Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

Administrative Supplement

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2. eTable 1: Practice characteristics

Characteristics of the pediatric practices at each site.

Site	Number of Practices	Range of Providers per Practice	Range of Children Ages 6-12 per Practice	Range of Estimated % Overweight	Population Sample
Buffalo, NY	9	3 - 12	1459 - 4000	19 - 35	1 Urban 4 Suburban 1 Rural 2 Diverse
Columbus, OH	15	4-13	1200 - 23556	30 - 49	1 Urban 1 Suburban
Rochester, NY	6	12 - 15	4617 - 4823	31 - 46	4 Suburban 2 Diverse
St. Louis, MO	6	2 - 6	1330- 5998	11 - 20	1 Urban 4 Suburban 1 Rural

3. Traffic Light Diet food examples

The traffic light food diet characterizes foods as either green, yellow, or red.

Green foods are "go foods" that PLAN participants are strongly encouraged to eat. These include non-starchy vegetables such as asparagus, cauliflower, celery, green leafy vegetables and peppers.

Yellow foods have healthy foods that have somewhat more calories per gram than green foods. These include foods from multiple food groups that include vegetables, fruits, grains, dairy products and condiments. Specific examples of yellow foods are artichokes, carrots, butternut squash, apples, blueberries strawberries, breads, bagels, rice, milk, yogurt, low fat cheese, eggs, chicken, and white fish. Condiments in the yellow food category include mustard, salsa, and yogurt-based salad dressings.

Red foods are recommended only in small quantities because they have the most calories per gram. They include examples from all food groups such as avocados, French fried potatoes and other fried vegetables, dried fruits, coconut, fruit juices, cookies, sugared cereals, whole milk, sour cream, ice cream, red meats, nuts, processed meats like chicken nuggets, fried eggs and bacon.

eTable 2. Examples of the foods in the Traffic Light Diet

	EXAMPLE FOODS		
Food Groups	**GREEN**	**YELLOW**	**RED**
Vegetables	Asparagus, Broccoli, Cauliflower, Celery, green leafy vegetables, mushrooms, peppers, etc	Artichokes hearts in water, Tomato sauce, vegetable juice	Artichoke hearts in oil, Tomato sauces with oil
Starchy Vegetables		Beets, corn, mixed vegetables, parsnips, peas, potatoes, sweet potatoes, winter squash	French Fries, candied yams
Fruit		Apples, banana, berries, melons, clementine, oranges, grapes, etc.	Avocado, banana, berries in syrup, cherries in syrup
			Cranberries, dried berries, figs, raisins, fruit juice
Grains		Bagels, barley, biscuits, bread, cereal, crackers, pancakes, pasta, popcorn, rice	Cheez-It, goldfish, muffins, cheese crackers, butter popcorn, teddy grahams, stuffing

		Kix, special k, unsweetened cereals	Sweetened cereals, granola
Food Groups	Green	Yellow	Red
Dairy		Fat free, low fat, 1% cheese, cottage cheese, fat free and low-fat cream cheese, fat free and low fat milks, plain yogurt	Full fat cheese, cottage cheese, full fat cream cheese, whole mile, chocolate milk, flavored yogurt
Protein		Bean and legumes, 95% lean beef, chicken and turkey (no skin), eggs, low fat meat substitutes, lean cuts of pork, seafood	Baked beans, higher fat beef, chicken wings, duck, hot dogs, sausage, pepperoni, nuts and seeds
Fats, Oils, Sweets & Others			Alcohol, sugared drinks, oils, lard, candy, cakes, cookies, popsicles, pies, ice cream, frozen desserts, salty fried snacks
Soups		Broth type soups	Cream type soups
Condiments, Dressings & Other Ingredients		Cocktail sauce, hot sauce, salsa, relish, soy sauce, fat free and low-fat salad dressings	Butter, mayonnaise, chocolate syrup, maple syrup, artificial sweeteners

4. eTable 3: Coach training components and tools.

