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# Design and Rationale for NOURISH-T: A Randomized Control Trial Targeting Parents of Overweight Children with Cancer Transitioning off 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 conduct a pilot RCT to address the increasing overweight/obesity rates among PCS by targeting their caregivers as agents for PCS behavior change. We 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. We 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 effectiveness 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

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intervention, including determining optimum post-cancer treatment time to offer 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.

**Keywords**

Pediatric Cancer; Pediatric Obesity; Parent Training; Randomized Clinical Trial

## 1. Introduction

### 1.1. High rates of pediatric cancer survivorship have focused attention on long-term health behaviors.

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 survivors are classified as obese (BMI ≥95$^{th}$percentile ([%ile]) for age and gender) and 20% as overweight (BMI>85$^{th}$%ile and ≤ 94$^{th}$ %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]. A medical record review of off-treatment patients at one of our clinics reflected similarly high rates of overweight and obesity in PCS [14].

### 1.2. Cancer treatment and obesity.

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].

### 1.3. 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 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] that has been positively evaluated with overweight/obese children [33,34] for use with caregivers of PCS (ages 5–12) as they transition from active treatment to survivorship [35].

### 1.4. NOURISH-T: Targeting caregivers (parents/legal guardians) to promote healthy dietary intake and PA behaviors in PCS.

Consistent with pediatric obesity literature [36–38], 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 [39–43], and caregivers' behaviors and attitudes predict children's behaviors [44]. Parent behaviors, such as increased PA and healthy eating (both of which decrease in parents of children with cancer) [18], are targeted. 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 [45].

### 1.5. Specific Aims

Specific Aims are to test the feasibility and preliminary efficacy of an adapted intervention, NOURISH-T, to address the high rates of overweight and obesity in PCS by targeting caregivers as agents for change.

## 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 85$^{th}$ BMI percentile for age and gender), ages 5–12, and between 6 months- 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 4 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.

### 2.2. Participants --

Inclusion/Exclusion Criteria: Caregivers: Mothers and fathers (biologic/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 5–12 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 within 6 months of enrollment, and 6) be at or above the 85$^{th}$ BMI %ile [46]. 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 [47–49], 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 to explain study requirements. Research staff will contact interested caregivers to explain the study further and obtain caregiver consent and child assent.

### 2.4 Participant Retention:

This pilot RCT aims to assess feasibility, including retention, and preliminary efficacy. To maximize retention, reminders, monetary incentives, and regular phone and e-mail/sms text contact will be used. Contact with all participants will be made one week and again 24 hours before their scheduled assessment appointment(s). Contact information for 3 friends or relatives who will be able to provide participant contact information should they relocate or change phone numbers will be obtained. Prior work using focus groups suggests [14] high levels of participation due to perceived relevance of our study's aims to the caregivers' children. However, because of the unique challenges of research with PCS, relapse or unexpected health changes can occur, making some attrition due to relapse possible (this will be tracked). Additional strategies for retention were built into the NOURISH-T intervention project. We recognized that asking caregivers to participate in all intervention sessions in a face-to-face format might prove to be too difficult and burdensome; we therefore streamlined our protocol to allow for more telephone contact and combined assessments with intervention sessions wherever possible (strategies discussed more fully below). We also give our participants a monetary incentive – either a gift card or cash ($20) at each assessment point – pre-, post- and then follow-up. Participants who attend the final session are given Certificates of Completion.

### 2.5 Randomization:

A randomization scheme based at USF utilizing a random number generator with a 1:1 ratio of NOURISH-T to EUC conditions will be used to assign participants to a study arm after

consent. Originally, we planned to conduct NOURISH-T and EUC sessions in small groups. However, once we obtained IRB approval and reviewed our potential patient/participant lists, we concluded that the catchment areas for both ACH and UP would be a barrier to coordinating groups for the project. NOTE: Mothers and fathers will be invited to participate in the same arm as the PCS. Data from recent caregiver studies [50] have revealed that few fathers participate in intervention studies, yet half of our participants in a prior pilot were fathers [14]. We will track the number of fathers vs. mothers that participate and will test potential covariates such as caregiver gender for future intervention development.

