overall and by SOC and MACARTI arms using means and standard deviations, medians and interquartile ranges (IQR), or frequencies and percentages as appropriate. Two-sample testing, including both parametric (t-tests and Chi-square tests) and non-parametric (Wilcoxon and Fisher's) approaches were used to gauge dissimilarities between the study groups at baseline. Due to noted baseline covariate disparities between SOC and MACARTI arms (i.e. confounders), an inverse propensity-treatment weighted (IPTW) score was calculated, using binary logistic regression with a weighted standardized differences cutoff of 0.25, and added as an observation weight characteristic to the sample. These weighting methods are analogous to those utilized by Camacho-Gonzalez et al. (2017) and described in detail by Austin & Stuart (2015).

Linear mixed-effects growth models were employed to compare psychological measure differences and interactions within and between study arms from baseline (one month) to follow-up at 6 months and 12 months. To account for observed non-linear trends in psychological outcomes over time, separate regression models were run for data at baseline to 6 months and baseline to 12 months. For each growth model, the fixed effects were treatment arm (two levels) and study visit. Random effects were the participant-specific intercepts. Interactions were treatment arm by study visit and tested for differences in

outcome slopes (i.e., growth trends) between study arms. Model covariance was estimated separately for each arm to account for potential heterogeneity, and an unstructured variance-covariance matrix was employed. Model-estimated mean differences and 95% confidence intervals were calculated from baseline to endpoint within each study arm and at endpoint between study arms for each outcome. Effect sizes were derived by dividing each mean difference by the corresponding pooled standard deviation at baseline. Effect sizes were given as a supplemental metric to evaluate outcome change (within arms) and differences (between arms), and interpreted as small (0.2), moderate (0.5), and large (0.7).

Linear mixed-effects regression models were used to consider statistical associations between psychological measures and clinical characteristics [CD4+ and viral load (VL)], across the SOC and MACARTI arms, adjusted for study visit follow-up. CD4+ counts were split at 500 cells (<500 versus ≥500), and VL was split at the limit of detection (<40 versus ≥40). The fixed effects for each model were treatment arm (two levels) and clinical characteristic (CD4+ and VL, two levels). The random effects were participant-specific intercepts. Interactions were analogous to two-factor ANOVA and considered differences for all combinations of treatment arm and clinical characteristics. Pairwise comparisons were tested for all interaction levels, and p-values reported unadjusted. All observations in the regression analyses were evaluated weighted using the IPTW scores.

## Results

Four hundred thirty-five participants were tested and 49 of those were identified as HIV+ and enrolled in the MACARTI arm. The SOC screened 62 participants and identified 49 AIAWH meeting inclusion criteria. A total of 98 participants, 49 in each arm, were enrolled; 91% self-identified as Black and/or African American, 85% male, mean age was 21 years (SD=1.8 years), 78% identified as lesbian, gay, bisexual, and queer (LGBQ), 62% had an education level of high school or less, 23% reported current drug use (alcohol and/or illicit substances), and 14% endorsed a history of physical and/or sexual abuse.

### Kessler Psychological Distress

At six months, SOC patients saw a marginal decrease in K10 scores (Mean: -2.7, 95% CI: -5.6, 0.1,  $p=0.061$ ), but scores remained above the cutoff score of 20 indicating a clinical level of psychological distress suggestive of the presence of a mental disorder (State of Victoria, Department of Human Services, 2002); conversely, MACARTI participants had a mean 3.6 (95% CI: -6.8, -0.5) point decline in K10 scores, reaching a 6-month value of 17.9 (Table 2a). The decline in psychological distress by MACARTI patients from baseline to six months was statistically significant ( $p=0.024$ ); however, the 6-month difference in K10 scores between SOC and MACARTI patients was not significant ( $p=0.261$ ) (Table 2b). At 12-months, the mean SOC score remained above the clinical level of psychological distress (20.6, 95% CI: 17.1, 24.2), and the mean MACARTI score also returned to a clinical level of distress (23.3, 95% CI: 19.9, 26.8). There was no difference in mean K10 scores at 12 months between SOC and MACARTI participants (2.7, 95% CI: -2.2, 7.6,  $p=0.276$ ). There were no associations between K10 scores and clinical characteristics between study arms (Tables 3 and 4).

