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Design and rationale for NOURISH-T: A randomized control trial targeting parents of overweight children off cancer treatment

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ABSTRACT

Approximately 40% of off-treatment pediatric cancer survivors (PCS) are overweight or obese, which increases their risk for negative long-term physical health complications. Consistent with the Institute of Medicine's (IOM) emphasis on patients transitioning from treatment to cancer survivorship and increasing long-term healthy behaviors in these survivors, we plan to conduct a pilot RCT to address the increasing overweight/obesity rates among PCS by targeting their caregivers as agents for PCS behavior change. We plan to focus on parents' behaviors, attitudes and roles in promoting healthier eating and physical activity (PA) in PCS and adapt an evidence-informed, manualized parent intervention – NOURISH – found to be effective for parents of overweight and obese children and adolescents in reducing child and adolescent BMI. We plan to adapt NOURISH for caregivers of 5–12 year old PCS (6 months–4 years off active cancer treatment). Our pilot feasibility RCT — NOURISH-T (*N*ourishing *O*ur *U*nderstanding of *R*ole modeling to *I*mprove *S*upport for *H*ealthy *T*ransitions) evaluates: 1) the preliminary efficacy of NOURISH-T for PCS, compared with an Enhanced Usual Care (EUC) control condition, and 2) factors to consider to improve future adaptations of the intervention. The project will enroll caregivers of PCS at two pediatric oncology clinics into the 6-week intervention (or EUC) with assessments occurring pre- and post-6 weeks of intervention, and at a 4-month follow-up.

1. Introduction

Approximately 80% of pediatric cancer patients are expected to live to adulthood, but many experience long-term health sequelae [1–3], including an increased risk for weight gain and decreased physical activity (PA) [4–7], which worsen over time [8,9]. Five years post-treatment, 21% of all pediatric survivors are classified as obese (BMI ≥ 95th percentile ([%ile]) for age and gender) and 20% as overweight (BMI ≥ 85th %ile and ≤94th %ile for age and gender) [10], with some diagnostic subgroups at even greater risk for post-treatment obesity (e.g., acute lymphoblastic leukemia and specific sarcomas) [10,11], placing overweight/obese pediatric cancer survivors (PCS) at greater health risk than overweight/obese children in the general population [12,13]. One of our clinics reported similarly high rates of overweight and obesity in PCS [14].

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The association between cancer treatment and future obesity has been documented [15–18], with cranial radiation and exposure to corticosteroids identified as possible causes [4,10,19,20]. However, consumption of high-fat diets and physical inactivity during treatment are likely key factors influencing post-treatment weight gain, as healthy eating and PA decline [5,21]. Although these patterns might be unavoidable during treatment, they are associated with health complications when continued post-treatment [12]. Healthy lifestyle changes, including increasing PA and improving dietary habits, might prevent future chronic illness, reduce the risk for recurrent disease and improve quality of life QOL in PCS [5,6,11,14,21–26].

Despite the association between cancer treatment and future obesity, few interventions have addressed the negative impact of cancer therapies on the eating and PA behaviors of PCS [23,27]. A few small-scale studies have addressed the impact of unhealthy behaviors [28–32], but most do not utilize evidence-informed treatments. The current randomized control trial (RCT) pilot modifies an evidence-informed 6-week social-cognitive-behavioral parent intervention (*N*ourishing *O*ur *U*nderstanding of *R*ole *M*odeling to *I*mprove *S*upport and *H*ealth — NOURISH) [33] targeting overweight/obese children [33,34] for use with caregivers of PCS (ages 5–12) as they transition from active treatment to survivorship [35]. Because we are dealing with a specific target population, we also extend our age range from that used in the original NOURISH (ages 5–11) project.