## 3. Interventions

### 3.1. Enhanced Usual Care Control:

Caregivers randomized to the EUC will attend assessment sessions and an initial group wellness session moderated by an independent interventionist. Whenever possible, the assessment will be combined with the wellness session to reduce participant burden (travel and time). The wellness session will address the role of diet and exercise in pediatric overweight. Much of the material for this session is pulled from the publically available We Can! manual [51].

EUC participants will receive a binder and a manual that contains URLs to various We Can! website pages expanding upon session information, such as PA and nutrition. In addition, as we did in our original NOURISH pilot [33,34], EUC caregivers will receive nationally available print or web-based brochures on pediatric overweight on 2 occasions during the study so that similar (but not as intensive) information is provided in the intervention and EUC arms of the study. Because post-EUC intervention assessments will take place about six weeks post-wellness session, EUC participants will receive e-mailed or mailed printed materials at two weeks and five weeks post session. Finally, EUC participants will also receive pedometers to assess PA at three time points.

Assessments will be conducted prior to, or in combination with, the wellness session, six weeks post-wellness session and then again four months following post-assessment. To maximize EUC retention, e-mail reminders about web links for follow-up information and assessment sessions will be made. We will also call all EUC participants approximately two months after the six week post-assessment appointment– our brief “booster” phone call session. Participants will be asked questions regarding progress in goal accomplishment, obstacles, concerns, as well as the utility of materials received during the course of the study.

### 3.2. NOURISH-T Intervention:

Consistent with Ewing’s work which found a retention rate of 85% in a 10-session intervention with parents of obese, Medicaid-insured children [52], we plan a combined face to face session with individual participants, or when possible to coordinate, up to 3 participants in a small group, + telephone delivery of NOURISH-T. Specifically, the first and last/sixth sessions will be in standard face-to-face group format. (It is notable that a consistent meeting time is established with each family, as would have occurred with all face-to-face sessions.) Whenever possible, to reduce participant burden, the assessments will

be conducted either prior to the first session or immediately following the final/sixth face-to-face session. Four sessions will be conducted via telephone conference arranged individually with each family. Manualized sessions are < 1 hour in length.

Group leaders supervised by licensed psychologists will introduce the session topic after the previous session's homework, goals and goal-setting strategies are reviewed. The NOURISH-T session will be used to establish weekly PA and dietary goals, allowing for the opportunity to problem-solve potential activity barriers. In addition to the telephonic dietary and PA session that will provide basic information about nutrition and PA to participants, NOURISH-T participants will be offered an additional combined session in which they will be able to meet with a pediatric oncology dietician and physical therapist. These professionals will meet with participants in small groups towards the end of each six-session cycle. These sessions will focus on providing families with specific strategies for reaching their nutrition and PA goals. To the extent possible, these sessions are meant to supplement the psycho-educational information sessions held telephonically and focus on individual issues raised by each family. We will track whether families choose to participate in this additional session. E-mail and text reminders about homework and follow-up sessions will be sent.

As in EUC, NOURISH-T participants will receive additional materials via e-mail or by standard postal service. All participants will be provided a binder at the first session that will include materials for that session as well as the following session. After the first session, participants will be mailed materials to be used for each subsequent session. During telephone sessions, participants will be asked to follow along with the materials sent to them during the session to help reinforce the information provided. Participants will also engage in relevant exercises (e.g., a brief mindful eating exercise) over the phone. Step-by-step instructions of these exercises will also be included in their materials so that they can follow along with the group leader. They will also be encouraged to add all materials mailed or e-mailed to them to the binder so that they will have these materials organized and be able to refer to them once the intervention is completed. NOURISH-T participants will also receive a booster phone call 2 months post-intervention and will receive additional educational mailings regarding nutrition and PA.

