

# Improving Health Behaviors of Pediatric Cancer Survivors with Obesity: Participation and Attrition Considerations

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## Abstract

**Purpose:** This investigation explored factors associated with Pediatric Cancer Survivors' (PCS') participation and retention in an intervention aimed at improving healthy lifestyle behaviors and reducing BMI: NOURISH-T.

**Design:** Parents of eligible PCS were randomized to either NOURISH-T or an Enhanced Usual Care session (EUC).

**Methods:** Parents and PCS were assessed on anthropometric and self-report indices of healthy eating and physical activity behaviors at baseline, post-intervention and 4 months follow-up.

**Participants:** A total of 53 dyads participated in the study, with an additional 14 dyads providing baseline data. These 14 dyads did not participate in either NOURISH-T or EUC or follow-up assessments and were treated in this study as a No Contact group.

**Findings:** PCS' sex, age, and BMI at diagnosis emerged as key factors associated with intervention completion.

**Implications:** Factors needing to be considered in designing behavioral interventions for PCS and their families intervention are discussed.

**Keywords:** Pediatric Cancer; Obesity; Clinical Trial; Retention

As pediatric cancer survival rates have increased dramatically, so too has the focus on longer-term health sequelae and behaviors [1, 2]. Obesity rates in pediatric cancer survivors (PCS) range from 40 to 50%, higher than that observed in healthy children (35%) [3, 4]. Moreover, five years after diagnosis, the rate of obesity in PCS doubles, which is largely attributed to the consumption of high fat diets and physical inactivity [5]. By adulthood, PCS show diminished exercise capacity and excessive weight gain, both of which worsen over time [6, 7], highlighting the importance of addressing behavioral factors related to obesity in early post-treatment.

We tested the preliminary efficacy of an intervention for PCS with overweight/ obesity, *NOURISH for Healthy Transitions (NOURISH-T)*, targeting parents as agents of change in promoting healthy eating and Physical Activity (PA). A pilot randomized control trial compared six-sessions of NOURISH-T with a one-session Enhanced Usual Care (EUC) comparison. NOURISH-T yielded positive effects on parental and PCS BMI, dietary intake, and physical activity [8], compared with EUC. PCS and parents in NOURISH-T significant positive changes on targeted outcomes.

Unfortunately, attrition in pediatric obesity interventions is a well-documented problem and barrier to treatment success [9]. Attrition rates have been reported to range from 30-40+% to as high as 70-80%, thereby limiting positive effects [10].

The current study sought to identify factors associated with participation and retention in the NOURISH-T pilot. Identifying such factors will guide design of more effective interventions (with less attrition) aimed at increasing healthy lifestyle behaviors in PCS with obesity. Factors examined were those that are typically considered in pediatric cancer research, such as time since diagnosis and off treatment, concerns at diagnosis, child age and sex, and parental education [4].

## Methods

Detailed descriptions of the intervention conditions, study materials, and procedures are found elsewhere.<sup>8</sup> Briefly, the impact of six-manualized NOURISH-T sessions was compared to EUC (one session focused on wellness) on PCS and parental outcomes. Institutional Review Board approval was obtained and the study was registered with ClinicalTrials.gov, #NCT02815982. NOURISH-T topics relevant to changing eating and PA behaviors post-treatment were discussed and weekly goals were established to foster family behavioral change. EUC parents were provided a session addressing the role of diet and exercise in pediatric overweight [11] and received nationally available information on wellness. All participants were recontacted 2 months after post-intervention for a “booster” (NOURISH-T participants) or “check-in” (EUC participants) session and then 4-months post-intervention for follow-up assessment.

### Participants

Parent-PCS dyads were eligible if PCS were between 5-13 years old ( $M=9.9$  years), off treatment six months to < five years ( $M=2.0$  years), and were above BMI 85<sup>th</sup> percentile at time of study enrollment ( $M$  BMI percentile = 95.6). On average, parents had BMIs in the obese range (BMI  $M = 32.5$ ). PCS who relapsed, were unable to exercise or had serious cognitive deficits were excluded.

### Enrollment

A total of 53 parent/child dyads meeting criteria were enrolled. Randomization was accomplished with a 1:1 ratio to assign participants either to NOURISH-T ( $n = 27$ ) or EUC ( $n = 26$ ). A total of 16 dyads completed the baseline assessment and the intervention, but did not complete the post-intervention assessment; leaving a subset of 37 dyads (18 NOURISH-T and 19 EUC) with post-intervention assessment data. Another 14 families consented to the study and provided some baseline data, but did not participate beyond the initial consent process (i.e., did not engage in either intervention condition of the protocol; “No Contact” group) and were not included in any of the main analyses. Reasons for these 14 families not proceeding in the study included: ineligibility due to language and developmental delay barriers (3 PCS), relapse (2 PCS), moved out of the area (4 PCS), or withdrew from the study without any explicit reason (5 PCS).

