NIH/NCI - R01CA240319 (Stern, PI) Clinical Trials ID: NCT04656496

Translating Obesity
Interventions for
Pediatric Cancer Survivors
and their Parents

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June 10, 2023 Leukemia and Lymphoma Society



Overview of Presentation

- Brief Background of Rationale for our intervention
- What We Do
- What We Have Found So Far
- Strategies We Have Used to Engage and Retain Spanish Speaking Families in our Intervention





Our work is In line with NCI's annual plan priorities -NCI's healthcare delivery research program identified
Obesity, Cancer Survivorship, Wearable Sensors, and
Health Disparities research as emerging priority areas.

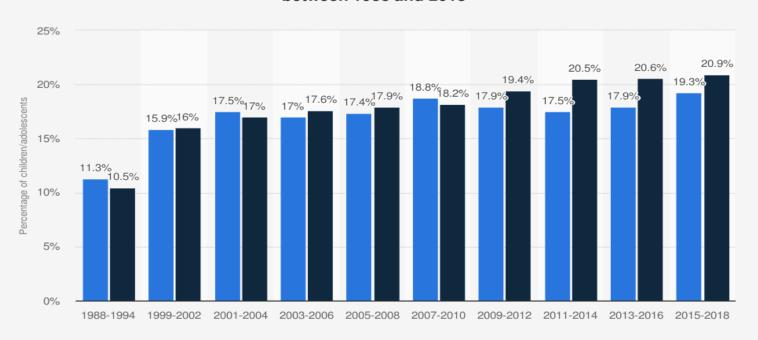
Background: As we All Know

Over the Past Three Decades, the prevalence of Obesity

(≥95th BMI %ile) in Children in the US has Tripled



Percentage of U.S. children and adolescents who were obese in selected periods between 1988 and 2018



● 6-11 years ● 12-19 years

Sources

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US Department of Health and Human Services; \mathtt{CDC}

Additional Information:

United States; NCHS; CDC; 6-19 years

WHAT WE KNOW about Pediatric Cancer:

- Over 80% of pediatric cancer patients live to adulthood.
- HOWEVER: Five years post treatment:
 - 21% of all Pediatric Cancer Survivors (PCS) are classified as obese [BMI >95th %tile for age and gender]
 - 20% as overweight (BMI 85-94th %ile).

Overall:

Estimates range from 40% (Acute Lymphoblastic Leukemia-ALL) to 50% (localized sarcomas)

RISKS AND RATIONALE FOR NOURISH-T+

- Pediatric cancer survivors with overweight/obesity are at significantly greater health risk for adult obesity and concomitant negative health consequences than children with overweight/obesity in the general population.
- By early/mid adulthood, Pediatric Cancer Survivors with obesity are <u>10.8 times more likely</u> to have CVD than healthy siblings





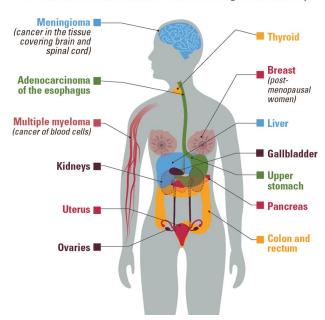


The Problem cont'd

- "Obesity may change the way young people react to chemotherapy" (Orgel et al., 2014-Blood)
- May explain why obese children with cancer often do more poorly on induction therapy than their peers without obesity.
- May Reduce rate of survival!

Obesity and Cancer Risk

13 cancers are associated with overweight and obesity



- About 3.6% of all cancer cases attributable to high BMI
- Higher Risk of Secondary cancers for childhood cancer survivors with obesity ^{1,2}

The <u>Damaging Health Effects</u> associated with cancer and its treatment are clearly compounded by obesity





Parental attitudes are also related to poorer eating and physical activity behaviors:

- The Vulnerable Child Syndrome
- Parental Over Protection





Parental attitudes cont'd

Our early, formative work found:

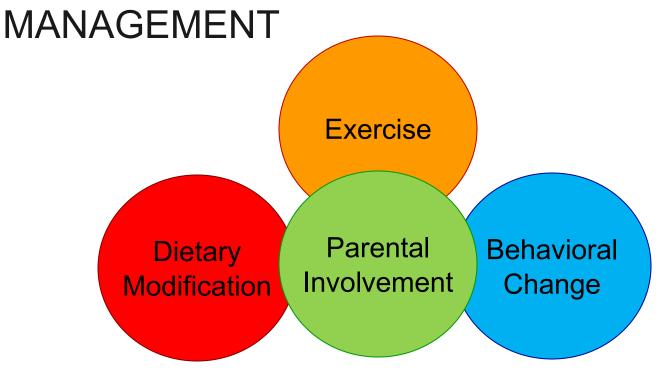
- <u>Caregivers</u> say that during treatment their major concern was on: <u>Quantity</u> of food intake, <u>Not Quality</u>
- Parents recognized that they engaged in <u>protective</u> <u>behaviors</u> and did not allow their children to participate in activities
- Providers said:
 - Parents are often accepting of obesity if you had cancer, at least you are not wasting away → heavier looks healthier to many lay people

What we Do Know:

- During treatment, families decrease healthy eating and physical activity and are unlikely to engage in preventive efforts
- We KNOW...Healthy eating and physical activity (PA) behaviors play an important preventive function, reducing the risk of adult obesity and other chronic diseases



BASIS OF PEDIATRIC WEIGHT



What parents DO is more important than what they say!

- Parents play a <u>key role</u> in molding their children's Physical Activity and Eating Behaviors.
- Overall → Eating and activity habits developed by adolescence are typically continued in adulthood



 Parental involvement improves children's outcomes

A Few Key Points:

- Rationale: Targeting Parents is Key in Effecting change
- Parent weight loss is associated with child weight loss
- When parents make dietary changes → Children show changes in calorie and fat intake
- Targeting the whole family can protect children's selfesteem and reduce their risk of developing further eating problems

Will an obese child become an obese adult?





Parents pass on their Genes and Create their children's environments

Both parents obese→ 80% likelihood → child obese

One parent obese → 40% likelihood → child obese

Neither parent obese → 7% likelihood → child obese

NOURISH

- NOURISH (Nourishing Our Understanding of Role modeling to Improve Support and Health)
- Targets Parental Behaviors
- (R01HD066216-01A1; Mazzeo, PI)
- OVERALL: Intervention parents showed improvements on measures of nutrition, exercise and feeding-related attitudes.



We adapted – our previous work with overweight/obese, but otherwise healthy children -- NOURISH –for Parents of Childhood Cancer Survivors*

*NIH/NCI –R21 CA167259-01A1 (Stern, PI)



Nourishing 1 Our Understanding of Role modeling to **I**mprove **Support** and Healthy **Transitions**

NOURISH-T targets parents of overweight/obese pediatric cancer survivors to promote the development of healthier eating and increased physical activity.



R21 Research Design

Caregivers of overweight/obese PCS (ages 5-12) between 6 mos. to 4 yrs. off cancer treatment

NOURISH-T 6 sessions

Enhanced Usual Care
1 session

Summary of Pilot Findings

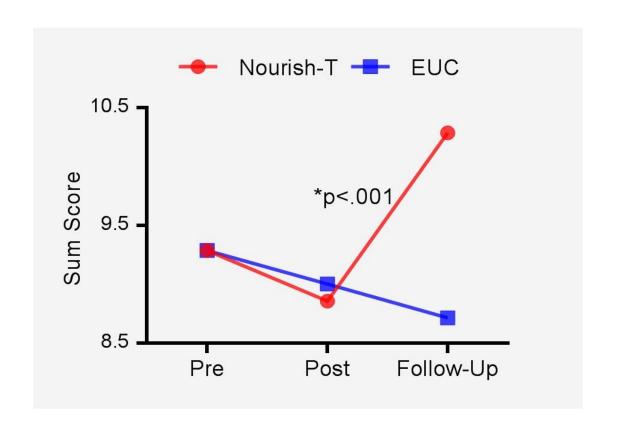
Our pilot R21 findings with Pediatric Cancer Survivors
 (PCS) found <u>strong evidence</u> for the importance of targeting
 parents to impact change in their children – promoting
 positive health behaviors