### 3.3. Theoretical foundations.

The original NOURISH program is grounded in Social Cognitive Theory (SCT) [53], emphasizing environmental, personal and behavioral interacting factors that influence PA and food choices [54,55]. NOURISH-T builds upon the strengths of NOURISH with revisions made based on the preliminary NOURISH-T focus groups to increase relevance to caregivers of PCS [14]. Behavioral strategies are emphasized throughout the program, e.g., parenting behavior in the context of cancer and obesity.

In addition, elements of Cognitive Behavioral Therapy (CBT) specifically address how caregivers' maladaptive cognitions about PCS impact parenting behaviors that may lead to unhealthy weight-related behaviors in PCS. Specifically, the concept of the "vulnerable child syndrome (VCS)", wherein parents of physically healthy children who have survived a serious illness view their child as more vulnerable to problems (e.g. medical, psychological

or behavioral), is explored [45,56–58]. Parents learn about relations between the VCS and overprotective behavior such as discouraging PA [59–61]. Therefore, NOURISH-T targets the social environment, maladaptive cognitions, and the links among these variables and behavior, aiming to increase caregivers' self-efficacy for behavioral change, and facilitate an authoritarian approach to parenting.

**3.3.1. NOURISH-T Session Content:** Throughout NOURISH-T, the interactive influence of social learning on behavioral outcomes (e.g., parent's modeling of healthy behavior) is emphasized. Behavioral strategies such as self-monitoring, contingency management, and stimulus control are integrated in these sessions. Further, because participatory experiences enhance overall intervention efficacy [62,63], these activities are incorporated throughout, including self-assessments, group discussions whenever possible and experiential activities (e.g. mindful eating exercises). Homework will be assigned between sessions so skills can be practiced [63]. We also focus on the caregivers' relationship with everyone in the family, not just the "identified patient" or overweight child, as is recommended [64,65]. Topics not in the original NOURISH that maximize relevance for caregivers of PCS were added (e.g., a greater focus on perceptions of vulnerability and parental over-protectiveness).

See Table A.1 for details regarding session content for the original NOURISH intervention, and adapted session contact for NOURISH-T.

### 3.4 Treatment Fidelity and Staff Training.

The NOURISH-T manual and study protocol will be finalized during the first 3 months of the RCT, and the protocol will assure implementation consistency and fidelity to treatment implementation (FTI). Study manual fidelity will be ensured via the following strategies: 1) Prior to beginning the study, all NOURISH-T and EUC group leaders will participate in separate training led by the PI at USF or UP. Group leaders will learn either the manualized NOURISH-T intervention or the EUC session (depending on assigned study arm) and will be blinded to the aims. Prototypes of all NOURISH-T sessions will be videotaped by the USF team and provided to group leaders at UP to use as a model; 2) Weekly session review and supervision of group leaders will be led by the site PI; and 3) all NOURISH-T group/telephone and EUC sessions will be audiotaped and coded for consistency across sessions by an assistant utilizing a fidelity checklist. The USF research team will code all audiotapes to ensure FTI. Group leaders will be re-trained if treatment fidelity falls below 90%. Preventing Contamination. Because we are recruiting caregivers with PCS off active cancer treatment, there is less likelihood that a caregiver might have the opportunity to talk with another about the study than if we were recruiting caregivers of children still on treatment. Moreover, we expect that a majority of our participants will be engaged individually in the project, rather than in small groups. However, to evaluate whether such possibilities occur and their possible effect, we will assess via an exit questionnaire whether caregivers discussed the intervention with others and track these data. Training in Cultural Competence. All staff will be trained in the delivery of culturally competent interventions which will include discussion of unique aspects of individuals' cultural backgrounds. Scenarios reflecting issues that may arise in the study and ways of managing them will be presented [66].

