FAmily CEntered (FACE) advance care planning: Study design and methods for a patient-centered communication and decision-making intervention for patients with HIV/AIDS and their surrogate decision-makers

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ABSTRACT

Although the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) has become a chronic illness, disease-specific advance care planning has not yet been evaluated for the palliative care needs of adults with HIV/AIDS. This prospective, longitudinal, randomized, two-arm controlled clinical trial aims to test the efficacy of FAmily CEntered advance care planning among adults living with AIDS and/or HIV with co-morbidities on congruence in treatment preferences, healthcare utilization, and quality of life. The FAmily CEntered intervention arm is two face-to-face sessions with a trained, certified facilitator: Session 1) Disease-Specific Advance Care Planning (Respecting Choices Interview); Session 2) Completion of advance directive. The Healthy Living Control arm is: Session 1) Developmental/Relationship History; Session 2) Nutrition. Follow-up data will be collected at 3, 6, 12, and 18 months post-intervention. A total of 288 patient/surrogate dyads will be enrolled from five hospital-based, out-patient clinics in Washington, District of Columbia. Participants will be HIV positive and ≥18 years of age; surrogates will be ≥18 years of age. Exclusion criteria are homicidality, suicidality, psychosis, and impaired cognitive functioning. We hypothesize that this intervention will enhance patient-centered communication with a surrogate decision-maker about end of life treatment preferences over time, enhance patient quality of life and decrease health care utilization. We further hypothesize that this intervention will decrease health disparities for Blacks in completion of advance directives. If proposed aims are achieved, the benefits of palliative care, particularly increased treatment preferences about end-of-life care and enhanced quality of life, will be extended to people living with AIDS.

1. Introduction

Despite the efficacy and availability of antiretroviral therapy and the associated longer life expectancy, there were 1285 deaths among persons with HIV in the District of Columbia (DC) between 2008 and 2012, with 41% of the deaths HIV-related [1]. Blacks in DC make up under half of DC residents but account for 75% of all residents living with HIV [1]. Likewise, among individuals living with HIV in 2012, 85.5% of deaths were Black residents [1]. Blacks nationwide are half as likely as Whites to have completed advance directives [2]. Barriers may include the historical experience of discrimination against Blacks by health care institutions, or misinterpretation of Do Not Resuscitate (DNR) orders as euthanasia or an attempt to deny beneficial care [3-6].

The negative consequences of no or poor Advance Care Planning (ACP) include unmet care or delivery of unnecessary or unwanted care [7-9], dismissing the importance of non-relative caregivers such as gay partners [10-16], loss of respect for autonomy and loss of decision-making capacity of the person living with HIV/AIDS (PLWHA) [17]. End of life discussions are often deferred to the physician or patients are handed an advance directive document by a clerk at the time of hospital admission. Often, patients have little comprehension of what advanced directives are. A surrogate decision maker might be identified, but with no communication between the surrogate and the patient about values and goals of care. Advance care planning can significantly reduce these negative consequences by optimizing quality of life (QOL) [18-26], facilitating autonomy, and increasing access to information and choice [27]. Disease Specific-Advanced Care Planning (DS-ACP) has demonstrated increased congruence in treatment preferences between patients and...
caregivers and increased likelihood that patients’ preferences will be honored [28–31]. However, the benefits of ACP for adult PLWHA have not yet been demonstrated through DS-ACP [32–35].

2. Objectives of the FACE ACP study

Our goal is to test the implementation of ACP among adult people living with AIDS or HIV and co-morbidities (e.g. Hepatitis C) in Washington, DC. We developed and tested a successful HIV-specific ACP program for HIV positive teens and their families, the Family CEntered (FACE) ACP [28–30] in consultation with Co-Investigator Linda Briggs, who was critical in developing adult models of ACP for other serious medical conditions [31,36,37]. FACE bridges important gaps in communication research with PLWHA. Our intervention promotes an active ACP decision-making process focused on the patient/surrogate dyad to address end of life treatment choices.

2.1. Aims and hypotheses

2.1.1. Aim 1

To determine the efficacy of FACE ACP on congruence in treatment preferences between PLWHA and their surrogates over time. The aim of congruence is to ensure that adult patients have a voice in their medical treatment even in the event when the patient cannot speak for him or herself, and that the surrogate decision maker knows what the patient wants and has made a commitment to honor the patient’s wishes. We hypothesize that the development of congruence may not be homogeneous and FACE may influence the pattern of congruence development. We further hypothesize that different patterns of congruence development may have different effects on health care utilization. Lastly, we hypothesize that compared to control, FACE participants will better maintain congruence over time.

2.1.2. Aim 2

To determine the efficacy of FACE on key components of QOL for PLWHA. We hypothesize that FACE participants will increase or better maintain psychosocial QOL compared to controls.

