Poster#1050

Viral Suppression Among People Initiating HIV Care: Outcomes from iENGAGE Trial

KR Amico*, R Modi, AO Westfall, J Willig, JC Keruly, S Napravnik, HM Crane, EB Quinlivan, AL Zinski
CE Golin, DM Long, RD Moore, M Saag, J Raper, MJ Mugavero for iENGAGE Study Team

Correspondence
mmugavero@uabmc.edu

ABSTRACT

Background: Optimizing engagement in HIV care represents the greatest opportunity to maximize the individual and population health benefits of sustained viral suppression (VS; <200 c/mL). Among people living with HIV (PLWH) initiating outpatient HIV care, early missed clinic visits and suboptimal retention in care (RIC) result in failure to achieve and sustain VS, impacting personal health outcomes and onward HIV transmission.

Methods: The NIH-funded iENGAGE trial (NCT01900236) enrolled PLWH within 14 days of their initial outpatient HIV care visit at 4 CFAR-affiliated academic HIV clinics. Participants were randomized to an intervention or standard of care (SOC) control arm (1:1). The intervention integrated and adapted 2 evidence-based approaches with demonstrated efficacy for RIC and ART adherence; enhanced personal contact/reminders and a 4 session counseling program based on Motivational Interviewing and grounded in a situated information, motivation and behavioral skills (sIMB) framework. Participant baseline and 48-week computer assisted surveys were done using validated instruments. A sample size of 400, with 10% attrition, provided >80% power to detect a 15% difference in 48-week VS, with 60% VS estimated in the SOC arm based upon historical data.

Results: Between 12/13 and 06/16, 371 participants enrolled (62% black, 19% women, 24% uninsured, 60% MSM, 25% CD4<200). Baseline psychosocial co-morbidities included: 31% depression, 31% anxiety, 35% high-risk alcohol use, 18% active substance use. Roughly half the sample (49%) reported unmet need for supportive services (e.g. housing, employment, food and transportation). Overall, 86% of participants achieved 48-week VS; 86% intervention, 87% SOC; p=0.87. Median time to VS was 63 days (IQR 42-101) and did not differ between the two study arms (HR=0.94, 95%CI=0.75-1.19).

Conclusions: Among new to care iENGAGE participants with substantial co-morbid psychosocial illness and unmet need for supportive services, 86% achieved 48-week VS in a median time of 63 days with no differences between study arms. The similarity of results by study arm and the higher than expected VS rate in the SOC group likely reflects a rapidly evolving HIV treatment landscape, which emphasizes the care continuum, rapid ART initiation and the emergence of integrase inhibitors as first-line therapies. Sustaining care engagement and VS among new to care PLWH beyond the first year is imperative to maximize the individual and population health benefits afforded by modern HIV treatment.

BACKGROUND

- Optimizing engagement in HIV care represents greatest opportunity to maximize benefits of sustained viral suppression
- Historically, roughly 60% of people living with HIV (PLWH) initiating HIV medical care achieve 48-week VS (<200 c/mL)[1]
- PLWH initiating HIV medical care must simultaneously develop and implement strategies to adhere to both care and ART
- Early missed clinic visits have resulted in delayed ART start, poor retention in care, delayed VS and increased mortality[1-3]
- An intervention to support adherence to care and ART for people initiating HIV care has potential to enhance VS

METHODS

- Randomized controlled trial of the integrating ENGagement and Adherence Goals upon Entry (iENGAGE; (NCT01900236))
- iENGAGE intervention: content from efficacious REPC[4] (retention, CDCHRSA9272007) & PACT[5] (adherence)
  - Situated Information, Motivation, Behavioral Skills (sIMB)
  - Counselors trained in motivational interviewing principles
  - Enhanced personal contact reminder & missed visit calls, and 4 in person adherence skills sessions (risk screener)
- Design: RCT comparing iENGAGE to SOC control (1:1)
- Study sites: 4 academically affiliated HIV clinics participating in CNICS[6] located in Baltimore, MD (JHU), Birmingham, AL (UAB), Chapel Hill, NC (UNC) & Seattle, WA (UW)
- Eligibility criteria: PLWH with no prior outpatient HIV medical care, enrolled within 14 days of their initial HIV care visit
- Primary outcome: 48-week VS (<200 c/mL)
- Secondary outcomes:
  - Time to viral suppression
  - Retention in Care: Visit adherence & 4-Month constancy
- Power: n=400 (10% attrition); >80% power to detect 15% difference in 48-week VS, with estimated 60% VS in control arm