Domain	Components of Training	Tools	Completion
Education	Principles in behavior, diet, exercise Parenting Delay discounting Social facilitation Study basics Don't Shoot the Dog, Friends Forever, Cooper ABA	Study manuals (parent), journal readings, website review Protocol, MOP, reference guides (food & activity) Books & quiz provided	Readings complete Readings complete Readings complete, passing quiz score
Interactive	In-person workshops Role-plays Pilot families	PIs and study team FBT experts TFC 2 families per coach with 12 sessions	Active participation Audio recordings reviewed by TFC
Skill Assessment	Parent manual readings & quizzes Treatment knowledge Height & weight training Simulation Calls	Website administered Institution provided 4 sequential FBT simulations	≥80% score Mastery of measurements Scored as competent
Ongoing Supervision	Weekly conference calls to discuss treatment concerns Supervisors complete fidelity rating checklist for reviewed audio sessions	Conference link provided, led by TFC Session audio recordings Fidelity rating checklist	Attendance Uploaded to secure site Scored as competent
Booster Trainings	Training workshops on various topics Competency score	TFC provide interactive workshops	Attendance ≥80% score

5. **eTable 4: Fidelity Checklist**

Domain	Treatment Component	Fidelity Items
Mastery Based Skills	Weight Change	Connect weight change to behaviors
	Behavioral Goals	Calorie range
		GREEN foods
		RED foods/drinks
		Daily check-in (Parent only)
		Praise statements (Parent only)
		Stimulus control (Parent only)
		Meal planning (Parent only)
		Self-weigh
		GREEN activity
		RED activity
		Healthy sleep routines
		Dinners prepared at home (Parent only)
		PA with family
		HE and PA with friends
		Accessing HE and PA resources in the community
	Food and Activity Reference Guides (FRG/ARG)	Demonstrate knowledge of the FRG and ARG
	Parenting	Discuss parental role in helping child make changes in the specified behavioral targets *(e.g., modeling, praise, daily check-ins, stimulus control, contingency management, rules and routines)*
	Reinforcement	Identify reinforcement and discuss importance of providing in timely manner
	Educational Materials	Discuss progress/understanding of educational material and quizzes
Session Content	Treatment Materials	Provide tailored review of information
		Engage family in session content
		Provide appropriate session materials
	Individualized Treatment	Ability to keep family focused on session
		Assess needs, motivation, and progress of family
		Ability to understand when to move family forward to next topic and/or goal
	Problem-Solving	Allow/encourage family to identify barriers and potential solutions
	Planning	Allow/encourage family to lead process

Domain	Treatment Component	Fidelity Items
		Provide and discuss homework for the upcoming week
Session Style	Time Management	Ability to adequately attend to all components of session outline (REFLECT, EDUCATE, PLAN)
		Generally, adheres to timing of outline in order to meet FBT session goals
	Collaboration	Ability to establish and build rapport
	Positivity	Avoid shaming/judgmental discussion
		Demonstrate modeling of the use of praise statements
	Listening	Utilizing the pause
		Address concerns/questions in appropriate manner
	Support	Ability to continually be supportive regardless of progress
		Demonstrate problem solving skills to move family forward
		Provide praise for accomplishments

Footnote: For every item, the supervisor listens to the audio recorded FBT sessions and rates the coach on adherence and quality. Adherence is scored as either Yes or No and quality is scored as either Needs Improvement, Meets Expectations, or Exceeds Expectations. If an item was not expected to be discussed in session, the supervisor has the option to rate adherence and quality as Not Applicable.

6. Power analysis and sample size calculations

Power computations for PLAN employ simulations and two-sided tests at the 0.05 level of significance. The simulations reflect the planned primary analysis of covariance and the fact that this is an individually randomized group treatment trial with the coach (N=3 per site) nested within the site (N=4 sites) in the FBT group but with no such nesting in the UC group. The analysis of covariance that is simulated in the power computations treats the 24-month value of the outcome measure as the dependent variable and the baseline value as a covariate. The use of this approach reflects the primary study goal of comparing 24-month values across groups, with the outcome being compared being percent over normalized BMI in the participating child. Each result is based on 1000 simulations.

