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Pediatric advance care planning (pACP) for teens with cancer and their families: Design of a dyadic, longitudinal RCCT

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ABSTRACT

Cancer is the leading cause of disease-related death for adolescents and young adults (AYAs) in the United States. Parents of AYAs with life-threatening illnesses have expressed the desire to talk to their children about end of life (EOL) care, yet, like caregivers of adult patients, struggle to initiate this conversation. *Building Evidence for Effective Palliative/End of Life Care for Teens with Cancer* is a longitudinal, randomized, controlled, single-blinded clinical trial aimed at evaluating the efficacy of FAmily CEntered disease-specific advance care planning (ACP) for teens with cancer (FACE-TC). A total of 130 dyads (260 subjects) composed of AYAs 14–20 years old with cancer and their family decision maker (≥ 18 years old) will be recruited from pediatric oncology programs at Akron Children's Hospital and St. Jude Children's Research Hospital. Dyads will be randomized to either the FACE-TC intervention or Treatment as Usual (TAU) control. FACE-TC intervention dyads will complete three 60-minute ACP sessions held at weekly intervals. Follow-up data will be collected at 3, 6, 12, and 18 months post-intervention by a blinded research assistant (RA). The effects of FACE-TC on patient-family congruence in treatment preferences, quality of life (QOL), and advance directive completion will be analyzed. FACE-TC is an evidenced-based and patient-centered intervention that considers QOL and EOL care according to the AYA's representation of illness. The family is involved in the ACP process to facilitate shared decision making, increase understanding of the AYA's preferences, and make a commitment to honor the AYA's wishes.

1. Introduction

ACP is the process of preparing for future medical decision-making using a series of conversations about goals of care between an individual and their surrogate decision-maker [1]. Ideally, it is initiated early in the course of a serious illness and is ongoing to reflect any updates about the patient's wishes. ACP provides an extra level of support for patients, their families, and their treating physicians. ACP involves (1) designation of a surrogate decision maker, heretofore referred to as family (a person who will make medical decisions for a patient if the patient cannot express their own preferences or cannot do so by law because they are too young); (2) discussions of goals of care in the context of disease specific hypothetical situations that might occur in the future if disease progresses; and (3) documentation of goals of care, especially for situations involving diagnostic uncertainty.

Failure to engage in ACP conversations with adult patients is associated with aggressive EOL care, which may be unwanted; decreased use of hospice and palliative care services; increased hospitalizations; decreased patient-family congruence regarding treatment preferences, decreased compliance with patient's wishes for EOL care, and decreased quality of EOL care [2–5]. Completing ACP discussions, on the other hand, results in less conflict, anxiety, depression and distress for patients, families and medical staff [6–11].

Parents of AYAs with life-threatening and life-limiting illnesses have expressed the desire to talk to their children about EOL care, yet, like caregivers of adult patients, struggle to initiate this conversation [12,13]. Pediatric ACP (pACP) is sometimes avoided because it is thought that only a physician should initiate such conversations and that these discussions would be especially distressing to younger patients [14,15]. However, a recent two-arm randomized controlled trial conducted at five urban hospitals has shown that ACP with AYAs is feasible and not psychologically harmful in the HIV/AIDS population

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[10]. A second two-arm randomized controlled pilot study has shown similar results in a cancer population [5]. Given that cancer is the leading cause of disease-related death for AYAs in the United States, AYAs with cancer represent an important population with whom to extend this research [9,12,13,16–18].

2. Objectives of the FACE-TC ACP study

The FACE-TC project involves a dyadic interview with both AYAs and a family decision maker, where participants will complete a facilitated conversation about values and goals of care, as well as concerns, fears and hopes for the future. The primary purposes of the study are to give AYAs with cancer a voice in the present if they cannot speak for themselves in the future, to ensure that families know what AYAs would want in a bad outcome situation, and to explore if the care desired is the care received for those AYAs who die during the study.