## Proactive Coping Inventory

At six months, significant declines in the reflective coping and strategic planning domains were observed in the SOC cohort, relative to baseline (Reflective Coping Mean Difference:  $-3.8$ , 95% CI:  $-5.7, -2$ ,  $p<0.001$ ; Strategic Planning Mean Difference:  $-2$ , 95% CI:  $-2.8, -1.2$ ,  $p<0.001$ ); whereas, no differences were observed in MACARTI participants (Table 2a). At the 6-month study session, MACARTI participants had statistically significant higher reflective coping and strategic planning scores over SOC (Reflective Coping Difference:  $3.3$ , 95% CI:  $0.2, 6.3$ ,  $p=0.040$ ; Strategic Planning Difference:  $1.5$ , 95% CI:  $0.3, 2.7$ ,  $p=0.013$ ) (Table 2b). At 12 months, reflective coping scores were not significantly different from baseline in either study arm. A significant difference in baseline to 12-month strategic planning scores was observed for SOC patients (Mean:  $-0.8$ , 95% CI:  $-1.4, -0.2$ ,  $p=0.010$ ), but no difference was observed in MACARTI participants ( $p=0.602$ ) (Table 2a). Differences in 12-month scores between SOC and MACARTI patients for reflective coping and strategic planning were not significant ( $p=0.540$  and  $p=0.397$ , respectively) (Table 2b).

For the clinical characteristics, reflective coping scores were significantly lower in SOC, relative to MACARTI, when  $CD4 \geq 500$  ( $p=0.046$ ); moreover, strategic planning scores were marginally lower in SOC patients with  $CD4 \geq 500$ , relative to all other groups (all  $p<0.1$ ). For viral load, SOC patients with  $VL>40$  had lower reflective coping scores than SOC and MACARTI patients with undetectable values ( $p=0.007$  and  $p=0.097$ , respectively). No differences in strategic planning scores were observed between the study arm and VL groups (Tables 3 and 4).

## HIV/AIDS Stress Scale

At both six and 12 months, SOC and MACARTI participants had decreases in mean HIV/AIDS Stress Scale scores from baseline; however, none of these differences reached statistical significance within arm (Table 2a) or between arms (Table 2b). There were no associations between HIV/AIDS Stress Scale scores and clinical characteristics between study arms (Tables 3 and 4).

## HIV Stigma Scale

At six months, SOC participants saw a marginally significant reduction in the discrimination domain of the HIV Stigma scale relative to baseline (Mean:  $-0.8$ , 95% CI:  $-1.7, 0.1$ ,  $p=0.065$ ); however, MACARTI patients had significant reductions in mean scores on the overall HIV Stigma Scale ( $-4.1$ , 95% CI:  $-6.8, -1.5$ ,  $p=0.003$ ), Distancing domain ( $-1.4$ , 95% CI:  $-2.6, -0.2$ ,  $p=0.018$ ), and Blaming domain ( $-1.8$ , 95% CI:  $-2.8, -0.8$ ,  $p=0.001$ ), as well as a marginal reduction on the Discrimination domain ( $-0.8$ , 95% CI:  $-1.8, -0.2$ ,  $p=0.098$ ) (Table 2a). While differences existed within the study arms, there were no 6-month study visit differences between study groups (Table 2b). Even so, interaction  $p$ -values indicated significant differences in slopes for overall HIV Stigma ( $p=0.041$ ), Distancing ( $p=0.008$ ), and Blaming ( $p=0.044$ ), pointing to steeper declines in score trends for MACARTI participants, relative to SOC. At 12 months, differences in mean distancing ( $1.6$ , 95% CI:  $0, 3.1$ ,  $p=0.049$ ) and discrimination ( $-1.2$ , 95% CI:  $-2.4, 0$ ,  $p=0.057$ ) scores were observed for SOC patients relative to baseline. Blaming was significantly lower in MACARTI participants (Mean:  $-1.6$ , 95% CI:  $-3, -0.2$ ,  $p=0.026$ ) (Table 2a). No differences