In comparison to our one-session control condition (EUC) those in the NOURISH-T 6-session pilot:

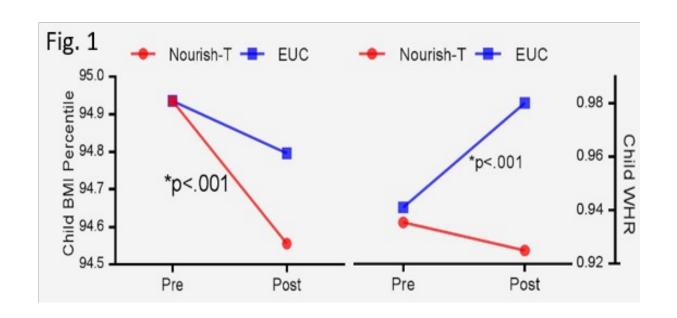
- Family eating improved (EUC decreased)
- 2. Parental BMI and W-HR decreased (EUC increased)
- 3. Child BMI and W-HR decreased (EUC increased)
- Overall child PA/steps increased (EUC decreased)

*See Stern et al (2018) Peds Blood and Cancer

FAMILY EATING TOGETHER BEHAVIORAL INDEX



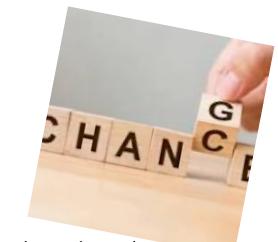
CHILD BMI %ile and WHR



LESSONS LEARNED

- 1. The old adage it will always take you longer than you think!
 - a. Unforeseen administrative barriers!
- 2. Whatever way you believe it might work
 - a. it might not!
- 3. Be *flexible* and *adapt*!
- 4. Think ease of dissemination

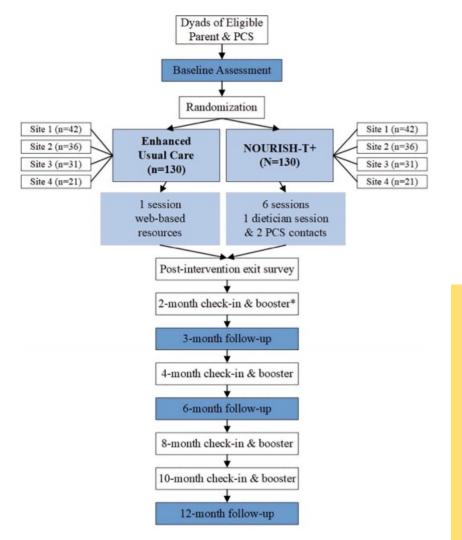
KEY CHANGES MADE TO NOURISH-T+



- Visual Connection via Web-based sessions (vs. phone)
- 2. One session with a dietician
- 3. Two separate sessions with the child with cancer (survivor)
- 4. Longer-term involvement, Now to 12 months
- 5. With Booster sessions throughout with our facilitators

STUDY DESIGN

R01 funded December 2019 Cluster randomized, controlled, repeated measures trial



Session 1	Overview, effects of cancer treatment on eating & exercise, Parental perceived vulnerability;
Session 2	Parenting style and role modeling for getting back to healthy; Introducing nutrition and healthy eating
Session 3	Getting back to <u>healthy-Focus on Dietary Intake</u> , meal planning, food accessibility, hunger scale etc.
Session 4	Increasing Physical Activity, Reducing sedentary behaviors and overcoming barriers to exercise
Session 5	• Mindfulness towards a healthy lifestyle: mindfulness in eating, physical activity, and sleep
Session 6	Getting back to Healthy, dealing with outside influences, Self-esteem and body-image, toxic env., Wrap-up