Tabulated power values employ sample sizes of 528 and that are between 65% and 95% of that total. Effect size estimates are generated using considerations and preliminary data discussed below. Usual care data involving an intervention and subjects most similar to our UC group is provided by Kalarchian[1] who randomized 81 8-12-year-old children with obesity to a usual care control condition and found an average percent overweight change of -0.17 $\pm$ 10.08 at 1 year. We expect some deterioration in this group at 2 years but will assume conservatively for the purpose of power computations that the two-year change will be 0 $\pm$ 10.08 in the UC group in the proposed research. Our estimated change in the FBT group begins with a review of six studies[2-7] authored by Dr. Epstein. There were 314 overweight/obesity children in those studies who received FBT interventions similar to the one we will employ. When we combined the data for those 314 children, we found an overall average decrease in percent over BMI of 10.6 $\pm$ 15.3 at 24 months.

In translating the above decrease of 10.6 $\pm$ 15.3 in percent over BMI at 24 months into the setting of the proposed research, we emphasize that the seven referenced studies implemented FBT in controlled academic settings where we anticipate better performance than is likely in the family practices we will employ in this study. To estimate the degree to which the effect is likely to be attenuated when we switch from highly controlled to more "real life" settings, we considered the following. The child weight management intervention MEND (Mind, Exercise, Nutrition, Do it) focused on children age 7-13 who exceeded the 91st weight percentile. MEND employed both (1) a community-based mass-implementation intervention[8] involving many programs and 9563 subjects who provided complete data and (2) a rigorous randomized trial (N=116)[9] analogous to the Epstein studies referenced in the preceding paragraph.[2-7] The 12-month results were reductions in BMI of 0.79 kg/m^2 in the community study as compared to 1.04 kg/m^2 in the intervention arm of the randomized trial. Thus, the reduction in the community-based MEND intervention was 76.0% of the magnitude that was observed in the family-based arm of the randomized trial.

Based on this 76.0%, our computations conservatively assume changes in the intervention group that are 50%, 60%, and 70% of the previously observed change of 10.6 $\pm$ 15.3 that was observed in the rigorous academic environment of Dr. Epstein's studies.[2-7] Thus, we base our power on a comparison of projected reductions of 5.3 $\pm$ 15.3 (50% of 10.6 $\pm$ 15.3), 6.4 $\pm$ 15.3 (60% of 10.6), and 7.4 $\pm$ 15.3 (70% of 10.6) in the FBT group as compared to 0 $\pm$ 10.08 in the UC group. In

addition, given projected standard deviations of 15.3 and 10.08 in the two groups, we use the maximum and the mean of those two values and thereby compute power assuming standard deviations of both 15.3 and 12.7. In performing the calculations summarized below, we emphasize that we will have actual or imputed 24-month data on all subjects. To see details of how we will impute the 24 month values when necessary, please see the section below titled "Implementation of the Intention-to-Treat Principle."

eTable 5 contains the results of the power computations using the parameters discussed above, assuming the compound symmetry covariance structure in both study arms and assuming an intraclass correlation coefficient (ICC) in the UC group of 0.01 and ICCs in the FBT group of 0.04, 0.06, 0.10, and 0.15. We assume a small ICC in the UC group of 0.01 because there is no clustering within that group meaning that the ICC should be essentially zero. While we do not have data with which to estimate the ICC in the FBT group, we note that many cluster trials that involve group interventions have reported ICCs in the 0.01 to 0.05 range. Since the PLAN intervention is individualized and since we expect PLAN children to have no contact with one another, we do not face the impact on the ICC that is present in many cluster trials. This argues for a very small ICC in the FBT group. By contrast, the fact that the same coach will be responsible for multiple children will inevitably increase the ICC above where it might otherwise be. Based on these considerations, we tabulate power for ICCs in the FBT group that range from 0.04 to 0.15. However, the many other studies that have used group interventions while yielding ICCs below 0.05 suggests that the ICC ultimately observed in PLAN will be substantially less than 0.1.

Results in eTable 5 indicate that if we recruit 100% of our original target of 528 families, power will be excellent for all tabulated scenarios with an ICC in the FBT group of 0.1 or less. For an ICC no bigger than 0.1, power remains adequate for most scenarios if we recruit at least 80% of the target (N = 432). If recruitment is below the 80% figure, an adequate power of at least 0.8 requires either the smaller of the two tabulated standard deviations or a mean difference that is at least 60% of the value observed in Dr. Epstein's studies (difference at least 6.4).