## 4. Outcome Measures

PCS and caregiver measures will assess height and weight, dietary intake, PA behaviors, QOL and perceptions. For younger PCS or those needing additional assistance, the child's caregiver and/or research assistant will complete or help him/her complete measures.

### 4.1. Anthropometric Measures.

Height will be measured to the nearest 1/4 inch using a stadiometer. Weight will be measured to the nearest 1/4 lb using a medical balance beam scale. These data will be used to calculate BMI. Hip (maximum girth of the hips, above the gluteal fold), and waist (narrowest part of the torso above the umbilicus and below the xiphoid process) circumferences will be assessed using an anthropometric measuring tape, and these data will be used to calculate waist–hip ratio.

### 4.2. Dietary Recall.

Three (pre and post-intervention/6 weeks later and 4 months follow-up) 24-hour recalls will be completed by caregivers using the *Automated Self-administered 24-Hour Dietary Recall (ASA24)* [67]. Caregivers will be trained on how to complete the ASA24 for themselves and also complete the ASA24 for their child [68]. Research assistants will provide guidance as needed. We focus on the frequency of sugar-sweetened beverages consumed weekly, frequency of family meals and fast food consumption as well as fruit and vegetable intake. The ASA24 is comparable in reliability to more expensive interviewer-recall methods [,69–71].

### 4.3. Pedometers.

PCS and caregivers will be trained to wear a piezoelectric, computer downloadable pedometer consecutively for 7 days prior to the pre- and post-intervention and 4 months post-intervention assessments. Pedometers are a low-cost objective method of assessing PA, have been shown to be efficacious with young children, and do not normally interfere with daily activities [72].

### 4.4. Child Sugar Sweet Beverage and Fast Food Intake.

This 13-item questionnaire will assess child intake of sugar sweetened beverages, breakfast and dinner habits, as well as frequency of fast food intake [33].

### 4.5. Physical Activity Questionnaire for children (PAQ-C).

This 9-item PA recall questionnaire will assess children's PA preference and frequency over a 7-day period. Internal consistency with various age groups and ethnic groups is high, consistently above $\alpha = .80$. Caregivers will complete this validated self-report 7-day recall PA measure for children in the study who are too young or unable to read or write. [71]Parent report of children's PA is appropriate for younger children [74,75].

### 4.6. *Pediatric Health-Related Quality of Life* (PedsQL4.0).

The PedsQL [76,77] is a 23-item scale assessing perceptions of how health affects daily life in four areas: physical, emotional, social, and school; items are rated on a 5-point scale ranging from 0 ('never') to 4 ('almost always'). Internal consistency is high ($\alpha$ = .88 for child report, and $\alpha$ = .93 for parents) [78], and the PedsQL discriminates effectively between healthy children and children with health problems [76,77].

The following measures are completed by Caregivers only:

### 4.7. Demographic information.

A demographic survey will provide a profile of participant by assessing for various participant variables such as gender, race/ethnicity, cancer and treatment information, age, living arrangements, parental education, income, insurance status, and history of other illnesses.

### 4.8. Child Feeding Questionnaire.

This 31-item questionnaire assesses parental approaches to and attitudes about feeding their children. In addition, the CFQ includes a brief assessment of parental weight status during childhood, adolescence, early adulthood, as well as current status. The CFQ yields reliable and valid scores in samples of caregivers with elementary age children [79,80].

### 4.9. Family Eating and Exercise Behaviors.

This 28-item questionnaire contains items that have been used in previous work by Neumark-Sztainer [81], Sallis [82] and in NOURISH [33,34]. This questionnaire assesses eating, exercise and weight-related habits of families, e.g., frequency of family meals, fast food consumption, television use during meals, fruit and vegetable and sugar sweetened beverage availability, as well as their encouragement of healthy food consumption, PA, and dieting in their children.