between SOC and MACARTI patients were observed at 12 months (Table 2b); however, trends in blaming scores showed statistically significant differences in trajectories, with MACARTI scores decreasing and SOC scores increasing ( $p=0.008$ ). No associations were noted between CD4 counts and measure outcomes across the study cohorts. Significantly higher blaming scores were noted in MACARTI patients with viral loads  $>40$  relative to those  $\leq 40$ .

### Clinical Outcomes, Retention, and Linkage to Care

Results relating to clinical outcomes (VL and CD4+ counts), linkage to care, and retention are reported elsewhere (Camacho-Gonzalez et al., 2017). MACARTI participants had fewer AIDS-defining conditions (20% vs 51%,  $p=0.002$ ) and higher CD4+ counts at baseline than the SOC arm and continued a growth trajectory of CD4+ counts over follow-up that was higher relative to the SOC ( $p=0.004$ ). While VL levels decreased significantly in both arms after one year, the proportion of participants who had undetectable VL after one year was higher in the MACARTI arm relative to the SOC arm (83 vs 41%,  $p<0.001$ ). Fifty percent of the MACARTI participants attended 100% of their scheduled clinical visits compared to 26% of the SOC participants (Camacho et al., 2017). These results support findings in the literature examining various intervention and observational studies that estimate approximately 51% of AYAWH achieve viral suppression, 62% are linked to care within 6–12 months, and 43% are retained in care over 1–3 years and underscores the importance of needing targeted HIV testing (Zanoni & Mayer, 2014).

### Discussion

Adolescents and young adults are disproportionately impacted by HIV. This multilevel, multicomponent intervention is one of the few studies aimed at identifying, linking, retaining, and increasing medical treatment adherence for AYAWH in HIV medical care. This sub-study of MACARTI examined the impact of MI and CM on a combination of self-reported scores for psychological distress, proactive coping, HIV/AIDS stress, and HIV stigma in association with clinical outcomes. Results suggest that MACARTI was an effective method for maintaining proactive coping and reducing psychological distress and HIV stigma within six months of initiating the intervention. This suggests that using a multicomponent intervention can be helpful in not only linking, engaging, and retaining in care but also reducing distress in this high-risk population. However, these differences did not maintain statistical significance when compared between the study groups at 12 months and both populations endorsed elevated psychological distress at this time point. The MACARTI focus on medical care and health needs did not directly address other sources of psychological distress unless requested by the participant. Therefore, other sources of distress may have influenced scores on this measure. Future studies should better explore the nature of distress and potential factors contributing to the ebb and flow of other extraneous variables that could impact stress experienced by this population.

From the 6-month to the 12-month study visit, only two MI-focused therapy sessions were provided compared to the three sessions provided in the initial three months of the study. It is possible that reducing the frequency of services contributed to an increase in distress.



Prospective studies should focus on the number of sessions needed to adequately reduce distress and maintain these results. This intervention may have proved too brief and too specific in its focus on health behavior change to address other presenting concerns.

MACARTI participants showed statistically significant reductions in HIV stigma total scores, blaming, and distancing scores compared to the SOC participants. Although the study design precludes drawing causal conclusions regarding this finding, one possibility is that MACARTI helped to foster an accepting care environment (including clinical staff and peers) that had the effect of attenuating stigma. This idea is supported by previous research investigating the role of an “HIV competent community” that provides vital emotional support and practical advice, promotes access to services, and encourages medical care and treatment adherence (Campbell et al., 2013). Future research on the MACARTI intervention could explore this further, including the possible role of brief MI-informed therapy on facilitating the reduction of stigma in the context of the overall intervention.