6 NOURISH-T+ Sessions

Session 1: Effects of Cancer Treatment on Eating & Exercise Behaviors

- Get to Know Participant Creating a Relationship
- Perceptions of Vulnerability
- Getting Back to Healthy

Session 2: Parenting Style and Role Modeling for Getting Back to Healthy

- Parenting Styles
- Introduction to Nutrition
 - MyPlate
 - Nutrition Labels
 - Serving Size vs Portion Size

Session 3: Dietary Intake

- Hunger Cues
- Food Accessibility & Skipping Meals
- Meal Planning

Be a Healthy Eating Role Model

Healthy Eating Made Easier™

Healthy Eating Starts With Families

The foods you serve and eat help raise healthy eaters. Here are a few eating habits you as parents can role model for your children:

- Eat breakfast; it helps your children learn in school. Also, breakfast eaters tend to weigh less as adults.
- * Take moderate portions.
- Limit but don't ban all extra foods like chips and candy.
- Drink water and milk instead of soft drinks, sports drinks or other sugar-sweetened beverages.
- Han meals and snack times for you and your children. Eat foods from all food groups—milk, vegetables, fruits, whole grains, lean meats, fish + beans.

Your Job

Set an **EXAMPLE**by eating the same
foods as your
children at the table.



SERVE foods from all 5 food groups.





Teach Healthu Habits

Children won't think healthy eating is important if you aren't eating nutritious foods.

Mark the choices you could do:

- Try new foods together.
- ☐ Eat snacks from the food groups most of the time and enjoy fun snacks sometimes.
- $\hfill \square$ Manage stress with movement—not food.
- Prepare meals with your kids. Ask them to set the table or chop the vegetables.
- Let your children decide what and how much to eat from what you serve.
- ☐ Show how much you enjoy eating together.

S.M.AR.T. GOALS

Goals should be Specific. For example, instead of saying:

- "I will eat healthier," say
- "I will eat 3 servings of vegetables each day."
- **M** Goals should be something you can <u>Measure</u>. For example, instead of:
- "I won't eat as many sweets," say
- "I will eat a piece of fruit instead of cookies 3 times next week."



Goals should be Action-oriented and Achievable. For example, instead of:

- "I won't eat snacks and watch T.V. this weekend," say
- "I will eat a healthy snack at least once while watching T.V. this weekend or...
- "I will exercise once this weekend for 30 minutes instead of watching television."



R Goals should be Realistic. For example, instead of:

- "I will never eat fried foods," say
- "I will eat fried foods only 1 time next week."



Goals should have a Time limit. For example, instead of:

- "I will try to start exercising soon," say
- "I will go to the gym 2 days next week."



Do: Set real numbers with

real deadlines.

Don't Say, "I want more visitors."



Do: Make sure your goal is trackable.

Don't Hide behind buzzwords like. "brand" engagement,"

> or, "social influence."





Do: Be honest vith yourself- you longow what you and your learn



Do: Give yourself a deadline.

Don't Keep pushing sowards a goal you might hit. "some day."

Serving-Size Chart

FOOD		SYMBOL	COMPARISON	SERVING SIZE		
Dairy: Milk, Yogurt, Cheese						
Cheese (string cheese)		TOTA	Pointer finger	1½ ounces		
Milk and yogurt (glass of milk)			One fist	1 cup		
Vegetables						
Cooked carrots	The second second		One fist	1 cup		
Salad (bowl of salad)			Two fists	2 cups		
Fruits						
Apple			One fist	1 medium		
Canned peaches		9	One fist	1 cup		
Grains: Breads, Cereals, Pasta						
Dry cereal (bowl of cereal)	a To		One fist	1 cup		
Noodles, rice, oatmeal (bowl of noodles)			Handful	½ cup		
Slice of whole-wheat bread			Flat hand	1 slice		
Protein: Meat, Beans, Nuts						
Chicken, beef, fish, pork (chicken breast)	Carrie I		Palm	3 ounces		
Peanut butter (spoon of peanut butter)			Thumb	1 tablespoon		

Mi Plato Saludable

Planee las porciones en su plato

1/2 Vegetales

Fruta o producto lácteo

Pregúntale a su nutricionista si usted debe comer fruta

o lácteos en sus comidas.