Consistent with pediatric obesity literature [36–39], this RCT pilots the feasibility and acceptability of targeting caregivers to facilitate behavioral changes in PCS (NOURISH for Healthy Transitions — NOURISH-T). Family-based pediatric obesity treatments show more long-term success than treatments that target children exclusively [40–44], and caregivers' behaviors and attitudes predict children's behaviors [45]. Parent behaviors, such as increased PA and healthy eating (both of which decrease in parents of children with cancer) [18], are targeted for this 6-week intervention as treatments targeting parents exclusively have been found to be more effective in long-term weight reduction compared to children-only interventions, and interventions targeting parents and children [36,38,39]. Also, parental attitudes such as over-protectiveness and perceived child vulnerability are addressed because they affect a parent's likelihood of encouraging exercise in PCS [46].

1.1. Aims

The aim of this study is to test the feasibility and preliminary efficacy of NOURISH-T on PCS dietary intake, QOL, PA, and BMI and to explore whether caregivers show improvements on these same health indicators as well as in perceptions of child vulnerability and over-protectiveness.

2. Overview of design and methods

This multi-site RCT pilot will enroll a total of 66 caregivers of PCS at All Children's Hospital, John Hopkins Medical Center (ACH) and the University of Pittsburgh and Children's Hospital of Pittsburgh (UP). ACH is the closest and largest regional children's hospital to the University of South Florida (USF), where the PI (MS) is based. USF and ACH have set up contractual arrangements for the purposes of this project and one of the authors serves as a Co-I on the project (GH). This RCT compares NOURISH-T, a 6-session evidence-informed, manualized intervention ($n = 33$) with an Enhanced Usual Care (EUC) control condition ($n = 33$). Caregivers of overweight/obese PCS (at or above 85th BMI percentile for age and gender), ages 5–12, and between 6 months and 4 years off of cancer treatment will be randomized to either NOURISH-T or to EUC. In addition to examining feasibility, study assessments and questionnaires will be completed at baseline, post-intervention and 4-months post-intervention.

2.1. Study sites

Over 18 months of data collection, approximately 110 ACH PCS and 175 UP PCS are expected to meet age eligibility criteria and be off of active cancer treatment between 6 months and 4 years. Based on chart reviews, we conservatively expect 37% of eligible patients to meet our BMI %ile criteria at 6 months post-active treatment (N at ACH = 41 and UP = 65 expected). Using power analyses as a guide (see Section 6.1 on power analyses estimates), we target n = 16 at USF/ACH for each condition and n = 17 at UP in each condition (NOURISH-T and EUC) to meet our target sample of n = 66. Our prior work has found 80% enrollment in a clinical trial [47].

2.2. Participants

Inclusion/exclusion criteria: *Caregivers*: Mothers and fathers (biological/adoptive/step parents/legal guardians) of PCS, 18 years or older and fluent in English, are the primary focus of the intervention. Caregivers are *ineligible* if they: 1) are non-ambulatory, 2) are pregnant and 3) do not reside with the PCS at least 50% of the time. *Eligible PCS* must: 1) be between 5 and 12 years of age at study entry; 2) be off of active cancer treatment for 6 months to 4 years; 3) reside with a participating caregiver; 4) be able to engage in PA tailored to current medical status; 5) *NOT* be taking medications that affect body weight, e.g., steroids and some ADHD medications within 6 months of enrollment, and 6) be at or *above* the 85th BMI %ile [48]. PCS who relapse during the intervention will be excluded from further involvement, although medical chart follow-up will be obtained (e.g., BMI) and attempts to obtain post-assessment information will be made. Eligibility criteria are based on prior parent intervention studies [33,34]. Both caregiver and PCS must meet eligibility criteria for the dyad to be enrolled. Because PCS are often in treatment for years and may experience social/emotional development delays [49–51], we will control for age and time since treatment in the analyses.

2.3. Recruitment

Eligible PCS at both sites will be identified from medical records and health care referrals. Letters describing the study will be sent to eligible caregivers by the medical team in accordance with IRB regulations. Eligible caregivers also will be informed of the study during outpatient appointments and by phone by clinic staff who will obtain consent to be contacted by research staff. Prior to data collection, a detailed assent/consent process will be conducted with caregivers and PCS during