### 4.10. Child Vulnerability Scale.

Parental perceptions of child vulnerability will be assessed using the Child Vulnerability Scale (CVS) [83], an eight item self-report scale rated on a 4-point scale ranging from 0 ("definitely false") to 3 ("definitely true"); higher scores reflect greater perceived child vulnerability. Previous studies have demonstrated adequate internal ($\alpha$ = .74) [83] and an aggregate correlation of $\alpha$ = .84 for test-retest consistency [84].

### 4.11. Parent Protection Scale.

This 25-item self-report measure reliably measures parental overprotection behaviors [59,84,85] (supervision, separation problems, dependence, control dimensions of protective parenting behaviors). Respondents are asked to rate each statement on a four-point scale ranging from 0 ("never") to 3 ("always") [85]. Higher total scores represent greater overall levels of parental protection behaviors. Previous normative studies have demonstrated moderate to high internal reliability ($\alpha$ = .73) and high test-retest reliability for the total score ($\alpha$ = .86) [86].

### 4.12. Parental HRQOL.

The MOS 36-Item Short Form Health Survey (SF-36) will measure general adult health functioning in eight domains. Internal consistency for this scale is high ($\alpha$ = .85) [87], and the SF-36 has been used with caregivers of pediatric cancer [88].

### 4.13. Satisfaction/Exit Surveys.

At the end of the final session, participants will complete a 20-item survey assessing what they liked/disliked about the intervention, as well what was/was not useful or helpful in reaching health goals. Responses will inform subsequent versions of NOURISH-T, to be evaluated in future translational work.

### 4.14. Intensity of Treatment Rating Scale. [89]

PCS medical records will be audited by clinic personnel to derive a level of treatment intensity from 1 (least intensive) to 4 (most intensive treatments) using e.g., diagnosis, stage or risk level, relapse status, and/or type of treatment modality used (e.g., surgery, chemotherapy or radiation).

### 4.15. Rating of Medical Late Effects.

Clinic personnel will rate PCS late effects following treatment, from no limitation of activity to significant restriction on daily activity and need for significant medical attention or equipment [90].

## 5. Data Management and Safety Monitoring Plan

Data will be centrally managed in a USF web-based master database so that USF and UP investigators can access the data. Code numbers will be used to identify participants and only HIPAA trained study staff will have access to identifiable information. All study staff will complete a human subjects' protection course. Study PI (MS) and UP site PI (EW) will continually evaluate the progress of the study at weekly meetings with their study staff. They will also hold teleconference meetings on a bi-weekly basis to discuss issues related to data collection, participant recruitment, accrual and completion of assessment, data quality and integrity issues, staff training, group treatment fidelity, etc. As participant data accrues, they will analyze data for evidence of clinical outcome. If over the course of the study there is concern about changes in the risk-benefit ratio, interim analyses will be conducted to determine if the study should proceed as originally designed. To further assure that data are monitored carefully and regularly, the PI will perform reviews of incoming data from both clinic sites on a monthly basis. The database will be checked for appropriateness of individual items and for validity and reliability across items.

## 6. Statistical Analyses

### 6.1. Adequacy of Sample Size.

This RCT sample size is based on the feasibility of completing the pilot within two years. The primary goals of this study are to determine the feasibility, acceptability and potential utility of an intervention to address the high rates of overweight and obesity in off-treatment

PCS by targeting caregivers as the mechanism for change. A power/sample size calculation was conducted using data from the NOURISH study as estimates for effects in this RCT trial. Using the RM-ANOVA model and assuming an alpha level of .05, a sample size of approximately 66 individuals (33 per group) would yield sufficient power (>90%) to detect a significant Group by Time interaction effect. These data will be used to guide, focus, and refine subsequent intervention development and studies. If we find that we have insufficient power to detect significant effects, we will be able to estimate effect sizes to guide future work. Although power to detect smaller weight losses and changes in dietary and PA behaviors and QOL may be limited, the proposed study serves to identify availability of eligible participants using our recruitment strategies, test feasibility of the treatment and measurement protocols, train staff in study tasks, and set up data collection, checking, storage, and retrieval capabilities [91].