Computations are for the primary outcome which is the percent over the 50th percentile of BMI in children. Results are generated using 1000 simulations of the primary analytic model: an analysis of covariance with the 24-month value as the dependent variable and the baseline value as a covariate. The analysis reflects the fact that this is an individually randomized group treatment trial in which the coach is nested within the site within the FBT group but which is different from a classic cluster randomized trial in that there is no such nesting within the control (UC) group. The total number of randomized families is assumed to range from 65% to 100% of the target of 528. Tabulations assume an ICC of 0.01 in the UC group and of 0.04, 0.06, 0.10, and 0.15 in the FBT group, mean differences of 5.3, 6.4 and 7.4 (which represent 50%, 60%, and 70% of observed results in previous studies), and standard deviations of 12.7 and 15.3.

eTable 5: Statistical power for two sided tests at the 0.05 level of significance.

ICC		SD	Mean diff	Statistical power associated with sample sizes ranging from 65% to 100% of original target of 528							
FBT grp	UC grp			N=528 (100%)	N=502 (95%)	N=476 (90%)	N=449 (85%)	N=422 (80%)	N=396 (75%)	N=370 (70%)	N=344 (65%)
0.04	0.01	12.7	5.3	0.95	0.95	0.94	0.92	0.93	0.92	0.89	0.89
			6.4	0.99	0.98	0.99	0.98	0.99	0.98	0.98	0.97
			7.4	1.00	1.00	1.00	1.00	1.00	1.00	0.99	1.00
		15.3	5.3	0.84	0.83	0.83	0.81	0.80	0.76	0.76	0.74
			6.4	0.96	0.94	0.95	0.92	0.91	0.91	0.88	0.87
			7.4	0.99	0.99	0.99	0.98	0.97	0.97	0.97	0.96
0.06	0.01	12.7	5.3	0.92	0.91	0.90	0.90	0.88	0.87	0.85	0.84
			6.4	0.98	0.98	0.98	0.98	0.97	0.96	0.95	0.95
			7.4	1.00	1.00	1.00	1.00	0.99	0.99	0.99	0.99
		15.3	5.3	0.80	0.79	0.77	0.78	0.74	0.73	0.70	0.68
			6.4	0.92	0.91	0.92	0.91	0.88	0.87	0.85	0.84
			7.4	0.97	0.97	0.96	0.97	0.96	0.95	0.93	0.94
0.10	0.01	12.7	5.3	0.85	0.83	0.81	0.83	0.80	0.80	0.76	0.76
			6.4	0.95	0.94	0.94	0.93	0.91	0.92	0.91	0.88
			7.4	0.98	0.98	0.98	0.98	0.98	0.97	0.97	0.97
		15.3	5.3	0.69	0.68	0.69	0.63	0.67	0.65	0.62	0.60
			6.4	0.84	0.82	0.84	0.81	0.81	0.77	0.76	0.78
			7.4	0.94	0.94	0.92	0.92	0.91	0.89	0.89	0.87
0.15	0.01	12.7	5.3	0.73	0.75	0.71	0.72	0.69	0.70	0.70	0.68
			6.4	0.86	0.85	0.83	0.85	0.85	0.84	0.83	0.81
			7.4	0.95	0.95	0.95	0.94	0.94	0.93	0.93	0.92
		15.3	5.3	0.57	0.59	0.55	0.56	0.53	0.53	0.52	0.52
			6.4	0.73	0.74	0.70	0.73	0.71	0.67	0.68	0.65
			7.4	0.86	0.82	0.86	0.83	0.82	0.81	0.80	0.79