### Measures

Assessments conducted at baseline, post-intervention, and 4-months follow-up were completed by both parents and PCS [8]. Highlighted here are the primary outcomes related to obesity, namely, anthropometric measures of parental BMI/PCS BMI percentile and Waist-hip-ratio.

### Statistical Analysis

Several steps were undertaken to evaluate factors related to attrition in the pilot RCT. First, we examined whether there were any differences in retention in the study as a function of whether parent/PCS dyads were randomly assigned to NOURISH-T or EUC. Second, baseline demographics were examined as a function of intervention condition: NOURISH-T vs. EUC. Bivariate analyses were then conducted using t-tests and Chi-square test to evaluate whether there were differences in the No Contact group vs. Intervention (combined NOURISH-T and EUC).

## Results

There were no significant differences in retention between NOURISH-T and EUC ( $p = .353$ ). Once families

committed to the project and completed the intervention and post-assessment, they generally continued through follow-up (Table 1). In addition, once enrolled, 87.5% of all NOURISH-T participants completed at least 3 or more sessions of the intervention, with 75% completing all 6 sessions. Those assigned to NOURISH-T who engaged in less than 3 sessions before dropping out from the intervention had reported annual incomes below \$15,000.

Table 1: Retention rate.

	NOURISH-T (n=27)	EUC (n=26)	Overall (n=53)
Completed Pre-Test ONLY	11 (40.7%)	9 (34.6%)	20 (37.7%)
Completed Pre- & Post-Test ONLY	5 (18.5%)	2 (7.7%)	7 (13.2%)
Completed Pre, Post, & Follow-Up	11 (40.7%)	15 (57.7%)	26 (49.1%)

Although there were no baseline differences between those assigned to NOURISH-T vs. EUC,<sup>8</sup> there were a few notable differences between families in either intervention condition and families who consented to be in the study, but did not complete measures at baseline. Analyses of differences (Table 2) between this No Contact group vs. Intervention (NOURISH-T or EUC) showed that PCS BMI%ile at diagnosis was significantly higher among the No Contact group (M BMI %ile = 91.5) than those completing either NOURISH-T (M BMI %ile = 73.7) or EUC (M BMI %ile = 68.8; combined M BMI %ile = 71.6;  $p < .01$ ). In addition, those in the No Contact group were off treatment for a significantly shorter time (M = .7 years) than those proceeding with either NOURISH-T or EUC (M 2.18 years;  $p < .001$ ).

For the intervention groups combined, child BMI%ile at baseline was related to parental participation in assessments, with higher child BMI%ile at baseline associated with lower participation rates over time. Specifically, for those cases only completing baseline, child BMI %ile was M = 98.9; among those completing pre and post assessments, child BMI %ile was M = 95.7, and for those completing pre-post and follow-up, child

BMI%ile at baseline was M = 93.9. Child age was related to post-assessment. Specifically, families completing only baseline assessment had significantly younger PCS (M age = 8.5) than those who completed both baseline and post-assessments (M age = 10.6). Time since treatment ended, however, was unrelated to participation rates. In addition, although the same number of male and female children were assigned to the interventions (NOURISH-T vs EUC), parents were less likely to follow-through beyond baseline assessment if their child was male (73% male) vs. female (27%). Those completing both pre- and post-assessments were more likely to have a female child (58%) and similarly, if completing all three assessments, 69% had a female child (Table 3).

Table 2: Predictors of Retention for NOURISH-T or EUC.

	No Contact (n=14)	EUC or NOURISH-T (n=53)	p-value
Child Age at Baseline <sup>^</sup>	10.0 (2.8)	9.7 (2.8)	.76
Child BMI at Baseline <sup>^</sup>	95.6 (4.0)	94.8 (4.5)	.56
<b>Child Sex Female</b>	<b>36.4 (4)</b>	<b>47.9 (23)</b>	<b>.36</b>
Parent BMI at Baseline <sup>^</sup>	32.5 (9.7)	29.4 (6.1)	.34
<b>Child BMI at Diagnosis<sup>^</sup></b>	<b>91.5 (11.4)</b>	<b>71.6 (29.6)</b>	<b>.01</b>
<b>Time Off Treatment<sup>^</sup></b>	<b>0.7 (0.5)</b>	<b>2.18 (1.3)</b>	<b>.001</b>