### 6.2. Analyses:

**Primary Aim. To document the feasibility of implementing NOURISH-T.—**For our primary aim, we will examine the data using descriptive statistics, graphical techniques and correlations. For categorical variables (e.g., participation and attrition rates) we will examine frequency distributions and, where appropriate, contingency tables and histograms. For continuous variables (e.g., measures of compliance and knowledge), we will examine frequency distributions. We will address all the criteria delineated in our Aims to fully evaluate feasibility of this trial. We will also examine via correlations to what extent caregiver responses varied as a function of PCS age, time since active cancer treatment ended, race, gender as well as dose (number of sessions attended).

**Secondary Aims.—**To assess the effect of NOURISH-T on PCS dietary intake, QOL, PA, and BMI and to explore whether caregivers show improvements in dietary intake, PA, BMI, QOL, perceptions of child vulnerability and over-protectiveness, *t* tests will be conducted at baseline to check for any significant differences between intervention and control groups. Medical chart data will be used for participants dropping out of the study, wherever possible. Study hypotheses will be tested using the Mixed Linear Model (MLM) [92,93] to fit a series of repeated measures ANOVAs (RM-ANOVA) to continuous outcome measures that repeat over time. These models will have one between subjects factor (Group: NOURISH-T or EUC), one within subject factor (Time: Pre- or Post- intervention) and the interaction between Group and Time. The Group by Time interaction term will allow us to test the hypothesis that the difference between the Pre- and Post- measurements is the same for the two Groups. Outcomes will be the PCS' scores at post-testing and 6-month follow-up. Covariates that may have an impact on continuous outcomes (e.g., age, gender, SES, race, time since treatment, diagnosis, protocol complexity/severity, number/gender of caregivers participating, mode of intervention delivery) can be incorporated into the model to test if a significant group by time interaction is still significant once adjusted for these covariates. Using a MLM to implement the RM-ANOVA allows us to use all available data even if a study subject has missing observations [94]. The MLM also allows us to test for and accommodate different variance-covariance structures to model the within subject variability. Outcome measures will be transformed if they do not meet normality assumptions.

### 6.3. Intent-to-Treat Analysis.

Analyses will be conducted using an intent-to-treat (ITT) approach [95]. This approach analyzes all data according to participants' assigned group, whether or not they actually complete the intervention. As recommended, we will use participants' most recent data as post-intervention scores. Thus, if participants drop out before completing the post-intervention assessment, their baseline scores will be "brought forward" and included in the analyses. This approach protects against validity threats posed by attrition. To determine whether attrition differs by treatment condition and more specifically if there is an association between treatment condition and attrition, chi-square analyses will be conducted.

## 7. Discussion

### 7.1. Overview:

Prevention of obesity in PCS as they transition from treatment to survivorship remains an important but understudied area of inquiry given obesity's well known association with cardiovascular and metabolic comorbidities [2,4,7]. By targeting PCS during their transition from treatment to survivorship, our study aligns well with the Institute of Medicine's (IOM) [35] report that stresses the importance of this transition period. The IOM report urges a shift from focusing on short-term outcomes to increasing long-term healthy behaviors in those transitioning to cancer survivorship. We address these concerns by challenging the current practice paradigm for overweight/obese, off-treatment PCS by testing the feasibility and preliminary utility of improving dietary intake and PA to increase healthy weight management and prevent future overweight/obesity [14,96–100]. We propose a new application for an efficacious intervention targeting caregivers by adapting an intervention (NOURISH) that has been shown to be effective in overweight/obese, but otherwise healthy children [101] to a high-risk population; this represents an important step in developing effective prevention efforts and will provide vital information for future intervention efforts (a planned larger-scale clinical trial).