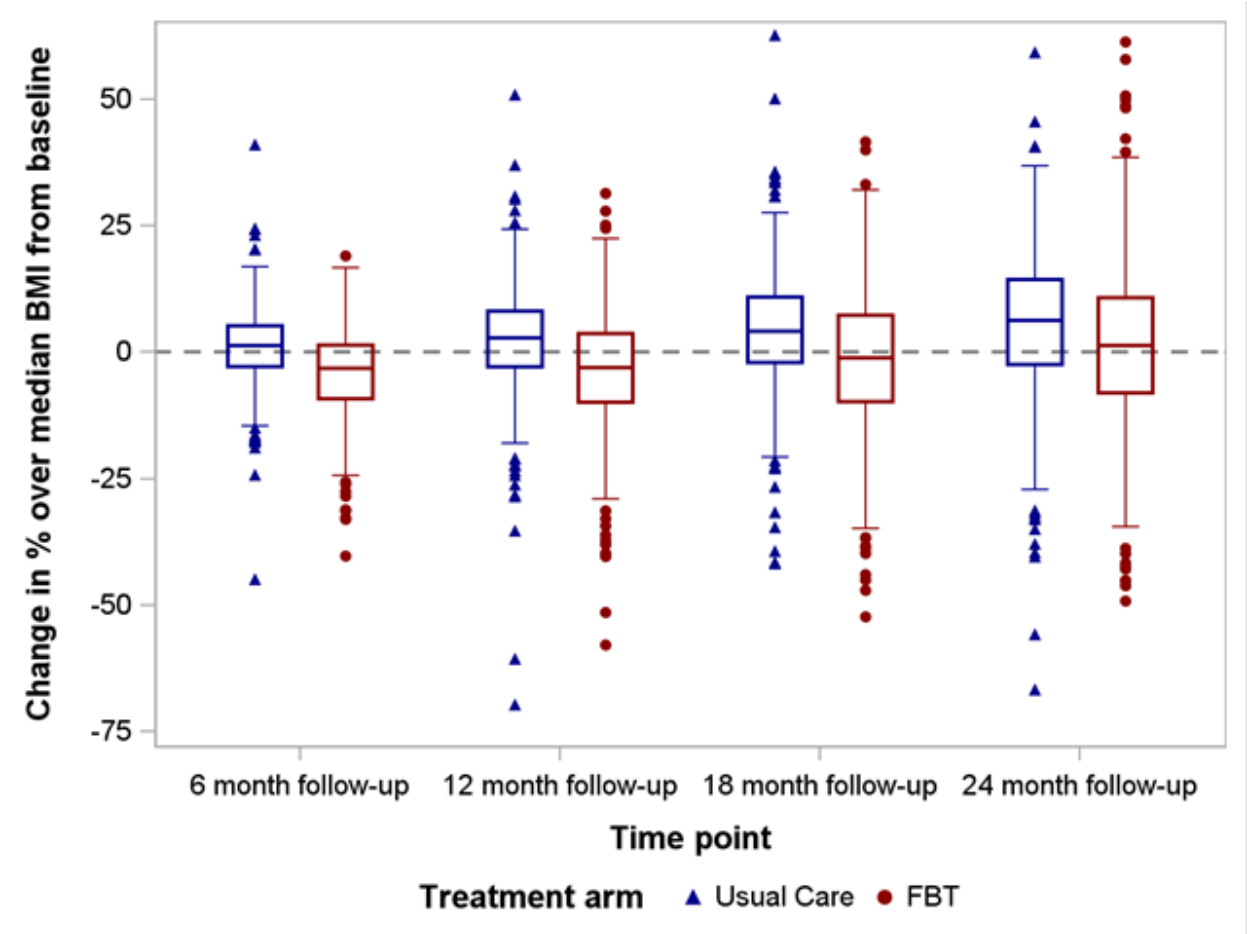
7. eTable 6: Comparison of families with and without participating siblings

Descriptive characteristics of families who had siblings participating versus those who did not have siblings participating.

