Assessing effects of behavioral intervention on treatment outcomes among patients initiating HIV care: Rationale and design of iENGAGE intervention trial

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ABSTRACT

During the initial year of HIV diagnosis, while patients are often overwhelmed adjusting to this life changing diagnosis, they must develop self-care behaviors for attending regular medical care visits and antiretroviral therapy (ART) adherence to achieve and sustain viral suppression (VS). Maintaining "HIV adherence" and integrating it into one's daily life is required to sustain VS over time. The HIV care continuum or "treatment cascade," an epidemiological snapshot of the national epidemic in the United States (US), indicates that a minority of persons living with HIV (PLWH) have achieved VS. Little evidence exists regarding the effects of interventions focusing on PLWH newly initiating outpatient HIV care. An intervention that focuses on both retention in care and ART adherence skills delivered during the pivotal first year of HIV care is lacking.

To address this, we developed a theory-based intervention evaluated in the Integrating Engagement and Adherence Goals upon Entry (iENGAGE) study, a National Institute of Allergy and Infectious Diseases (NIAID) funded randomized behavioral intervention trial. Here we present the study objectives, design and rationale, as well as the intervention components, targeting rapid and sustained VS through retention in HIV care and ART adherence during participants' first year of HIV care. The primary outcome of the study is 48-week VS (< 200 c/mL). The secondary outcomes are retention in care, including HIV visit adherence and visit constancy, as well as ART adherence.

1. Background and rationale

The first year of outpatient HIV medical care is a dynamic, formative and vulnerable time. While adjusting to a life changing diagnosis, patients must simultaneously develop HIV visit (i.e., retention in care) and antiretroviral therapy (ART) adherence behavioral skills to achieve plasma viral load suppression (VS) [1]. Successful attainment of adherence skills is essential to sustaining VS over time, with vital consequences to individual health and profound implications for secondary HIV prevention [2–4]. Continuous ART receipt (persistence) and consistent daily dosing are imperative to achieve optimal outcomes [5,6]. A majority of people living with HIV (PLWH) in the US fail to successfully navigate the HIV care continuum, which includes multiple steps required to achieve VS [7]. This continuum begins with HIV diagnosis and is followed by linkage to and subsequent retention in HIV medical care, ART receipt (including ART initiation and longitudinal receipt), and ART adherence [7]. In the year following HIV care initiation, missed visits are observed in 45–60% of patients with 1-year attrition seen in 25–40% [8–11], resulting in delayed initiation of or failure to start ART [9–11]. Even when early retention is sufficient to access ART, missed clinic visits, interrupted ART receipt, and sub-optimal ART adherence result in delayed VS [10,12], greater cumulative VL burden [10], and greater odds of clinical events and death [12–14].

Beyond the vital implications to individual health outcomes, failure of individuals to achieve VS has critical implications at a population level, propagating the continued spread of the domestic epidemic with an estimated 39,782 new cases in year 2016 [15]. To date, several ART adherence promoting interventions have been identified as promising,

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and approaches to facilitate retention in care and return to care are emerging [16]. What remains lacking is a consolidated intervention that focuses on both retention in care and ART adherence that is delivered at the time when most individuals are developing these skills, the first year of HIV care.

To address this, we developed a theory-based intervention evaluated in the Integrating Engagement and Adherence Goals upon Entry (iENGAGE) study, a National Institute of Allergy and Infectious Diseases (NIAID) funded randomized behavioral intervention trial. Here we present the study objectives, design and rationale, as well as the intervention components, targeting rapid and sustained VS through retention in HIV care and ART adherence during participants' first year of HIV care.

2. iENGAGE study objectives

Our primary objective was to develop and evaluate an integrated intervention by combining and adapting two evidence-based approaches; CDC's Retention in Care via Enhanced Personal Contact intervention (RIC/REPC) [17,18] and the Participating And Communicating Together ART adherence intervention (PACT) [19,20]. This adapted, integrated approach, entitled the iENGAGE Intervention, targeted VS (< 200 c/mL) at 48-weeks after initiation of HIV-care. The intervention components were unified by shared focus on information, motivation, and behavioral skills (IMB) [21–23] situated to the cultural, structural and emotional context in which HIV care is often negotiated [23].