On the HIV/AIDS Stress Scale there were no within group and between group statistically significant differences in the variable. Although the MACARTI arm placed more emphasis on the reduction HIV/AIDS stress, both study arms were provided psychoeducational presentations about topics, such as HIV disclosure and healthy relationships, that aimed to reduce stress and stigma and to improve interpersonal relationships as part of the standard of care at the clinic. It is possible the SOC arm benefitted sufficiently from these opportunities.

This study has some limitations of note. The small sample size and reliance on a convenience sample from a single site, geared towards underserved populations, without randomization limits the generalizability of the results. Consequently, future research is needed to test the MACARTI intervention using randomized designs in multiple clinical sites. Secondly, participant biases in testing site selection may have contributed to observed demographic differences in sexual orientation and gender identity between the study arms. This threat to external validity resulted in an oversampling of young, Black men who have sex with men (MSM) in the MACARTI arm. Another major study limitation is that the current design of the study does not permit for a deeper analysis of the specific effects associated with the different components of the MACARTI intervention. Future research could involve further evaluation to determine the specific effects associated with MI versus CM and other MACARTI components. One additional limitation is that MACARTI was designed to be a brief intervention to address linkage, engagement, and retention in care, future studies should examine the impact of more intensive therapy strategies intended to address psychological barriers to care and wellbeing.

Accounting for these study limitations, the current study provides evidence that a multicomponent intervention, such as MACARTI, that incorporates a psychotherapy intervention with case management can link, engage, and retain AYAWH in HIV-related care (Camacho, 2017). This intervention also provides support for incorporating psychotherapy intervention to favorably influence a reduction in psychological distress and improved proactive coping. Although these changes are only supported for the first six months of treatment, it shows some promise in addressing these variables. Furthering research to

include randomized controlled trials in multiple settings and across diverse demographic groups can further explicate the efficacy of the MACARTI model.

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**Table 1:**

Baseline characteristics for standard of care and intervention participants, the MACARTI Trial, Atlanta, Georgia, USA, 2012–2016

Characteristic, N (%)	Overall N = 98	SOC N = 49	MACARTI N = 49	P- Value	Unweighted Std. Diff	Weighted Std. Diff <sup>2</sup>
Gender						
Male	83 (84.7%)	36 (73.5%)	47 (95.9%)	0.004	0.656	0.097
Female	15 (15.3%)	13 (26.5%)	2 (4.1%)			
Race						
Black	89 (90.8%)	47 (95.9%)	42 (85.7%)	0.159	0.359	0.230
Other (White, Hispanic, Other)	9 (9.2%)	2 (4.1%)	7 (14.3%)			
Age (yr), Mean ± SD	21.5 ± 1.8	21.3 ± 1.8	21.7 ± 1.7	0.175	0.276	0.083
Work Status						
Employed/In School	74 (75.5%)	32 (65.3%)	42 (85.7%)	0.019	0.489	0.139
Neither	24 (24.5%)	17 (34.7%)	7 (14.3%)			
Education, N = 97						
High school or Less	60 (61.9%)	35 (72.9%)	25 (51%)	0.026	0.463	0.154
College or More	37 (38.1%)	13 (27.1%)	24 (49%)			
Ever Abused Alcohol	15 (15.3%)	3 (6.1%)	12 (24.5%)	0.022	0.528	0.083
Currently Using Drugs	22 (22.5%)	9 (18.4%)	13 (26.5%)	0.333	0.197	0.008
Physical and/or Sexual Abuse						
No Abuse	84 (85.7%)	42 (85.7%)	42 (85.7%)	1.000	<0.001	<0.001
Abuse Reported	14 (14.3%)	7 (14.3%)	7 (14.3%)			
Sexual Orientation Straight	22 (22.5%)	19 (38.8%)	3 (6.1%)	<0.001	0.850	0.198
Gay/Bisexual/Queer	76 (77.5%)	30 (61.2%)	46 (93.9%)			
Condom Usage						
Always/Usually	71 (72.5%)	33 (67.4%)	38 (77.6%)	0.258	0.230	0.249
Sometimes/Never	27 (27.5%)	16 (32.6%)	11 (22.4%)			
Ever had STI <sup>1</sup> – Patient Report, N = 97	47 (48.5%)	28 (57.1%)	19 (39.6%)	0.084	0.357	0.071
Any AIDS defining conditions, N = 94	34 (36.2%)	25 (51%)	9 (20%)	0.002	0.685	0.112