### 7.2. Potential benefits.

Our innovative study has the potential to help researchers, practitioners, patients, and families better understand the risks of obesity for young cancer survivors and ways in which parents/caregivers can help their children develop healthy habits and prevent obesity after cancer treatment has ended. Participants will benefit from their involvement in several ways. First, they will become more knowledgeable about how cancer treatment contributes to obesity. Also, parental feeding behaviors will be addressed. Thus, participants are expected to leave the sessions with a new set of skills that may help them to improve both their, and their children's, well-being. Second, it is hoped that the psycho-educational sessions will be a first step in the prevention of obesity in children whose parents have participated. Third, participants will be informed that the information from this research study may lead to a future overweight prevention program for children who have ended treatment for cancer. We also have made concerted efforts to reduce participant burden, e.g., using telephonic delivery of sessions whenever possible, incorporating e-mail and web-based information into the intervention to facilitate access to relevant information, conducting individual rather than group sessions, and combining face-to-face sessions with research assessment sessions, and

whenever possible, with routine clinic visits. These strategies will also enable us to demonstrate the generalizability of our protocol into most pediatric oncology clinic after care programs.

### 7.3. Challenges and Limitations.

Although this project has important translational implications, there are challenges in implementation and limitations associated with the protocol. A primary challenge is likely to be recruitment. Previous studies have documented that many families who have completed treatment report wanting to "forget" their cancer experience [102]. This attitude often translates into avoidance behaviors; families may decline to participate because they would rather not return to the pediatric oncology clinic for a follow-up project that is not viewed as "central" to their child's recovery and survivorship. Another challenge is related to the central thesis of our project that targets caregivers as a means of changing child behaviors. Although parental involvement in pediatric overweight treatment is typically considered essential [39–42], few investigations have evaluated the effectiveness of treatment that targets parents exclusively [103]. Families might resist the idea of focusing on caregiver behaviors as a means of changing child behaviors. Another major challenge concerns recruitment of participants who live some distance from the pediatric oncology clinic. At both ACH and UP, many families travel as much as two hours to the clinic. This may be a major burden to participants/families when asked to come to the clinic for assessments and face-to-face sessions including longer-term follow-up. We have thus modified the original NOURISH [33] protocol to better meet potential participants' needs. We now offer the option of individual sessions, as well as small groups, and have reduced the number of in-person sessions to a maximum of two (vs. six) in NOURISH-T. Ultimately balancing treatment intensity with participant burden and feasibility is our priority.

Attention effects and contamination between treatment and control groups are potential threats to the internal validity of this study. Although reduced from the original NOURISH program, the NOURISH-T group will still have more face-to-face contact with clinicians compared with the control group and will receive more information related to pediatric cancer and obesity. As noted above, the EUC condition will receive publically available information about wellness and obesity. We considered alternatives, however, there is no standard of care in most pediatric oncology clinics with regard to pediatric cancer and obesity, therefore we concluded that a closely matched control group focused on some other topic besides wellness would not make a great deal of sense and would in fact reduce ecological validity. Further, although contamination between groups is certainly possible, it is less likely because families are no longer coming to the pediatric oncology clinic on a regular basis and are less likely to "bump" into other participants who were randomly assigned to the other condition of the project. We also ask in our exit interviews/questionnaires whether participants knew other families participating in our project. This information will be carefully tracked.

Limitations also include the small size of the anticipated sample. Although we have calculated our power estimates to suggest the likelihood of finding effects, the target sample size is relatively small due to the nature of pediatric cancer – relatively small numbers of

potential participants available at any one site, which is why even for our small RCT, we run our project at two clinic sites (ACH and UP). If we find encouraging effects, we plan to conduct our project at several pediatric cancer sites throughout the country to increase the generalizability and power of our findings.