3. Study outcomes

VS (< 200 c/mL) at 48 weeks on study was the primary outcome. Secondary outcomes included viremia copy-years, an area under the curve estimate of cumulative VL burden developed by our team [10], ART adherence, and retention in care, as measured by visit adherence and constancy. This study will also evaluate modifiers and mediators of iENGAGE intervention efficacy.

4. Study design

The iENGAGE study is a randomized controlled behavioral intervention trial implemented at four academically affiliated HIV clinical sites: the University of Alabama at Birmingham (UAB), the University of North Carolina at Chapel Hill (UNC), John Hopkins University (JHU) and the University of Washington at Seattle (UW).

5. Research procedures

5.1. Inclusion and exclusion criteria

The study sample consisted of adults 18 years and older with documented HIV infection who were initiating care at one of the four participating sites, English speaking, not moving in next 12 months, and able and willing to provide informed consent to participate. Participants were enrolled within 14 days of their initial primary care appointment, aligned with the focus on intervening immediately upon initial HIV care entry. We excluded patients who had prior outpatient HIV care or were not willing to provide informed consent.

5.2. Screening

All participating sites identified a process using administrative records to generate a list of potential patients new to outpatient HIV care coming to clinic, which differed across sites depending on the type of electronic health record (EHR) used and clinic work flow. At UAB, monthly electronic data query using the Cerner EHR was used to generate a list of potential patients. Research staff also reviewed the UAB 1917 HIV Clinic provider schedule every morning to identify if new patients were added. At JHU and UW, potential participants were identified using the EPIC EHR scheduling platform weekly. At UNC, patients labeled as “NSI” (New Specialty ID, which is the designation for new HIV patients at the ID Clinic) via WebCIS were identified weekly. Potential participants were also asked if they had ever received any kind of outpatient HIV medical care after being diagnosed, with eligibility restricted to those reporting no previous HIV care. Once participants were screened and deemed eligible for study inclusion the enrollment process began.

5.3. Enrollment

During enrollment, an informed consent process was completed, followed by baseline assessment. The baseline assessment consisted of a computer administered self-interview (CASI) questionnaire that included a battery of instruments [Depression (PHQ-8) [24], Anxiety (PHQ-A) [25], Substance abuse screen (ASSIST) [26,27], Alcohol abuse screen (AUDIT-C) [28], Quality of life (EQ-5D) [29], Sexual risk assessment (HRAP), ART adherence (ACCTG, VAS, SRS) [30], Coping (9 of 14 subscales from Brief COPE) [31], Social support (MOS-4) [32], HIV Stigma scale (Bunn and Earnshaw) [33,34], Disclosure, HIV-related self-efficacy [35], and adapted Unmet Needs (from CDC RIC) [36]]. The survey was administered in a private setting at the clinic or in designated research rooms. The CASI program included skip instructions to transition the respondent to applicable questions based on prior responses. Sites were given the flexibility to determine, on an individual basis, when the CASI was administered within first two weeks (0–14 days) of their first HIV primary care provider (PCP) visit date. On completion of the baseline CASI (lasting approximately 45 min) participants were randomized to the intervention or control arm.

5.4. Randomization and study arm assignment

iENGAGE utilized a 1:1 ratio for allocation to the treatment and control arms at each of the participating sites. A permuted block randomization was employed for treatment arm assignment, with block size randomly varied between 2, 4 or 6. Randomization was stratified by site. Research study staff was masked to treatment arm assignment. After completion of CASI survey, both study personnel and patients were unmasked to treatment arm assignment to conduct the iENGAGE intervention. A randomization list was generated using SAS at UAB and incorporated in the iENGAGE research database for study arm assignment across the study sites.

Fig. 1 describes iENGAGE research assessments and delivery of intervention components for all participants.