FAMILY HEALTH

www.institute.org

siganos (**) (**)



El agua es la mejor bebida para usted.



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STOP. RETHINK YOUR DRINK. GO ON GREEN.



Red - Drink Rarely, If At All

- Regular sodas
- Energy or sports drinks
- Fruit drinks



Yellow - Drink Occasionally

- Diet soda
- Low-calorie, low-sugar drinks
- 100% juice





Green - Drink Plenty

- -Water
- Seltzer water
- Skim or 1% milk







Eating better on a budget

Get the most for your budget! There are many ways to save money on the foods that you eat. The three main steps are planning before you shop, purchasing the items at the best price, and preparing meals that stretch your food dollars.

Plan, plan, plan!
Before you head to the grocery store, plan your meals for the week. Include meals like stews, casseroles, or soups, which "stretch" expensive items into more portions. Check to see what foods you already have and make a list for what you need to buy.

Get the best price
Check the local newspaper, online, and at the store
for sales and coupons. Ask about a loyalty card for
extra savings at stores where you shop. Look for specials
or sales on meat and seafood—often the most expensive
items on your list.

Gompare and contrast
Locate the "Unit Price" on the shelf directly below the product. Use it to compare different brands and different sizes of the same brand to determine which is the best buy.

Buy in bulk
It is almost always cheaper to buy foods in bulk. Smart choices are large containers of low-fat yogurt and large bags of frozen vegetables.

Before you shop, remember to check if you have enough freezer space.

Buy in season

Buying fruits and vegetables in season can lower the cost and add to the freshness! If you are not going to use them all right away, buy some that still need time to ripen.

Convenience costs...
go back to the basics
Convenience foods like frozen dinners, pre-cut fruits
and vegetables, and take-out meals can often cost more
than if you were to make them at home. Take the time to
prepare your own—and save!

Easy on your wallet
Certain foods are typically low-cost options all year
round. Try beans for a less expensive
protein food. For vegetables, buy cabbage,
sweet potatoes, or low-sodium canned
tomatoes. As for fruits, apples and bananas
are good choices.

Cook once...eat all week!

Prepare a large batch of favorite recipes on your day off (double or triple the recipe). Freeze in individual containers. Use them throughout the week and you won't have to spend money on take-out meals.

Get creative with leftovers
Spice up your leftovers—use them in new ways.
For example, try leftover chicken in a stir-fry, over a
garden salad, or in chili. Remember, throwing away food is
throwing away your money!

Eating out
Restaurants can be expensive. Save money by getting the early bird special, going out for lunch instead of dinner, or looking for "2 for 1" deals. Ask for water instead of ordering other beverages, which add to the bill.

6 NOURISH-T+ Sessions (cont.)

Session 4: Reducing Sedentary Behaviors and Overcoming Barriers to Exercise Success

- Physical Activity Guidelines
- Sedentary Lifestyle & Screen Time
- Create Physical Activity Plan

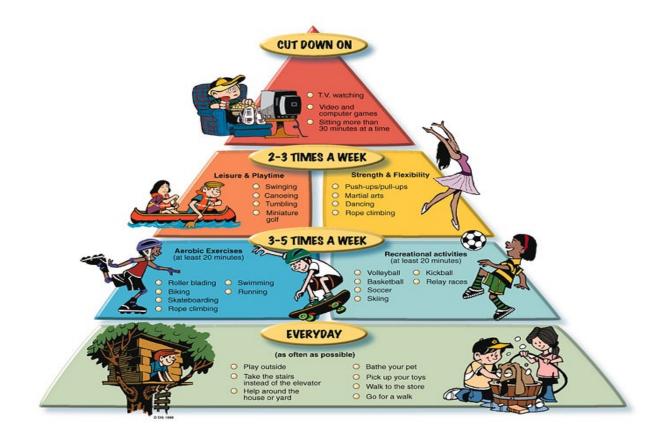
Session 5: Mindfulness Towards: Nutrition, Physical Activity, and Sleep

- Introduction to Mindfulness
- Discussion of High-Risk Eating Habits
- Sleeping Habits

Session 6: Getting Back to Healthy. Dealing with Outside Influences.

