Methods for the FAmily CEntered ACP Clinical Trial in Adult PLWH in Washington, D.C.
*Note the current manuscript is a LCA of baseline information from patients only.

Subjects

From October 2013 through March 2017, patients with HIV infection and their chosen surrogate decision-makers, heretofore referred to as families, were recruited from five DC hospital-based HIV-clinics. Participating hospitals are members of the DC Center for AIDS Research (DC-CFAR). FACE ACP enrolled dyads consisting of adult PLWH aged 21 years or older and their chosen family member who was at least 18 years old. Inclusion criteria were amended to include all HIV-positive individuals receiving care at study sites to increase enrollment and consistent with current policy recommendations to include all stages of illness. Participant inclusion criteria required knowledge of HIV diagnosis and ability to speak and understand English, as not all measures were translated and participants would be signing a legal document. In order to ensure competency to participate in decision-making exclusion criteria were: signs of HIV dementia, homicidality, suicidality or psychosis on secondary screening by trained study staff. The institutional review board at each site approved the protocol. Written, informed consent was obtained from all study participants. A Safety Monitoring Committee reviewed the study data and human subject's protections yearly. This study was registered at clinicaltrials.gov, Identifier: NCT01775436.

Procedures

We conducted a 2 parallel-group, randomized controlled clinical trial with an intent-to-treat design. Providers identified potentially eligible PLWH who were then approached during a clinic visit by a trained research assistant (RA). Following baseline assessment, enrolled dyads were randomly assigned at a ratio of 2:1 to receive Family-Centered (FACE) ACP (n=155 dyads) or Healthy Living Control (HLC) (n=68 dyads). This ratio was decided upon out of ethical concerns, as previous studies using the FACE ACP model showed benefit with adolescents living with HIV and cancer. The data coordinating center created a computer-generated randomly permuted block randomization scheme blocked by study site to ensure relative balance across conditions over recruitment. PLWH/family dyads independently completed questionnaires at baseline (prior to randomization) and 3-months post-intervention.

Interventions

FAmily CEntered (FACE-HIV) ACP

Trained facilitators administered the FACE Intervention Sessions 1 (~60 min) and 2 (~60 min). The goals of Session 1, where the Respecting Choices ACP Interview was completed, were: 1) facilitate goals of care conversations between the PLWH and their family or family members; and 2) prepare the family to be able to fully represent the PLWH's treatment preferences, if the patient could not communicate. The goals of Session 2, where the Five Wishes advance directive was completed, were: 1) to confirm patient's surrogate decision-maker; and 2) to confirm end-of-life treatment preferences. The Five Wishes, in addition to being an advance directive, designates the health care power of attorney and two back-ups, if the first person is not available. The facilitator sent a secured email to the treating physician after session completion with a brief summary of the goals of care conversation and a copy of the Five Wishes. The facilitator followed site-specific procedures for entering the documents into the medical record (paper chart or EHR).

Healthy Living Control (HLC)

Control (HLC) Sessions 1 (~60 min) and 2 (~60 min). Session 1: Developmental History- the goal was to obtain a developmental history to control for time and attention spent with the participants in the FACE intervention. If the family member only knew the patient as an adult, the development of their relationship was discussed, using a structured questionnaire. All medical questions were removed to prevent any risk of contamination with the intervention. Session 2. Nutrition (~60 min) assessed nutritional status to counsel participants on optimal nutrition to boost immune functioning and to control for time and attention spent with the FACE intervention group.