<sup>1</sup> Sexually Transmitted infection

<sup>2</sup> Baseline propensity balancing results are presented in the supplemental materials of Camacho-Gonzalez et al. (2017); a cutoff of <0.25 was utilized to indicate covariate balance.

**Table 2a:**

6-month and 12-month within arm differences in measure outcomes

	SOC				MACARTI			
	Baseline Mean (95% CI)	Endpoint Mean (95% CI)	Mean Diff.* (95% CI)	P-Value (ES)	Baseline Mean (95% CI)	Endpoint Mean (95% CI)	Mean Diff.* (95% CI)	P-Value (ES)
<i>6-Month Follow-up</i>								
K10 Total Score	23.0 (19.9, 26.1)	20.3 (17.0, 23.6)	-2.7 (-5.6, 0.1)	0.061 (0.25)	21.5 (18.9, 24.1)	17.9 (15.2, 20.6)	-3.6 (-6.8, -0.5)	0.024 (0.48)
PCI								
Reflective Coping	38.6 (36.2, 41.0)	34.8 (32.3, 37.3)	-3.8 (-5.7, -2.0)	<0.001 (0.47)	38.9 (37.1, 40.7)	38.0 (36.1, 39.9)	-0.9 (-2.9, 1.2)	0.390 (0.19)
Strategic Planning	14.5 (13.6, 15.4)	12.5 (11.5, 13.4)	-2.0 (-2.8, -1.2)	<0.001 (0.61)	14.0 (13.2, 14.7)	14.0 (13.2, 14.7)	0.0 (-0.8, 0.9)	0.959 (0.01)
HIV/AIDS Stress Score	29.1 (21.1, 37.1)	23.3 (15.0, 31.6)	-5.8 (-12.4, 0.8)	0.084 (0.18)	27.0 (20.5, 33.4)	21.3 (14.5, 28.1)	-5.7 (-13.0, 1.7)	0.128 (0.32)
Stigma Total Score	21.8 (18.6, 25.0)	21.5 (18.2, 24.7)	-0.4 (-2.8, 2.0)	0.757 (0.03)	24.0 (21.6, 26.4)	19.9 (17.3, 22.4)	-4.1 (-6.8, -1.5)	0.003 (0.57)
Distancing	6.9 (5.6, 8.2)	7.7 (6.4, 9.0)	0.8 (-0.3, 1.9)	0.157 (0.19)	8.0 (7.0, 9.0)	6.6 (5.5, 7.6)	-1.4 (-2.6, -0.2)	0.018 (0.51)