6. Intervention arm

6.1. Development of intervention component: integration of CDC RIC and PACT

iENGAGE integrated components of the CDC RIC/REPC and PACT evidence-based interventions to create a comprehensive iENGAGE intervention component. The iENGAGE protocol team consolidated core components of each intervention, including the use of MI strategies, education and information sharing, and shared-decision making from PACT and the risk screener directed approach and enhanced personal contact used in RIC, as well as emphasis on connection to available wrap around services and to address unmet needs that might impact engagement and adherence’. iENGAGE intervention is an individually tailored approach to optimize the participant information, motivation, and behavioral skills (IMB) [21,22] as conceptualized in the situation application of the IMB model to engagement in care (sIMB) [23]. The ‘situated’ aspect of the IMB model, as applied to engagement in care [23], emphasizes that intervention activities are developed and

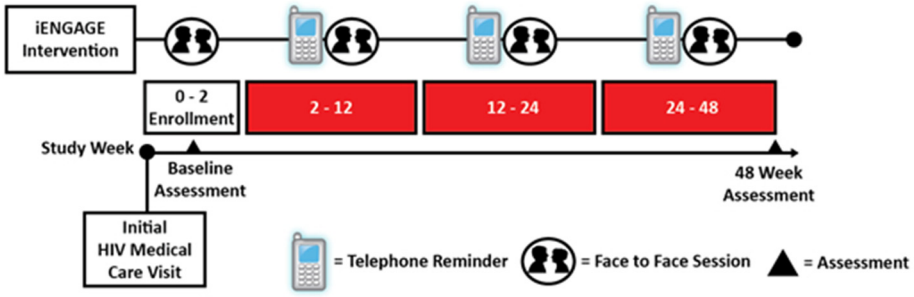

Fig. 1. iENGAGE study timeline.

delivered in the context of cultural, structural, and emotional factors that a given individual may need at a given point in time to optimize his or her health outcomes [37]. Specifically, the information, motivation and behavioral skills considered in the screeners and counseling work identified potential resources and barriers from a multi-level perspective - the individual, community, and structural factors such as access to programs, case management, and policies affecting care and adherence.

iENGAGE used several intervention strategies from CDC RIC/REPC and PACT to promote high impact, relevant opportunities to build participant knowledge, motivation, and skills for dynamic self-care demands (entry into care, adjustment to a new diagnosis, ART initiation, medical visit attendance over time, early and on-going adherence to medications). Specific intervention components are included in Tables 1 and 2. Early intervention content provided more standard informational content (knowledge) that many patients seek when initiating HIV care. Subsequent intervention content was flexible and tailored to the specific needs of each individual patient's circumstances and drew heavily on motivational interviewing skills and strategies [38]. Using client-centered and motivational interviewing strategies, clients in the intervention arm were engaged in exploring and building strengths needed to attend HIV care visits and also to adhere to medication once they started ART, over the course of their first year in HIV care.

The intervention could include navigation or some degree of case management if the counselor determined collaboration with treatment team members or service providers was indicated. The intervention did not include accompaniment to visits outside of the clinic or contact outside of counselor working hours.

Table 1
iENGAGE intervention component: face-to-face sessions.