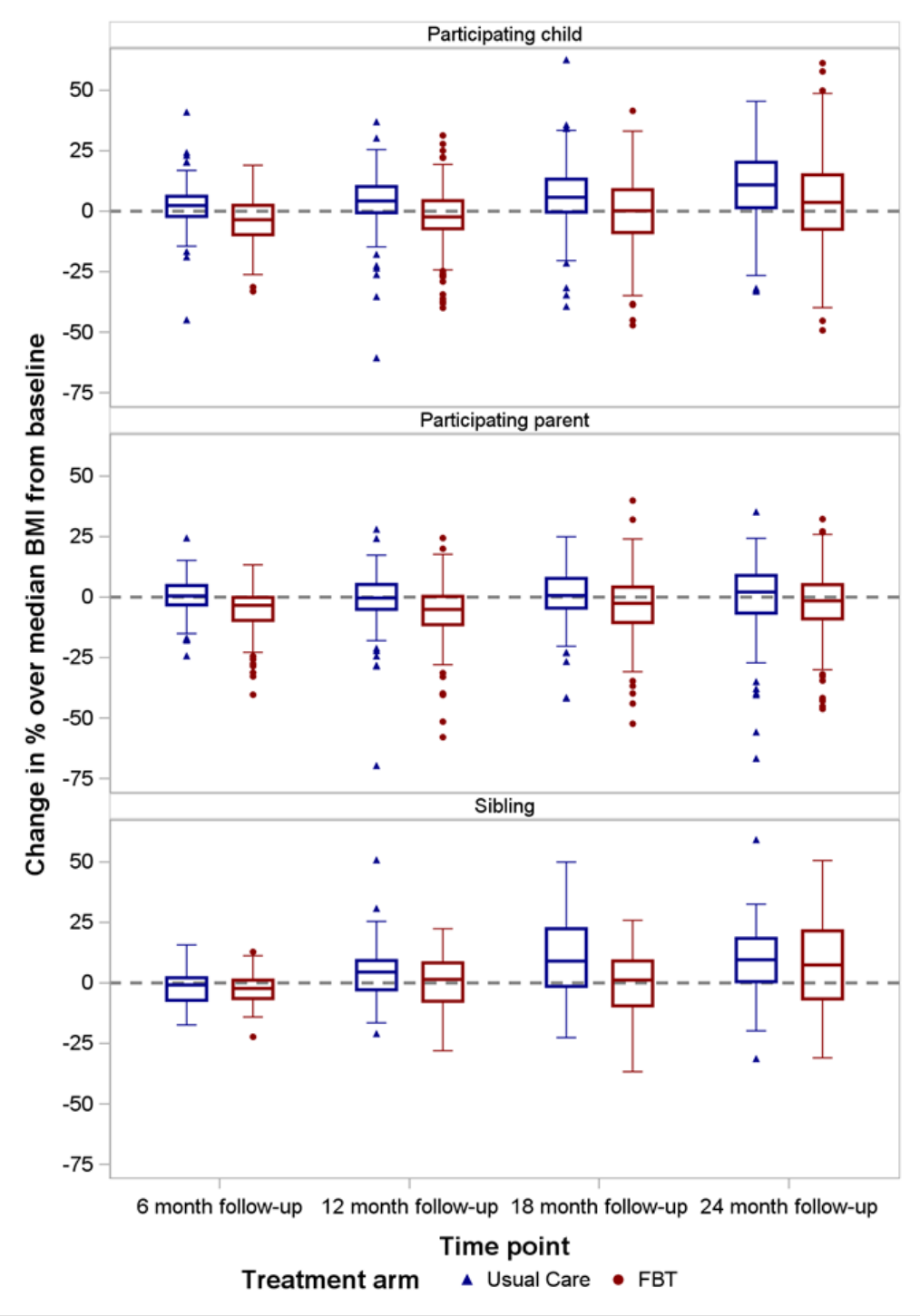
	Families with sibling participation	Families without sibling participation
n	94	358
	N (%)	N (%)
Targeted Child Sex		
Female	57 (60.6)	185 (51.7)
Male	37 (39.4)	173 (48.3)
Targeted Parent Sex		
Female	85 (90.4)	303 (84.6)
Male	9 (9.6)	55 (15.4)
Treatment		
Usual Care	43 (45.7)	183 (51.1)
FBT	51 (54.3)	175 (48.9)
Race		
American Indian	1 (1.1)	0 (0)
Asian	1 (1.1)	7 (2.0)
African American	25 (26.6)	98 (27.4)
White	49 (52.1)	209 (58.4)
Multiracial	12 (12.8)	27 (7.5)
Other	4 (4.3)	14 (3.9)
Refused	2 (2.1)	3 (1.9)
Ethnicity		
Hispanic	13 (13.8)	29 (8.1)
Non Hispanic	81 (86.2)	329 (91.9)
	Mean (SD)	Mean (SD)
Targeted Child % over median BMI, baseline	61.6 (26.6)	58.8 (27.1)
Targeted Child % over BMI change, 0-24 months	8.3 (16.7) [n = 83]	6.8 (16.9) [n = 317]
Parent BMI, baseline	37.6 (7.2)	36.9 (7.9)
Parent BMI change, 0-24 months	-0.2 (2.8) [n = 68]	-0.4 (3.1) [n = 254]
Family Size	4.8 (1.3)	4.4 (1.2)
Targeted parent years of Education	14.9 (2.3)	15.0 (2.3)
Annual Household Income (thousand $)	83.6 (55.5)	84.0 (55.5)