Blaming	7.7 (6.6, 8.8)	7.3 (6.1, 8.4)	-0.4 (-1.3, 0.5)	0.391 (0.10)	8.6 (7.7, 9.6)	6.8 (5.8, 7.8)	-1.8 (-2.8, -0.8)	0.001 (0.61)
Discrimination	7.3 (6.1, 8.4)	6.4 (5.2, 7.6)	-0.8 (-1.7, 0.1)	0.065 (0.19)	7.4 (6.5, 8.2)	6.6 (5.7, 7.4)	-0.8 (-1.8, 0.2)	0.098 (0.35)
<i>12-Month Follow-up</i>								
K10 Total Score PCI	21.6 (18.2, 25.1)	20.6 (17.1, 24.2)	-1.0 (-3.8, 1.8)	0.480 (0.08)	22.0 (18.8, 25.1)	23.3 (19.9, 26.8)	1.4 (-2.2, 5.0)	0.447 (0.15)
PCI								
Reflective Coping	38.7 (36.6, 40.8)	37.9 (35.7, 40.0)	-0.9 (-2.4, 0.6)	0.249 (0.11)	38.5 (36.6, 40.5)	38.8 (36.7, 40.8)	0.2 (-1.7, 2.2)	0.810 (0.05)
Strategic Planning	14.4 (13.6, 15.3)	13.6 (12.8, 14.5)	-0.8 (-1.4, -0.2)	0.010 (0.26)	13.9 (13.2, 14.6)	14.1 (13.4, 14.9)	0.2 (-0.6, 1.0)	0.602 (0.11)
HIV/AIDS Stress Score	30.7 (21.0, 40.5)	23.9 (13.8, 34.0)	-6.9 (-15.6, 1.9)	0.123 (0.19)	26.6 (18.8, 34.5)	26.3 (17.4, 35.2)	-0.3 (-11.4, 10.7)	0.952 (0.02)
Stigma Total Score	22.1 (18.4, 25.9)	23.3 (19.4, 27.1)	1.1 (-2.3, 4.5)	0.514 (0.08)	23.7 (20.9, 26.6)	20.9 (17.8, 24.1)	-2.8 (-6.9, 1.3)	0.182 (0.37)
Distancing	7.0 (5.5, 8.4)	8.5 (7.0, 10.1)	1.6 (0.0, 3.1)	0.049 (0.30)	7.8 (6.5, 9.1)	7.3 (5.9, 8.7)	-0.5 (-2.4, 1.4)	0.588 (0.18)
Blaming	7.5 (6.1, 8.8)	8.3 (7.0, 9.7)	0.9 (-0.3, 2.0)	0.126 (0.17)	8.6 (7.5, 9.7)	7.0 (5.8, 8.2)	-1.6 (-3.0, -0.2)	0.026 (0.54)
Discrimination	7.7 (6.5, 9.0)	6.5 (5.2, 7.9)	-1.2 (-2.4, 0.0)	0.057 (0.26)	7.3 (6.4, 8.3)	6.7 (5.7, 7.8)	-0.6 (-2.1, 0.8)	0.387 (0.25)