- Child Self-Esteem & Body Image
- Peer Relationships & Peer Pressure
- Toxic Environments
- How to Cope with Setbacks

Children's Activity Pyramid





Haz cosas que te parezcan divertidas.

Completa los 60 minutos de actividad física de una vez o repártelos en todo el día. Tú decides.

Tengo una hora de entrenamiento de basquetbol después de las clases.

Juego *kickball* en el recreo, voy a educación física y doy un paseo con el perro después de la cena.

Voy en bicicleta al parque a jugar fútbol con mis amigos.



CLEAN UP YOUR SLEEP HYGIENE

13 simple tricks, will help you get a good nights sleep.



6. Exercise, being physically active during the day can help you fall asleep more easily and sleep more deeply at night.



12. Avoid consuming alcohol, nicotine and THC before bedtime.



 Go to bed and get up at the same time every day, including on the weekends and during vacations.



7. Keep a sleep diary, experiment and figure out what works best for you.



13. Reduce your fluid intake before bedtime.



2. If you can't fall asleep or wake up and can't get back to sleep, get out of bed, read, sketch, or do another calming activity in low light.

3. Make sure your bedroom is

quiet, dark, relaxing, and at

a comfortable temperature.



8. Limit exposure to bright light in the evenings, turn off electronic devices at least 30-60 minutes before bedtime.



9. Establish a relaxing bedtime routine.

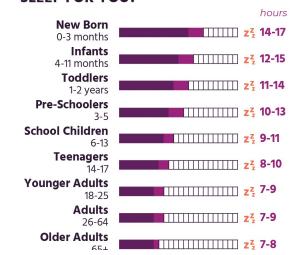


4. Remove electronic devices, such as TVs, computers, and smart phones, from the bedroom.



10. Don't eat a large meal before bedtime. If you are hungry at night, eat a light, healthy snack.

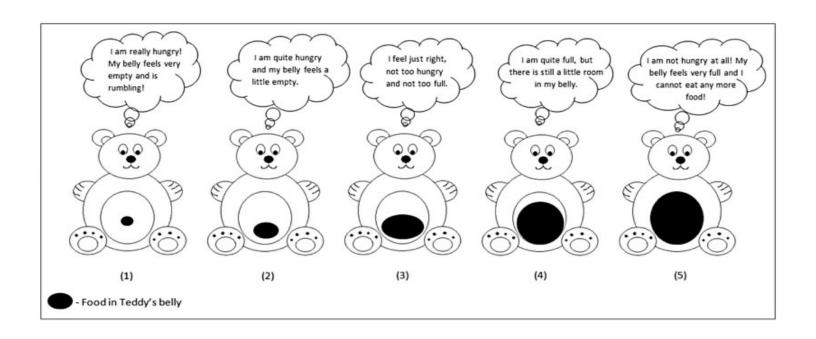
WHAT'S THE RIGHT AMOUNT OF SLEEP FOR YOU?



Mindful Eating Exercises: The Mindful Bite



Children's Hunger Scale



THE DAILY Self Love



Enhanced Usual Care

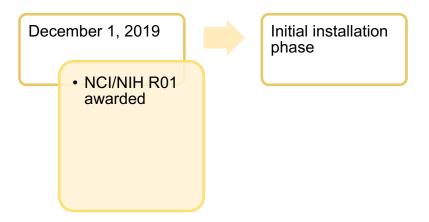
- Initial session providing basic information about the role of diet and exercise in children
- [We Can! Manual]

 Caregivers and children attend baseline; post- and follow-up assessment sessions

 Caregivers receive nationally available print or webbased brochures on pediatric overweight/obesity at two time points across the study



IMPACT OF COVID-19



STUDY PROTOCOL HAD TO BE REVISED

MOVED all clinic activities to USF via zoom

Delays in study implementation allowed for additional in-depth refinement of our intervention manuals.