2.1.3. Aim 3

To minimize health disparities in ACP between Blacks and non-Blacks and identify factors associated with disparities. We hypothesize that Blacks in the FACE intervention will complete advance directives at a rate comparable to non-Blacks, and at significantly greater rates compared to controls.

3. Study design

3.1. Overview

This study is a prospective, longitudinal, two-arm randomized controlled clinical trial (RCCT). This trial will test the efficacy of the FACE intervention on study outcomes over 18 months post-intervention. PLWHA/surrogate dyads (N = 288) will be enrolled and randomized to the FACE ACP intervention or Healthy Living Control (HLC) condition at a ratio of 2:1 (N = 192 FACE ACP dyads and N = 96 HLC dyads) with the goal of obtaining data from approximately 202 dyads at 18 months post-intervention (Fig. 1. FACE consort diagram).

![Fig. 1. FACE consort diagram.](image-url)
3.2. Inclusion of women and minorities

Gender distribution is approximately 50% male, 49% female and 1% transgender. Racial distribution is approximately 83% Black. Ethnic distribution among all racial groups is approximately 8% Hispanic or Latino.

3.3. Participant dyads

During enrollment, PLWHA will choose a surrogate decision-maker, using the Disease Specific ACP guidelines [38]. Patient/surrogate dyads commit to being in the study regardless of which arm they are randomly assigned.

3.4. Sites

Through recruitment at five hospital-based, out-patient clinics in Washington, DC, we will meet our enrollment goals and have adequate statistical power to increase generalizability of findings. Block randomization by study site to condition will control for idiosyncrasies of site-specific effects. Each study site’s interdisciplinary team are experienced in research recruitment, specifically having successfully recruited and retained PLWHA, including Black PWLHA [39].

3.5. Eligibility, recruitment, consent, randomization

The study has been approved by the five participating sites’ Institutional Review Boards (IRB) and will be reviewed twice a year by the FACE Safety Monitoring Committee. Study research assistants (RAs) in consultation with Health Care Providers (HCPs) approach potentially eligible participants. HCPs are not present at the time of approach to prevent any perception of coercion. PLWHA and surrogate decision-makers complete written informed consent. Participant eligibility is verified prior to completing baseline study measures. Inclusion and exclusion criteria are presented in Table 1.

Once consent is obtained, RAs administer the screening assessments. The consent and screening process takes approximately 45 min. The baseline visit also lasts approximately 45 min. Based on the randomized group assigned, FACE ACP and HLC participants will receive two 60–90 minute sessions scheduled one week apart. Sessions 1 and 2 will be followed by process questionnaires administered by the RA-Assessor. Post-intervention follow-up visits at months 3, 6, 12 and 18 will be conducted to assess outcomes.

Dyads are randomized to either FACE ACP or HLC groups using a randomly permuted block design and a 2:1 ratio, controlling for site and perinatal verse other modes of transmission. Randomization is performed via RedCAP at the coordinating site once the dyad has completed baseline procedures.

4. Assessment and outcome measures

Outcome assessments will be conducted at screening, baseline, following sessions 1 and 2, and post intervention follow-up visits, with the exception of the Statement of Treatment Preferences, which is administered at the time of Session 1. See Table 2 for schedule of study assessment and measures.

5. Interventions

5.1. Research team

Each site has a Co-Investigator (Co-I) and three research assistants (RAs), the RA-Interventionist, RA-Control, and RA-Assessor. Site Co-Is oversee site activities and provide weekly, face-to-face supervision of the RAs. Research assistants are trained to competency criteria and assist with recruitment, screening, enrollment and baseline screening measure collection. Booster training sessions for RAs are held as needed.

Table 1

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td>Patient</td>
<td></td>
</tr>
<tr>
<td>1. Age 21 or older at time of enrollment</td>
<td>1. In Intensive Care Unit</td>
</tr>
<tr>
<td>2. Aware of his/her HIV diagnosis</td>
<td>2. &lt;21 years of age at time of enrollment</td>
</tr>
<tr>
<td>3. Outpatients or inpatients (except Intensive Care Unit) with advanced HIV as determined by:</td>
<td>3. Unaware of his/her HIV diagnosis</td>
</tr>
<tr>
<td>a. Detectable viral load (&gt;200 copies per ml) on two occasions in the last 1-year period</td>
<td>4. Non-English speaking</td>
</tr>
<tr>
<td>b. CD4 count &lt;200 ever</td>
<td>5. Active psychosis or homicidal or suicidal ideation, determined at screening from a structured questionnaire</td>
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<tr>
<td>c. Current opportunistic infection</td>
<td>6. Score consistent with Dementia on HIV Dementia Scale</td>
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<tr>
<td>d. HIV-infected with a co-morbidity that may significantly limit life expectancy, including malignancy, cirrhosis, cardiomyopathy, end stage renal/kidney or liver disease, diabetes, HIV Associated Neurological Disorder (HAND), etc.</td>
<td>7. Developmentally delayed</td>
</tr>
</tbody>
</table>

Only the RA-Assessor is permitted to administer post-randomization assessments.