\* Calculated as Endpoint minus Baseline;

<sup>1</sup> Effect size calculated by dividing the mean endpoint difference by the weighted standard deviation for each study arm at baseline;

<sup>2</sup> Effect sizes interpreted using Cohen's criteria: 0.2 (small), 0.5 (moderate), 0.7 (large)

**Table 2b:**

6-month and 12-month differences in measure outcomes by study arm

Measure	SOC			MACARTI			Mean Endpoint* Difference (95% CI)	Endpoint P-Value	Effect Size $f_{1,2}$	Int. P-Value <sup>3</sup>
	Baseline Mean (95% CI)	Endpoint Mean (95% CI)	Baseline Mean (95% CI)	Endpoint Mean (95% CI)	Mean (95% CI)					
<i>6-Month Follow-up</i>										
K10 Total Score	23.0 (19.9, 26.1)	20.3 (17.0, 23.6)	21.5 (18.9, 24.1)	17.9 (15.2, 20.6)	-2.41 (-6.64, 1.81)	0.261	0.25	0.678		
PCI										
Reflective Coping	38.6 (36.2, 41.0)	34.8 (32.3, 37.3)	38.9 (37.1, 40.7)	38.0 (36.1, 39.9)	3.25 (0.15, 6.34)	0.040	0.48	0.037		
Strategic Planning	14.5 (13.6, 15.4)	12.5 (11.5, 13.4)	14.0 (13.2, 14.7)	14.0 (13.2, 14.7)	1.53 (0.32, 2.73)	0.013	0.57	0.001		
HIV/AIDS Stress Score	29.1 (21.1, 37.1)	23.3 (15.0, 31.6)	27.0 (20.5, 33.4)	21.3 (14.5, 28.1)	-1.94 (-12.59, 8.70)	0.719	0.07	0.979		
Stigma Total Score	21.8 (18.6, 25.0)	21.5 (18.2, 24.7)	24.0 (21.6, 26.4)	19.9 (17.3, 22.4)	-1.56 (-5.67, 2.54)	0.452	0.16	0.041		
Distancing	6.9 (5.6, 8.2)	7.7 (6.4, 9.0)	8.0 (7.0, 9.0)	6.6 (5.5, 7.6)	-1.09 (-2.76, 0.58)	0.197	0.31	0.008		
Blaming	7.7 (6.6, 8.8)	7.3 (6.1, 8.4)	8.6 (7.7, 9.6)	6.8 (5.8, 7.8)	-0.45 (-1.97, 1.07)	0.562	0.12	0.044		
Discrimination	7.3 (6.1, 8.4)	6.4 (5.2, 7.6)	7.4 (6.5, 8.2)	6.6 (5.7, 7.4)	0.13 (-1.32, 1.57)	0.864	0.04	0.975		
<i>12-Month Follow-up</i>										
K10 Total Score PCI	21.6 (18.2, 25.1)	20.6 (17.1, 24.2)	22.0 (18.8, 25.1)	23.3 (19.9, 26.8)	2.69 (-2.18, 7.57)	0.276	0.24	0.302		
Reflective Coping	38.7 (36.6, 40.8)	37.9 (35.7, 40.0)	38.5 (36.6, 40.5)	38.8 (36.7, 40.8)	0.91 (-2.03, 3.85)	0.540	0.13	0.371		
Strategic Planning	14.4 (13.6, 15.3)	13.6 (12.8, 14.5)	13.9 (13.2, 14.6)	14.1 (13.4, 14.9)	0.48 (-0.64, 1.60)	0.397	0.19	0.045		
HIV/AIDS Stress Score	30.7 (21.0, 40.5)	23.9 (13.8, 34.0)	26.6 (18.8, 34.5)	26.3 (17.4, 35.2)	2.41 (-10.90, 15.72)	0.721	0.08	0.360		
Stigma Total Score	22.1 (18.4, 25.9)	23.3 (19.4, 27.1)	23.7 (20.9, 26.6)	20.9 (17.8, 24.1)	-2.32 (-7.24, 2.59)	0.351	0.21	0.149		
Distancing	7.0 (5.5, 8.4)	8.5 (7.0, 10.1)	7.8 (6.5, 9.1)	7.3 (5.9, 8.7)	-1.22 (-3.29, 0.85)	0.244	0.28	0.095		
Blaming	7.5 (6.1, 8.8)	8.3 (7.0, 9.7)	8.6 (7.5, 9.7)	7.0 (5.8, 8.2)	-1.34 (-3.10, 0.43)	0.136	0.31	0.008		
Discrimination	7.7 (6.5, 9.0)	6.5 (5.2, 7.9)	7.3 (6.4, 8.3)	6.7 (5.7, 7.8)	0.17 (-1.51, 1.85)	0.844	0.04	0.555		

\* Calculated as MACARTI minus SOC;

<sup>1</sup> Effect size calculated by dividing the mean endpoint difference by the weighted standard deviation of the full sample at baseline;

<sup>2</sup> Effect sizes interpreted using Cohen's criteria: 0.2 (small), 0.5 (moderate), 0.7 (large);

<sup>3</sup> Int. p-value is based on a Study Arm

\* Time interaction and tests for difference in slopes for each model

**Table 3:**

Differences in outcome measures by CD4 counts (&lt;500 vs. 500)