- Additional facilitator training (session role playing)
- b. Identified or developed resources
- c. Translating materials into Spanish



PARTICIPANTS



We offer NOURISH-T+ in Spanish and English

*To overcome language barriers --All recruitment materials, flyers and our videos about the project (shown to potential participants in the peds oncology clinics) also available in Spanish



Buena Salud después del Tratamiento de Cáncer

Sesiones ofrecidas en USF en inglés y español Un nuevo programa breve para padres para mejorar los comportamientos de estilos de vida saludables en niños que han terminado su tratamiento de cáncer.



¿Para qué es este programa?

- Este es un nuevo programa breve para padres que tienen preocupaciones acerca de los comportamientos de alimentación y el peso de sus hijos después del tratamiento de cáncer.
- Este programa es parte de una investigación que tiene como objetivo estudiar si enseñar a los padres habilidades para una alimentación saludable y la práctica de ejercicios físicos ayuda a mejorar la salud y comportamientos de estilo de vida del niño (Dr. Marilyn Stern, Pl, Universidad del Sur de la Tlorida — USF).

¿Quién puede participar en este programa?

Posibles participantes deben tener al menos 18 años y proveer cuidados a un niño que:

- Tiene cerca de 5-14 años
- Ha estado sin tratamiento activo por al menos 6 meses
- Está sobrepeso para su edad

¿Qué se le pedirá hacer a los padres?

- Asistir a sesiones interactivas v virtuales ofrecidas por USF.
- Llenar cuestionarios breves acerca de ellos mismos v sus hijos.
- Participar en evaluaciones de seguimiento justo después de que el programa termine así como 3, 6 y 12 meses después del programa.
- A su niño también se le pedirá que participe en las evaluaciones de seguimiento y posiblemente asista a dos sesiones cortas con usted.

¿Qué ganarán los padres por estar en este programa?

- Información sobre cómo el tratamiento de cáncer afecta los comportamientos de estilo de vida de los niños.
- Conocimiento y habilidades que pueden ayudarle a mejorar su propio bienestar al igual que el de sus hijos.
- Consejos sobre cómo promover una buena salud en niños que han finalizado el tratamiento
- Compensación por su tiempo hasta \$405 para los padres y hasta \$40 para sus hijos.

¿A quién debería decirle si quiero participar en este?

Si le gustaría participar en este estudio o si tiene preguntas, por favor contacte a:

la Dra. Stern al (813) 974-0966 o <u>mstern1@usf.edu</u> o al equipo del estudio a través de nourisht.usf@gmail.com o 727-401-4535.

IRB#000244 - Sponsored by the National Institutes of Health - National Cancer Institute



PROGRESS RECRUITNG A CULTURALLY DIVERSE SAMPLE

- As of 6/01/23, 178 dyads have been consented for the study.
- M PCS BMI%ile =95; M age = ~10 years;
- 91% of parents expressed great concern about child's weight
- Of the 116 dyads enrolled, over 50% are of minority status and
- 30% indicated Spanish as their preferred language for participation in the trial.
- Nearly 12% of participating adults are fathers.







Some Findings Related to Changes in Our Approach



Low-income families, regardless of language preference take longer to complete baseline assessments

Barriers with actigraphs/baseline!