Face-to-face sessions			
Session	# of weeks from first clinical care visit	Focus	Outline of steps
1	0–2	The first session focuses on introducing the Client to the iEngage program, providing basic education through effective communication of health information and orienting the Client to ongoing HIV care, including regular attendance of medical appointments. The session also provides an opportunity for the client to process (cognitively and emotionally) their HIV diagnosis and develop trust and rapport with the iEngage counselor. By the end of the session, the client will have completed the iEngage screener and will have developed a plan to help them stay in care.	1. Introduction/Build Rapport 2. Frame iEngage 3. Discuss Education/HIV Literacy 4. Discuss Adjustment Process 5. Identify Strengths and Challenges 6. Narrow down (if needed), Expand (if needed), Explore and Identify Modules 7. Modules (note that counselors can engage in all or only in parts of the skills building portion of the module. All modules are assumed to be delivered in a way that exemplifies client-centered and motivational interviewing principles). The menu of modules included organization, prioritization of Self Care, Communication with Treatment Team, Treatment Anxiety, Affect management/problem solving and Attitudes, Structural Problem Solving and Referrals. In addition, as add ins we included add in for dealing with HIV stigma and add in for disclosure of HIV status. 8. Review All Goals 9. Thank Client and Remind of Next Visit/Contact
2 3 4	2–12 12–24 24–48	Each follow-up session focuses on maintaining positive attitudes and motivation as well as the skills that have been developed in previous sessions. Many clients will also start ART at some point during the intervention. A special add-in for those starting ART is available for those starting ART and the screener has items that address ART adherence that should be asked at each visit when the client is prescribed ART. Each visit includes a check in on goals from the last visit, questions about education material, and the client's overall adjustment to living with HIV. The same process of administering and discussing the screener and developing a session plan together is used, with appropriate modules and possible add-ins (e.g., stigma and/or disclosure worksheets) to build motivation and skills. Sessions culminate in goals and closing the session, as well as appropriate documentation. Note that the final session (visit 4) should also discuss termination and how the client will maintain gains on their own over time.	1. Welcome: Always spend the first few minutes reestablishing rapport 2. Review: (a) Review the specific goals set at the last visit (b) Check in on education and adjustment (c) Check ART status 3. Explore: Re-administer screener, explore, identify session plan 4. Modules: Implement modules as new or revisiting 5. Goals: Review goals and close visit 6. Close and Document Whenever the client is prescribed ART, ART education and medication management activities are added to the session (Step 2) and ART screener items are included on the screener with appropriate follow-up on reported challenges (Step 3).

Table 2
iENGAGE intervention component: interim contacts.

Interim contacts with participants between visits		
Type of contact	Timeline	Outline
Brief interim encounters	2 weeks after each encounter with them	• Offer support • Provide coaching • Update the locator information • Refer unmet needs to the appropriate individuals in your clinic
Appointment reminder calls	7- and 2-days prior to HIV primary care visit date	Counselors place reminder calls for all scheduled primary medical care visits This includes: • 7-day reminder: 7 days prior to the HIV primary care visit date • 2-day reminder: 1–2 days prior to the HIV primary care visit date
Missed visit calls	1–2 days of missed primary care visit	• Discuss the challenges related to the missed appointment • Reinforce information from the modules • Provide support and coaching • Encourage them to reschedule
Unscheduled contacts	May occur at any time during the 12-month intervention period	Unscheduled contacts may occur at any time during the 12-month intervention period, and can/may take place on the phone or in person, and may be initiated by the client or the interventionist • AD HOC calls to/from client • AD HOC encounters at the clinic • SUPPORT SERVICE CONTACT for referrals are made to clinic or community support services that result from scheduled or ad-hoc encounters

6.1.1. Components of intervention

iENGAGE offered a number of support mechanisms (Tables 1 and 2). As depicted in Table 1, intervention arm participants had 4 scheduled face-to-face counseling visits at clinic, typically but not necessarily in line with clinic medical care visits (at enrollment, and between 2 and 12 weeks, 12–24 weeks, and 24–48 weeks after randomization respectively). In addition to the *face-to-face* component, counselors placed *interim* and *visit reminder calls* to participants (Table 2). Finally, *missed visit outreach* was implemented for any missed visits while the participant was on study in the intervention. We describe each component below.

6.1.1.1. Face-to-face sessions. The first intervention session, which occurred within the first 2 weeks after randomization focused on introducing the client to the iENGAGE program, providing basic education through effective communication of health information and orienting the participant towards HIV self-care. Each iENGAGE session generally broke into rapport building (first 5 min), followed by providing, clarifying and discussing relevant information (15 min), and the remainder of the visit engaging in MI-informed exploration and problem solving around use of HIV care and ARVs, which included use of an adapted version of the RIC/REPC screener for potential barriers to returning for their next clinic medical visit (adapted also to cover barriers to ART adherence). As intervention sessions progressed, less time on information discussions and more time on exploration of motivation and behavioral skills characterized the intervention approach. During the last two scheduled sessions, iENGAGE counselors also discussed the termination of the iENGAGE intervention and the gains that each client could maintain over time on their own. At the final session, each participant received an appreciation card and study completion certificate.