5.2. FACE ACP intervention

In Session 1, the RA-Interventionist, through the Respecting Choices Interview®, [38], facilitates conversation about goals, values and experiences which inform decision-making about EOL treatment preferences. In Session 2, the RA-Interventionist facilitates completion of an advance directive. See Table 3. Sessions are conducted in a private office. Session 1 is audio or video-taped to monitor fidelity to the protocol and possible contamination between the study arms. Review is provided by the Principle Investigator (PI) or selected Co-I (Briggs). Trained/certified facilitators include mental health professionals and graduate students in public health, psychology, counseling and nursing.

5.3. Healthy Living Control (HLC)

The HLC also uses a dyadic approach; however, participants do not receive the ACP intervention curriculum. Dyads assigned to the HLC condition also meet twice, one week apart, also for approximately 60 min each session, See Table 4.

6. Data analysis

Statistical analyses will use outcome measure scores (e.g. congruence in treatment preferences, QOL, healthcare utilization) and time varying-covariate variables (Highly Active Antiretroviral Therapy
6.1. Analytical plans

6.1.1. Aim 1

Congruence in decision-making for EOL care will be measured based on agreement (i.e. both patient and his/her surrogate choose the same option) on the Statement of Treatment Preferences. Kappa coefficients will be applied to assess chance-adjusted agreement between patient and surrogate responses. Latent Growth Model (LGM) will be applied to explore the trajectory of congruence development over time [48–50]. Then the GMM will be used to test Hypothesis A by examining the heterogeneity of congruence development [51,52]. Fig. 2 shows the GMM, in which $y_0$–$y_3$ are repeated measures of congruence at different time points.

Latent growth intercept and latent growth slope are two latent growth factors, representing the initial level of congruence and rate of change in congruence, respectively. The time scores in the model are set to 0 for Session 1 visit, and 1 for the first follow-up visit (month 3) for the purpose of model identification. Instead of assuming a linear or nonlinear polynomial function (e.g. quadratic or cubic), time scores are set free (denoted by * in Fig. 2) to be model estimated. As such, the pattern of change or type of congruence development trajectory will be determined by data. The latent class in the model is a categorical latent variable that captures the pattern of congruence development trajectories. Time-invariant covariates (e.g. race) will be used to predict the trajectories of the congruence development over time, as well as the pattern of congruence development trajectories, and time-varying covariates (HAART adherence, religion/spirituality) may be included to predict the level of congruence at different time points. Hypothesis B will be tested by regressing a distal outcome (e.g., health care utilization) on the latent class of congruence development trajectories (see Fig. 2). To test Hypothesis C, we will regress the latent growth slope factor and the latent class variable on FACE ACP, controlling for covariates. The impact of the FACE on the rate of change in congruence over time is allowed to vary across different classes of congruence development trajectories. In Fig. 2, dotted lines indicate interactions between covariates and the latent class variable. As attrition is inevitable in longitudinal studies, robust model estimator (e.g. MLR) using the full information maximum likelihood (FIML) will be used for model estimation. Importantly, missing at random (MAR), instead of missing completely at random (MCAR), can be assumed [52–57].

6.1.2. Aim 2

Similarly, the GMM will be used to examine the development trajectory of QoL and effects of FACE on its trajectory. The same time-invariant covariates (age, gender, race, education) will be controlled,
Table 3

<table>
<thead>
<tr>
<th>Session 1</th>
<th>Session 1 Goals</th>
<th>Session 1* Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundation</td>
<td>1. To facilitate conversations and shared decision-making between the patient and surrogate about palliative care, providing an opportunity to express fears, values, spiritual and other beliefs and goals with regard to death and dying 2. To prepare the surrogate to be able to fully represent the patient’s wishes</td>
<td>Patient and surrogate dyad together: Stage 1 assesses the patient’s understanding of current medical condition, prognosis, complications; Stage 2 explores patient’s philosophy regarding EOL decision-making and their understanding of the facts; Stage 3 reviews rationale for future medical decisions the patient would want the surrogate to understand/act on; Stage 4 uses the Statement of Treatment Preferences to describe clinical situations common to AIDS and related treatment choices; Stage 5 summarizes the discussion/need for future discussions as situations/preferences change. Gaps in information are identified and referrals are made. (This session will be videotaped.)</td>
</tr>
<tr>
<td>Disease-Specific Advance Care Planning (DS ACP) Interview 8</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Interview 8</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Briggs and Hammes, formerly Respecting Choices Interview 8</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>After session, dyad is giving Gunderson health information sheets on 1) CPR and 2) Tube Feedings by RA-Interventionist.</td>
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</table>