*Spanish-preferring families take longer to complete baseline assessments (44 vs. 28 days) and

tend to take longer to complete the intervention itself



Single parents take longer to complete the intervention 83% of single parent families are minorities; 23% are Spanish speaking preferred

Some Findings Related to Changes in Our Approach



Ethnicity and diet quality: Preliminary findings indicate that Hispanic PCS had significantly lower total vegetable and fatty acid scores (p=0.02) compared to non-Hispanic PCS



Overall, Intervention and Assessment Sessions take longer when in Spanish

-- linguistic factors; relationship building



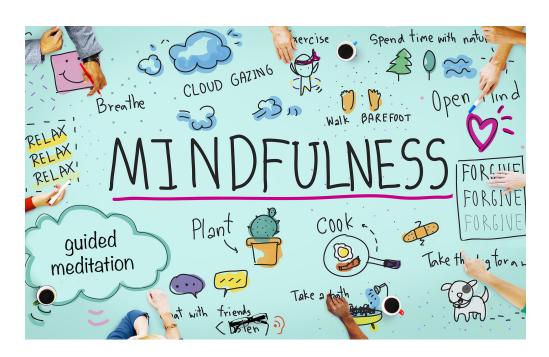
Parenting style differences (often more permissive) - not statistically significant, but anecdotally reported;

*Spanish preferring families tend to have more children at home

Strategies We Have Used to Engage and Retain Spanish Speaking Families in Our Intervention

Having and Showing Patience is KEY Being Flexible

Emphasizing: Self Kindness "Practice Not Perfection"



Awareness of Cultural Differences is Key

Having talented bilingual staff

Validating their experiences as a parent

 Interventionists report needing to spend more time talking about parenting styles and importance of role modeling

Acknowledging multiple stressors (re: child, family, culture, food insecurity)

Awareness of Cultural Differences is Key

Awareness of Cultural Differences is Key

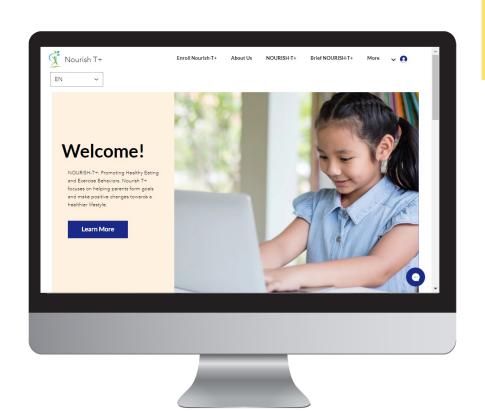
Interventionist report they are often more directive with Spanish speaking families;

we are currently coding interactions to validate these impressions



RETENTION

- Booster/check-in sessions
- Resource dissemination
- Text messaging to participant SMART Goals
- Website dedicated resource hub



PARTICIPANT TESTIMONIALS

("Field of Dreams motto")

"This program motivated me to join a water aerobics class that I love. I am drinking more water and eating more fruits. My son is playing outside more that the weather is nice and is back in school. He is also drinking more water and eating healthier. We are keeping more fruits, cheese, and baby carrots around for snacks."

"Wonderful program. I have learned a lot. Thank you."

"I was able to share all the information I learned with my family, and we all were very motivated."

WHAT WE ARE DOING WELL

"Muy contenta porque e aprendido mucho." [Very content because I have learned a lot.]

"Ha sido muy buena y los folletos me han ayudado a mejorar y a saber que hacer en cuanto a la nutrición y el ejercicio."
[It has been very good and the brochures have helped me improve and to know what to do as to nutrition and exercise.]

PARTICIPANT TESTIMONIALS cont'd

"The NOURISH-T program I had was great and the nutritionist gave me plenty of information I did not know. You are great this program has me changing my eating habits and making better choices."

"I appreciate the way the questions led me to see specific factors in our family (busyness of our schedules and the pressure of school) that disrupt intentions to exercise and to eat healthy, mindful meals."

PARTICIPANT TESTIMONIALS

WHAT WE CAN DO BETTER

I can not think of anything. I thought the program was perfect for my family.

"I WISH IF THE SESSION WERE IN PERSON."

"Ayudar amas personas a ver la realidad de comer saludable."

[To help people to see the reality of eating healthy.]

"Considero que todo esta muy bien pues da buena orientación."

[I consider that everything is very good because it gives good orientation.]





https://www.usf.edu/cbcs/cfs/academics/rmhc/ihope-lab/index.aspx

THANK YOU! For more information, visit our website at www.nourisht-study.com

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ANY QUESTIONS?