3. Study design

3.1. Overview

This study is a prospective, longitudinal, two-arm, randomized, controlled, single-blinded, clinical trial (RCCT) with an intent-to-treat design. Data will be collected during baseline and study intervention, as well as 3, 6, 12, and 18 months post-intervention. Dyads (N = 130 dyads; 260 subjects), composed of AYAs with cancer and their family decision maker, will be enrolled and randomized to either the FACE-TC intervention (N = 87 dyads) or TAU control (N = 43 dyads) at a 2:1 ratio, because of the demonstrated benefits of pACP in our previous studies [4,5,8–10]. Estimating there will be up to 30% attrition, our goal is to have complete data through the 18 month visit for 91 dyads (N = 182 subjects). A visualization of the study visits (Fig. 1) and the Consort Diagram (Fig. 2) provide details of enrollment, randomization, arm allocation, and follow-up. We estimate that approximately 40% of the sample will be minorities, including African-American, Hispanic-Latino, or Asian participants, and approximately 50% of the sample will be female.

3.2. Sites

Participants will be recruited from the established pediatric oncology and palliative care programs at Akron Children's Hospital and St. Jude Children's Research Hospital, from which we have created our interdisciplinary study team. Approximately 520 AYAs ages 14–20 years utilize these oncology programs per year, so we anticipate meeting our enrollment goal of 130 dyads. Given this goal, we will have adequate statistical power to conduct our analyses and generalize our findings (see Sample size and power section for details). Block randomization by study site will control for site-specific effects. Children's National Health System will serve as the coordinating center only, as FACE-TC was pilot tested at this location thereby creating potential contamination effects at the site.

3.3. Research team

Each site has a Co-Investigator, blinded RA-Assessor, RA-interventionist, and a Clinical Coordinator. Site Co-Investigators will provide weekly supervision to study staff during scheduled meetings and help maintain recruitment goals, participant retention, safety of subjects, and fidelity to the protocol. A three-day training will be conducted for study staff prior to opening enrollment. After training in the research protocol, the RA-interventionists and RA-Assessors will be responsible for participant recruitment, enrollment, and baseline data collection. The RA-Interventionists have been certified in the respecting choices ACP program as facilitators and will administer the intervention sessions. Only the blinded RA-Assessor will administer post-randomization outcomes assessments.

Booster training sessions will be held for study staff as needed. As the Coordinating Center, Children's National staff designed and will maintain the database using the Research Electronic Data Capture System (REDCap) (https://catalyst.harvard.edu/services/redcap/), perform data quality checks, and be responsible for the statistical analyses. Staff at Children's National will also help ensure the two sites maintain fidelity to the protocol and regulatory compliance through monthly conference calls and twice yearly site monitoring visits during study intervention implementation.

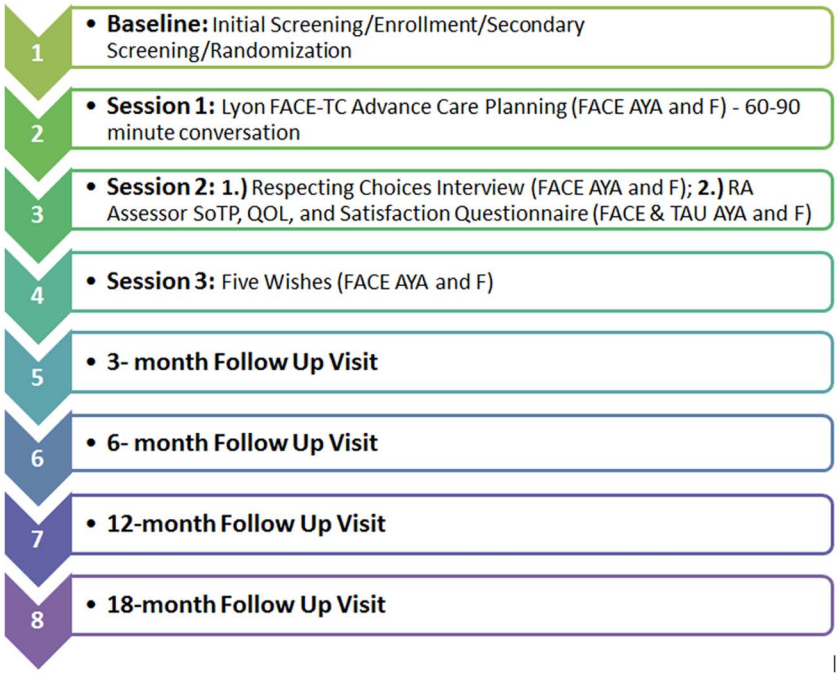

Fig. 1. FACE- TC study visit visualization. Key: FACE AYA = adolescent/young adult patient in intervention; TAU AYA = adolescent/young adult in control; F = family/surrogate decision maker; SoTP = statement of treatment preferences; QOL = Quality of Life Questionnaire.