Measure	SOC			MACARTI			Pairwise Comparison P-Values					
	CD4<500 (0)	CD4 500 (1)	CD4<500 (2)	CD4 500 (3)	0 vs. 1	0 vs. 2	0 vs. 3	1 vs. 2	1 vs. 3	2 vs. 3		
K10 Total Score	21.4 (18.8, 23.9)	21.8 (17.3, 26.3)	21.9 (19.1, 24.7)	20.1 (16.7, 23.6)	0.840	0.770	0.573	0.973	0.558	0.354		
PCI												
Reflective Coping	37.6 (35.8, 39.5)	35.7 (32.8, 38.6)	38.4 (36.7, 40.1)	39.3 (37.2, 41.4)	0.162	0.539	0.232	0.110	0.046	0.424		
Strategic Planning	13.8 (13.0, 14.5)	12.7 (11.5, 13.9)	14.0 (13.4, 14.6)	14.0 (13.2, 14.8)	0.060	0.643	0.654	0.051	0.062	0.966		
HIV/AIDS Stress Score	25.3 (18.7, 31.9)	28.3 (16.6, 40.1)	25.5 (19.0, 31.9)	19.3 (11.1, 27.6)	0.616	0.973	0.261	0.671	0.216	0.201		
Stigma Total Score	22.2 (19.5, 24.8)	20.9 (16.3, 25.6)	21.8 (19.5, 24.0)	20.9 (18.0, 23.8)	0.608	0.822	0.541	0.754	0.999	0.635		
Distancing	7.3 (6.3, 8.3)	7.2 (5.3, 9.0)	7.3 (6.4, 8.2)	6.9 (5.8, 8.1)	0.913	0.979	0.637	0.905	0.819	0.593		
Blaming	7.9 (6.8, 8.9)	7.2 (5.5, 8.9)	7.8 (6.9, 8.7)	7.2 (6.0, 8.3)	0.452	0.887	0.391	0.573	0.996	0.400		
Discrimination	7.0 (6.1, 7.9)	6.8 (5.2, 8.5)	6.9 (6.1, 7.6)	6.8 (5.8, 7.7)	0.819	0.787	0.675	0.966	0.934	0.838		

Table 4:

Differences in outcome measures by detectable VL (40 vs. &gt;40)

Measure	SOC				MACARTI				Pairwise Comparison P-Values							
	VL=40 (0)	VL>40 (1)	VL=40 (2)	VL>40 (3)	0 vs. 1	0 vs. 2	0 vs. 3	1 vs. 2	1 vs. 3	2 vs. 3	0 vs. 1	0 vs. 2	0 vs. 3	1 vs. 2	1 vs. 3	2 vs. 3
K10 Total Score	20.9 (17.9, 23.9)	21.6 (19.1, 24.2)	19.9 (16.9, 22.9)	22.2 (19.5, 24.9)	0.604	0.625	0.531	0.380	0.754	0.113						
PCI																
Reflective Coping	38.7 (36.5, 40.8)	36.5 (34.6, 38.4)	38.7 (36.9, 40.5)	38.5 (36.9, 40.2)	0.007	0.969	0.925	0.097	0.113	0.833						
Strategic Planning	13.8 (12.9, 14.6)	13.6 (12.8, 14.3)	13.9 (13.3, 14.6)	13.9 (13.3, 14.6)	0.517	0.754	0.734	0.444	0.415	0.984						
HIV/AIDS Stress Score	25.0 (17.0, 32.9)	26.4 (19.7, 33.2)	21.8 (14.7, 28.9)	24.3 (17.9, 30.7)	0.685	0.557	0.895	0.346	0.645	0.518						
Stigma Total Score	21.7 (18.5, 24.8)	22.2 (19.5, 24.9)	20.5 (18.0, 23.0)	22.2 (20.0, 24.4)	0.725	0.566	0.785	0.371	0.981	0.233						
Distancing	7.0 (5.8, 8.2)	7.5 (6.5, 8.5)	6.9 (5.9, 7.9)	7.4 (6.5, 8.3)	0.429	0.923	0.593	0.446	0.921	0.433						
Blaming	7.7 (6.6, 8.9)	7.8 (6.8, 8.8)	6.9 (5.9, 7.9)	8.1 (7.2, 9.0)	0.946	0.261	0.614	0.204	0.614	<b>0.019</b>						
Discrimination	7.0 (5.9, 8.1)	7.0 (6.1, 7.9)	6.7 (5.9, 7.6)	6.9 (6.1, 7.6)	0.893	0.750	0.874	0.640	0.765	0.820						