Table 4

<table>
<thead>
<tr>
<th>Session 1</th>
<th>Session 1 Goals</th>
<th>Session 1* Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundation</td>
<td>Developmental History. Adapted Bailey Developmental History form will be administered, with all medical questions removed from the developmental history to prevent any risk of contamination with the experimental FACE condition. After session, dyad is given Gunderson health information sheets on 1) CPR and 2) Tube Feedings by RA-Interventionist.</td>
<td>To take a non-medical developmental history. The RA-Control will conduct the session in a structured interview format to provide a control for time (approximately 45–60 min) and attention. For surrogates who do not know the patient’s developmental history, a set of relationship questions is asked.</td>
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<tr>
<td>Session 2</td>
<td>Nutrition Session. Using the American Academy of Pediatrics Bright Futures counseling guides, participants will be asked questions about nutrition.</td>
<td>Patient and surrogate dyad participate together: 1. Conversation is facilitated by RA-Control in a private room. 2. The patient will be asked first, then the surrogate, to parallel the structure of the intervention. 3. If surrogate is friend/partner, please refer to questions specific to friend/partner in the script. (This session will be videotaped.)</td>
</tr>
<tr>
<td>Session 2 Foundation</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Session 2 Goals</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>3</td>
<td></td>
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<tr>
<td>Session 2* Process</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>To provide nutrition information using the American Academy of Pediatrics Bright Futures counseling guides. Content in this review is not related to advance care planning or the FACE intervention.</td>
<td>This structured questionnaire/information will be administered to the patient/surrogate-dyad by the trained RA-Control together in a private room. The patient will be asked first, then the surrogate to parallel the structure of the intervention.</td>
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</table>

while time-varying covariates (HAART adherence, religion/spirituality) will be included in the model to predict measures of QOL at different time points.

6.1.3 Aim 3

The rate of completing advance directives among participants at baseline and each follow-up time point will be documented and the rate disparity between Black and non-Black participants at each of these time point will be described and tested by intervention groups using Chi-square statistics and logistical regression.

6.2 Sample size and power

In longitudinal studies, the number of repeated measurements plays an important role in statistical power, because there is a tradeoff between the sample size and the number of repeated measurements [58]. Various sample sizes were estimated corresponding to various combinations of effect size and autocorrelation. For a modest autocorrelation of 0.30 and a small effect size of 0.25, the estimated sample size for a longitudinal analysis to achieve a power of 0.80 at 0.05 level is about N = 188 at each of the 4 observation time points. Our proposed baseline sample (N = 288) will ensure a large enough statistical power for statistical analyses using traditional models. With application of the advanced latent growth analytic models for longitudinal data analysis, the statistical power would be larger than the traditional analytical methods for a given sample size [58,59].

7. Discussion

FACE offers five advancements over current standard of care: 1) promotes shared decision-making with families; 2) integrates the evidence-
based Disease-Specific ACP curriculum [38]; 3) differs from previously published research on advance directive documentation alone [60,61] by involving the patient/surrogate decision-maker in conversations about treatment preferences, then sharing them with the primary HCP; 4) is grounded in Leventhal’s theory of self-regulation and illness representations [62–64]; and 5) acknowledges those who prefer to have their doctor or family make these decisions for them. Recruitment for dyadic EOL studies has challenges such as identifying a surrogate, scheduling patients and surrogates, and dealing with conflicts that may arise [65,66]. To date, 15% of PLWHA interested in participating could not identify potential surrogate they trusted enough to make decisions for them. An additional site was added to meet enrollment goals. Hiring staff committed to flexibility assisted in addressing scheduling problems. Conflicts are managed by involvement of study ethicist or chaplain. Selection bias may occur as individuals may be hesitant to participate in EOL studies, so demographic data and reason for declining are collected from those who chose not to participate. Threats to validity may arise due to RA’s personal values about death and dying. Fidelity procedures are in place to process RA’s emotional reactions to implementing the intervention. Finally, some adults who wanted to participate could not, because their chosen surrogate decision-maker was their child who had participated in our adolescent study.

8. Conclusion

This study will provide replicable, evidence-based model for facilitating decisions about EOL care informed by the patient’s representation of illness and lived experience with the involvement of their chosen surrogate decision-maker. Surrogates can then be assured, they honored their loved one’s wishes, and patients can feel supported to the end, trusting that their families were there.

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