FIGURE 1

Schema for study assessments and iENGAGE intervention activities

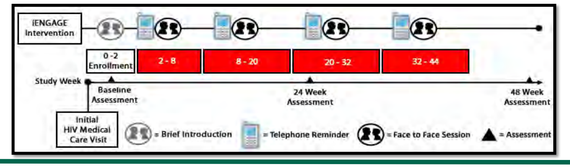


TABLE 1

Baseline characteristics of iENGAGE study participants enrolled 2013-2016 (n=371)

Characteristic	N (%) or Mean (±SD)
Age (years)	36 (±12)
Male	294 (79%)
Black / African American	231 (62%)
Uninsured	87 (24%)
Men who have sex with men (MSM)	219 (60%)
Depression (PHQ>10)	107 (31%)
Anxiety	113 (31%)
High risk alcohol use (AUDIT-C)	127 (35%)
Current substance use	64 (18%)
Financial assistance need (last 6 mo)[1]	179 (49%)
Household expenditure need (last 6 mo)[2]	194 (53%)
Substance use treatment need (last 6 mo)	125 (34%)
CD4 count <200 cells/μL	85 (25%)
UAB site[3]	153 (41%)
iENGAGE intervention arm	185 (41%)

[1] includes financial, employment, benefits assistance
[2] includes housing, transportation, food, groceries, meals and childcare
[3] UNC 76 (21%), JHU 78 (21%). UW 64 (17%)

RESULTS

- From December 2013 to June 2016, n=371 participants met eligibility, provided consent, enrolled in iENGAGE trial (Table 1)
- 48-week VL available in 314 participants (85%);155 iENGAGE intervention (84%) and 159 SOC control (85%) participants
- Overall, 271 (86%) participants achieved 48-week VS (<200 c/mL) in a median 63 days (IQR 42-101 days) with no significant differences b/t study arms (Table 2, Figure 2; HR=0.94, 95%CI=0.75-1.12)
- No significant differences were observed by study arms for visit adherence or four-month constancy retention measures (Table 2)
- Notably, 304 participants (82%) met HRSA HAB retention indicator (non *a priori* outcome), with no significant difference b/t study arms

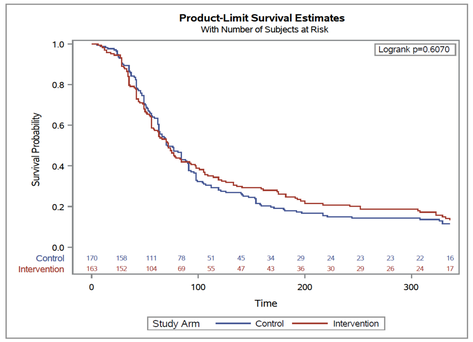
TABLE 2

Primary and secondary outcomes among iENGAGE intervention (n=185)and SOC control (n=186) participants

Outcome	iENGAGE arm	SOC control arm	P-value
48-week VS (<200 c/mL)	133 (86%)	138 (87%)	0.87
Visit adherence	84% (±25)	81% (±26)	0.23
Four-month constancy	98 (53%)	88 (47%)	0.28

FIGURE 2

KM plot depicting median time to VS (<200 c/mL) in iENGAGE intervention and SOC control arm



CONCLUSIONS

- Among a sample of new to care PLWH with substantial co-morbid illness and unmet supportive service needs, 86% achieved 48-week VS in a median time of 63 days
- There were no significant differences in VS or retention in care outcomes b/t the iENGAGE intervention & SOC control arms
- Higher than anticipated 48-week VS in the SOC control arm likely reflects a rapidly evolving HIV treatment landscape with emphasis on the care continuum, guidelines recommending earlier ART start and the emergence of integrase strand transfer inhibitors as 1st line ART

IMPLICATIONS

- Well resourced clinics supported by the Ryan White Program can assist PLWH in achieving rapid VS upon care entry, even in the setting of psychosocial co-morbidities and unmet needs
- Clinic-based interventions are needed to support sustained care retention & VS longitudinally, along with interventions at the community-clinic interface to increase medical care engagement

CITATIONS

[1] Mugavero MJ et al. *J Acquir Immune Defic Syndr* 2012,61:574-580
[2] Ulett K et al. *AIDS Patient Care and STDs* 2009,23:41-49
[3] Mugavero MJ et al. *Clinical Infectious Diseases* 2014;59:1471-79
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[6] Kitahata et al. *Int J Epi* 2008;37:948-55

Acknowledgements: This project was supported by NIH: R01AI103661, the CFAR Network of Integrated Clinical Systems (CNICS); grant R24AI067039, and UAB Center For AAIDS Research P30AI027767