Notes: % (n), <sup>^</sup>mean (SD), p-values from t-tests

## Discussion

Attrition in clinical trials for PCS is particularly problematic because of the numerous late effects associated with obesity in cancer survivors. This study examined findings from an intervention for PCS with obesity (NOURISH-T) to identify factors that might be important to consider in developing intervention programs for young survivors and their families. Results

suggest that PCS sex, age, and BMI at diagnosis are key factors for participant retention. The importance of intervening at the time of diagnosis are suggested by our findings on BMI for PCS. However, adherence to our protocol and rates of consenting to participate were higher for families with PCS off treatment for a longer time. One strategy might be to help families dealing with childhood cancer become aware of the importance of maintaining a healthy weight and lifestyle behaviors as much as possible earlier in the treatment process. These discussions can be individually tailored as a function of the child's BMI/overweight/obesity status at diagnosis. We found that

parents were more adherent to our intervention when their child was not overweight/obese at diagnosis and became obese following treatment; however, families with PCS who present as overweight or obese at diagnosis are particularly at-risk for later cardiovascular negative effects and have poorer survival rates.<sup>3,7</sup> Also worth noting is the sex difference in retention in this trial. This might suggest that parents were more concerned with obesity when they had daughters. Alternatively, perhaps girls were more receptive to the changes targeted in the interventions than boys. Future research should investigate this issue in greater detail.

**Table 3:** Predictors of Retention at Post-test and follow-up for NOURISH-T and EUC combined.

	Pre-test Only	Pre-test & Post-test	p-value	Did not complete follow-up	Completed follow-up	p-value
Child Age at Baseline <sup>^</sup>	8.5 (2.1)	10.6 (2.8)	.02	9.3 (2.4)	10.7 (3.1)	.07
Child BMI at Baseline <sup>^</sup>	98.9 (3.9)	95.7 (3.9)	.05	96.1 (4.2)	93.9 (3.8)	.12
Child Sex= Female	26.7 (4)	57.6 (19)	.05	27.3 (9)	69.2 (18)	.001
Parent BMI at Baseline <sup>^</sup>	31.5 (6.8)	33.1 (11.1)	.56	31.3 (6.2)	32.9 (12.3)	.51
Parent Age <sup>^</sup>	36.3 (9.4)	41.1 (8.3)	.09	37.2 (8.8)	41.5 (1.9)	.10
Parent Sex Female	73.3 (11)	75.8 (25)	.56	67.9 (19)	73.1 (19)	.45
Child Age at Diagnosis <sup>^</sup>	3.6 (1.4)	6.0 (3.8)	.01	4.2 (1.9)	6.2 (4.0)	.03
Child BMI at Diagnosis <sup>^</sup>	77.5 (33.5)	70.0 (29.1)	.59	84.6 (21.4)	68.1 (31.2)	.06
Time Off Treatment <sup>^</sup>	2.1 (1.3)	2.2 (1.3)	.82	1.9 (1.4)	2.1 (1.2)	.60
Child's Weight was a Concern Before Treatment	16.7 (2)	42.3 (11)	.12	29.4 (5)	38.1 (8)	.42
Income Over \$60,000	46.7 (7)	50.0 (16)	.54	42.9 (9)	53.8 (14)	.33
Parents= Married	66.7 (10)	87.5 (28)	.20	71.4 (15)	88.5 (23)	.18
Parent Education= College Degree +	26.7 (4)	56.3 (18)	.05	42.9 (9)	50.0 (13)	.42
Hispanic	93.3 (14)	78.8 (26)	.21	-	-	-
White/Caucasian	93.3 (14)	96.9 (31)	.54	-	-	-
Notes: % (n), <sup>^</sup> mean (SD)						

Despite clear limitations of our study, such as limited sample size and reliance on some self-reported measures, our findings suggest additional directions for future research. PCS's weight status at diagnosis is a factor that must be given greater attention. Interventions for this especially high risk group of children with cancer are needed. Clearly eating well is an issue that must be addressed and capitalizing on parents' expressed interest in learning strategies to facilitate a healthy lifestyle for their families must be emphasized.

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## Author Statement on Contributions

The authors of this paper, Stern, Gray and Mazzeo, each contributed to the preparation of this manuscript.

Dr. Marilyn Stern: Conceptualization, Methodology, Data Curation, Supervision, Writing – Original draft preparation, Funding Acquisition.

Dr. Heewon Gray: Formal Analysis, Writing –Review & Editing

Dr. Suzanne Mazzeo: Conceptualization, Writing – Review & Editing

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