6.1.1.2. Interim phone contacts. Planned interim contacts occurred between intervention visits via telephone at about the 2-week mark after each session. During these encounters counselors offered support, coaching, referred unmet needs of participants to appropriate individuals in the clinic, and updated the locator information.

6.1.1.3. Appointment reminder calls. Counselors placed reminder calls for all scheduled primary medical care visits at 7 days prior to the HIV primary care visit date and then a 2-day reminder.

6.1.1.4. Missed visit calls. Counselors also placed calls to clients after any missed primary care visit (within 1–2 days of a missed visit) and ad hoc calls to/from client as appropriate. These ad hoc calls were documented as unplanned encounters. During missed visit calls the counselor discussed the challenges related to the missed visit, reinforced information from the *face-to-face* sessions, provided support and coaching, and encouraged participants to reschedule their appointment. Counselors documented all missed visit contact attempts and results.

6.1.1.5. Supervision. Training on the intervention was conducted by behavioral scientists on the study team (KRA and CG) to provide iENGAGE Interventionists at each site the necessary background in providing case management and counseling services. Initial trainings were conducted as in person workshops of 2 days at UAB and UW, followed by conference calls every week for the initial year, and then twice monthly and then monthly calls. Periodic review of recorded interviews by the study trainer (KRA) was also conducted with feedback. An in person booster training workshop was conducted during the second year at UAB and feedback was provided. Phone trainings were provided to new counselors that joined the team later during the study period. Interventionists at each site implemented only the intervention activities. Standard of care control participants did not interact with the interventionists.

6.2. Control arm

Control arm participants received standard of care (SOC) treatment at each participating site, which was captured via a SOC survey regarding retention in care and ART adherence strategies administered to clinic directors and service providers.

6.3. Follow up

6.3.1. Quarterly calls

All participants were called by research staff at each site at about 3, 6 and 9 months during the study period to address any study-related questions or concerns and to ensure that the locator information was correct. At the 9-month quarterly call, participants were scheduled for the final 48-week assessment. Notably, all research evaluation calls were made by study staff distinct from the counselors from the intervention arm to avoid contamination.

Table 3
Baseline characteristics of 371 participants enrolled in integrating ENGagement and Adherence Goals upon Entry (iENGAGE).

Characteristic	N (%)[d] or mean ± SD
Age (years)	37.1 ± 12.0
Race	
Black/African American	231 (62)
White	109 (29)
Other	31 (8)
Ethnicity	
Hispanic	20 (5)
Non-Hispanic	351 (95)
Gender	
Male	294 (79)
Female	71 (19)
Transgender	6 (2)
Site	
Johns Hopkins University	78 (21)
University of Alabama at Birmingham	153 (41)
University of North Carolina at Chapel Hill	76 (20)
University of Washington	64 (17)
Depression (PHQ8 score) (N = 348)[e]	7.4 ± 5.8
No depressive disorder (< 10)	241 (69)
Major depression (10–19)	94 (27)
Severe major depression (≥20)	13 (4)
Anxiety (PHQ-anxiety) (N = 360)	
None	247 (69)
Panic symptoms	76 (21)
Panic disorder	37 (10)
Alcohol use (AUDIT-C score) (N = 364)	2.8 ± 2.8
No risk	191 (52)
Low risk	46 (13)
High risk	127 (35)
Lifetime substance use (ASSIST)	
Cocaine/crack (N = 360)	135 (38)
Amphetamines (N = 368)	69 (19)
Opiates (N = 368)	47 (13)
Marijuana (N = 367)	277 (75)
Injection drug use (IDU) (N = 367)	29 (8)
Substance use last 3 months (ASSIST)	
Cocaine/crack (N = 360)	34 (9)
Amphetamines (N = 368)	22 (6)
Opiates (N = 368)	18 (5)
Marijuana (N = 367)	185 (50)
Injection drug use (IDU) (N = 367)	13 (4)
Sexual partners last 6 months	
0	76 (20)
1	100 (27)
2	55 (15)
3	38 (10)
4–5	40 (11)
≥6	62 (17)
HIV disclosure	
Anyone (excluding health provider) (N = 370)	290 (78)
More than one person (N = 369)	232 (63)
Spouse/significant other (N = 365)	109 (30)
Current sexual partner(s) (N = 365)	90 (25)
Past sexual partner(s) (N = 365)	114 (31)
Family member(s) (N = 365)	195 (53)
Friend(s) (N = 365)	83 (23)
Religious leader(s) (N = 365)	7 (2)
Supportive service needs last 6 months	
Counseling (N = 369)	121 (33)
Substance use treatment (N = 368)	30 (8)
Housing (N = 367)	92 (25)
Emergency financial assistance (N = 367)	129 (35)
Employment assistance (N = 366)	89 (24)
Transportation (N = 368)	125 (34)
Food, groceries or meals (N = 367)	137 (37)
Benefits assistance (N = 367)	124 (34)
Child care (N = 367)	10 (3)
Social support (MOS4)[a]	
Emotional/informational (N = 369)	163 (44)
Tangible (N = 367)	146 (40)
Affectionate (N = 364)	211 (58)
Positive social interaction (N = 365)	189 (52)
Quality of life (EuroQOL-5D)	