Other limitations include the fact that we have modified the protocol to reduce participant burden – this is a positive on one hand because it increases the translatability of our program to other pediatric clinics. On the other hand, this also introduces extraneous factors (e.g., running NOURISH-T individually vs. in small groups, participants missing sessions or having to reschedule and therefore extending the number of weeks necessary to complete the 6 sessions, missing the additional dietary and PA session, etc.) that must be controlled in the analyses. The range of time off treatment is also large (from 6 months to 4 years). This is a limitation, although we hope to analyze the data to determine whether there is an optimal time-period post-treatment to offer intervention. However, with a small sample size, the number of variables that can be controlled effectively will be limited. Despite the potential limitations, we believe that the benefits of our intervention far outweigh these limitations.

### 7.4. Summary.

Most pediatric cancer patients survive into adulthood, but are at an increased risk of weight gain and decreased PA [4–6]. Although this association between cancer treatment and future obesity has been documented, research investigating the negative effects of cancer therapy is limited. To address this, the NOURISH intervention was adapted into the NOURISH-T, which targets caregivers of PCS to improve the dietary and PA behaviors. This pilot RCT will contribute to the field by providing information and data regarding the feasibility and preliminary efficacy of the intervention compared to a controlled condition. It is also expected that information will be garnered concerning the optimal time-period post-treatment to offer the intervention.

We believe that our project offers the opportunity to bring pilot feasibility clinical trial findings into practice. Our findings will be translatable for use in pediatric oncology aftercare clinics thus further increasing their potential impact.

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## Table A.1

Outline of NOURISH and NOURISH-T session content

| Current NOURISH session content | Proposed NOURISH-T session content |
|---|---|
| Session 1: Overview, Toxic Environment, and Role Modeling: 1) Purpose of NOURISH; 2) Role modeling; 3) How to raise healthy eaters in unhealthy environment | Session 1: Overview, Effects of cancer treatment on eating & PA: 1) Purpose of NOURISH-T; 2) Cancer treatment & overweight/obesity; 3) Strategies to transition back to a “healthy family” ; 4) Importance of parent behaviors in promoting healthy eating & PA; 5) Discuss parental perceived vulnerability |
| Session 2: Role Modeling and Session 5: Family Meals: 1) Caregiver promotion of healthy eating & activity; 2) Increasing number & quality of family meals | Session 2: Role Modeling, Parent perceptions of child vulnerability (Recap), Family dynamic changes: 1) Caregiver promotion of healthy eating & PA; 2) Specific role-modeling techniques |
| Session 3: Dietary intake: 1) Reading nutrition labels; 2) Portion sizes; 3) Cultural issues & eating fruits & veggies | Session 3: Dietary intake: 1) Healthy dietary intake for PCS and families; 2) Portion sizes; 3) Mindful eating; 4) Importance and suggestions for eating fruits & veggies |
| Session 4: Reducing Sedentary Behaviors, Overcoming Barriers to Exercise: 1) Importance of regular PA; 2)Caregiver role modeling of activity; 3) Barriers to regular PA; 4) Concept of lifestyle PA | Session 4: Reducing Sedentary Behaviors and Overcoming Barriers to Exercise: 1) Effects of treatment on sedentary behavior in child, parent & family; 2) Importance of regular PA; 3) Caregiver role-modeling of activity; 4) Barriers to regular PA; 5) Concept of lifestyle PA |
| Session 5: Parenting Styles: 1) How passive, authoritarian, & authoritative parenting styles influence the feeding relationship. | Session 5: Parenting styles, Re-parenting, Feeding Relationship: 1) How passive, authoritarian, & authoritative parenting styles influence the feeding relationship; 2) Parent role in transitioning family to healthy eating & PA |
| Session 6: Body Image, Media and Teasing: 1) Promoting child healthy body image; 2) Media influence on appearance perception | Session 6: Body image, social acceptance, and identity as a cancer survivor: 1) Facilitation of self-acceptance of cancer-related body changes; 2) Healthy body image; 3) Reintegration of child’s/family to school and social life; 4) Wrap-up |