6.3.2. 48-week final assessment

The 48-week assessment consisted of completing a CASI survey and blood draw to capture the plasma viral load (VL) value. The CASI questionnaire included IMB measures for HIV visit (sIMB-RIC) [39–41] and ART adherence (LWIMB-AAQ) [42–44] using AIDS Clinical Trials Group (AACTG) instrument, Visual Analog Scale (VAS) and Self Reporting Scale (SRS) in addition to the instruments done at the baseline assessment. Table 4 lists the instruments and domains used for iENGAGE assessments.

6.3.3. Exit survey

Participants also took an exit survey during this visit to describe their experience with the iENGAGE study.

6.4. Outcomes

The primary outcome of the study is 48-week VS (< 200 c/mL), aligned with short-term individual and public health goals of HIV treatment. In addition, we evaluate viremia copy-years (VCY) [45], a measure of cumulative plasma VL burden, as a secondary virologic outcome measure. VCY is an area under the VL curve estimate of VL burden.

6.4.1. Secondary outcomes

6.4.1.1. Retention in care. Measuring retention in care is complex, and several measures have been used with no gold standard established [46]. We used visit adherence and visit constancy measures, which provide complementary information and have several advantageous properties for research purposes. Visit adherence is a proportion that captures the number of “attended” visits in the numerator and the number of total scheduled visits (“attended” plus “no show”) in the denominator during a period of interest [46–49]. Visit constancy evaluates the proportion of pre-specified time intervals with at least 1 attended clinic visit during an observation period of interest [46]. Time intervals have typically ranged between 3 and 6 months in accordance with treatment guidelines, with a 4-month interval applied for the new to care iENGAGE study sample [11,13,46,50–53]. We used the sIMB-RIC measure to evaluate IMB model based factors of HIV visit adherence [39–41], which include the social-environmental, affective, and adjustment aspects of information, motivation, and skills to ‘situate’ the core factors identified by the IMB model [23].

6.4.1.2. ART adherence. We measured ART adherence by patient self-report using AACTG, VAS and SRS. In addition to ART adherence, we measured the distinct but related construct of ART persistence, or durability [3,54,55]. Persistence is a quantification of the duration of ART exposure measured cumulative time participant engaged in ART regimen as the time from initiation to change or discontinuation of therapy, recorded allowing for switches or substitutions of individual antiretroviral medications. We also measured ART exposure as the proportion of days on treatment during the observation period. We used the LW-IMB-AAQ measure to evaluate IMB model based factors of ART adherence [42–44].

6.5. Sample size and power

The study was designed to have at least 80% power to detect an absolute difference of 15% in the intervention arm assuming 60% of the standard of care arm patients would have 48-week VL suppression (based on historical data from CNICS sites). A 10% lost to follow-up was assumed. The total sample size was planned to be 400 (200 patients per arm) which would yield 360 analyzable patients.

6.6. Results

Enrollment ended in April 2016. Of 941 patients screened, 372 were

Table 3 (*continued*)

Characteristic	N (%)[d] or mean ± SD
No mobility problems (N = 369)	317 (86)
No self-care problems (N = 368)	358 (97)
No problems with usual activities (N = 370)	300 (81)
No pain/discomfort (N = 367)	209 (57)
No anxiety/depression (N = 369)	165 (45)
Stigma (Bunn; range 1–4)	
Enacted stigma (N = 337)	2.2 ± 0.7
Disclosure concerns (N = 345)	3.1 ± 0.6
Negative self-image/internalized stigma (N = 343)	2.3 ± 0.7
Public stigma (N = 342)	2.7 ± 0.7
Anticipated stigma (Earnshaw; range 1–5)	
Family (N = 360)	2.7 ± 1.4
Friends (N = 360)	2.8 ± 1.3
Healthcare workers (N = 366)	1.8 ± 0.9
Coping[b]	
Active coping (N = 365)	3.3 ± 0.9
Denial (N = 364)	1.8 ± 1.0
Substance use (N = 363)	1.6 ± 0.9
Use of emotional support (N = 367)	2.6 ± 1.1
Behavioral disengagement (N = 361)	1.3 ± 0.7
Positive reframing (N = 366)	2.9 ± 1.0
Acceptance (N = 364)	3.4 ± 0.8
Religion (N = 367)	2.7 ± 1.1
Self-blame (N = 364)	2.3 ± 1.1
HIV treatment self-efficacy[c]	9.0 ± 1.5

[a] Social support MOS4 reported in the table represents participants who reported social support "most of the time" or "all of the time".

[b] For coping the range is from 1 ("not doing this at all") to 4 ("doing this a lot").

[c] For HIV treatment self-efficacy the range is 0 ("I can't do it at all") to 10 ("completely certain I can do it").

[d] Percentages described in the table are rounded and may not add up to 100.

[e] For measures with missing data, the number of patients that answered the question(s) is shown in parentheses in the left column.

enrolled across the four participating sites. One participant was subsequently found not to be new to care immediately after their randomization to the intervention arm and was removed from the study. Baseline characteristics for the 371 enrolled patients are summarized in Table 3. The average age of participants was 37 (± 12) years. About 79% were males and 62% were African Americans. Roughly, 31% of participants reported moderate/severe depression and panic symptoms/syndrome. Around 52% of participants stated having 2 or more recent sexual partners and 78% disclosed their HIV status to someone. Approximately 35% participants reported needing supportive services like counseling, emergency financial assistance, transportation help and help with food groceries or meals and benefits assistance. The percentage of participants that described no self-care problems was 97%, no mobility problems (86%), no problems with usual activities (81%), no pain or discomfort (57%) and no anxiety or depression (45%). The average score of 3 and above for coping domains was for active coping and acceptance.

48-week assessments were completed September 2017, with aggregation of study data for primary and secondary outcomes analyses ongoing.

7. Conclusion

The iENGAGE study is a NIAID-funded 4-session, in clinic, randomized behavioral intervention trial aimed at evaluating behavioral support for improving treatment outcomes among patients initiating HIV care. The primary outcome of the study is 48-week VL suppression (< 200 c/mL). The iENGAGE intervention consists of integrated components of the CDC/HRSA RIC and PACT, which are well aligned with the IMB model of ART adherence, and its application to engagement in care (sIMB). The unifying IMB model is guided by the need to promote multiple HIV adherence behaviors simultaneously. The 'situated' aspect of the IMB model provided an ideal framework for the iENGAGE intervention because of its contextualization of individual behavior in relation to multiple social and structural influences. The primary outcome of 48-week VL suppression (< 200 c/mL), and secondary outcome of retention in care are well aligned with emphasis on the HIV care continuum and National HIV/AIDS Strategy with profound implications for individual and population health.

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Conflict of interest

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