8. Raw data for weight outcomes

eFigure 1. Change in percent over median BMI from baseline by treatment group, for the full family sample



9. **eFigure 2: Change in percent over median BMI from baseline by treatment group, stratified by family role**



10. eTable 7: Full model output for primary and secondary analyses

eTable 7a: Primary Analysis of Covariance for Child Outcomes

Model	Model Effect	Estimate (95% CI)	p-value
Adjusted for site and baseline % over median only	FBT - UC	-6.22 (-12.079, -0.362)	0.037
	Baseline % over median BMI	1.064 (1.005, 1.122)	<.001
	Study Site: Buffalo - St. Louis	1.892 (-2.326, 6.11)	0.379
	Study Site: Columbus - St. Louis	3.126 (-1.145, 7.398)	0.151
	Study Site: Rochester - St. Louis	-5.247 (-9.721, -0.773)	0.022
Adjusted for site, baseline % over median, follow-up time, months of follow-up during COVID, baseline age, sex, race, parent education, and household income	FBT - UC	-6.214 (-10.136, -2.292)	0.002
	Baseline % over median BMI	1.07 (1.011, 1.129)	<.001
	Study Site: Buffalo - St. Louis	2.046 (-2.07, 6.162)	0.330
	Study Site: Columbus - St. Louis	0.323 (-4.292, 4.938)	0.891
	Study Site: Rochester - St. Louis	-4.977 (-9.269, -0.686)	0.023
	Months between baseline and 24-month follow-up	0.243 (-0.401, 0.886)	0.460
	Months of follow-up after start of COVID-19 pandemic	0.416 (0.113, 0.718)	0.007
	Child sex: Female - Male	0.263 (-2.753, 3.28)	0.864
	Child race: White - Black	-8.512 (-12.384, -4.64)	<.001
	Child race: Other race - Black	-1.687 (-7.648, 4.274)	0.579
	Child age at baseline	-2.447 (-3.235, -1.66)	<.001
	Household income (in $1000's)	-0.011 (-0.047, 0.025)	0.541
	Parent education: High school graduate or less - Graduate degree or higher	0.708 (-4.921, 6.337)	0.805
	Parent education: Some college or Bachelor's degree - Graduate degree or higher	-0.646 (-4.553, 3.262)	0.746

eTable 7b: Full family longitudinal analysis

Effect label	Estimate (95% CI)	p-value
FBT - UC	-5.163 (-6.579, -3.747)	<.0001
Follow-up months	0.176 (0.095, 0.257)	<.0001
Study site: Buffalo - St. Louis	2.299 (0.279, 4.32)	0.0260
Study site: Columbus - St. Louis	-0.063 (-2.135, 2.009)	0.9523
Study site: Rochester - St. Louis	-1.146 (-3.114, 0.821)	0.2525
Baseline % over median BMI	-0.046 (-0.067, -0.026)	<.0001
Family role: Parents - Participating children	-2.228 (-5.585, 1.129)	0.1899
Family role: Siblings - Participating children	-0.541 (-1.954, 0.873)	0.4514
One-month increase in follow-up during COVID	0.237 (0.073, 0.402)	0.0047
Sex: Female - Male	0.3 (-0.885, 1.486)	0.6147
Race: White - Black	-3.548 (-5.064, -2.031)	<.0001
Race: Other race - Black	-1.968 (-4.403, 0.467)	0.1128
Age at baseline	-0.059 (-0.157, 0.039)	0.2374
Household income (in $1000's)	0.002 (-0.015, 0.019)	0.8131
Parent education: High school graduate or less - Graduate degree or higher	0.478 (-2.064, 3.02)	0.7121
Parent education: Some college or Bachelor's degree - Graduate degree or higher	1.103 (-0.577, 2.784)	0.1978

eTable 7c: Full family longitudinal analysis, with treatment effect stratified by family role

Effect label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.48 (-8.05, -4.91)	<.0001
Treatment effect in Parents	-3.97 (-5.68, -2.26)	<.0001
Treatment effect in Siblings	-5.32 (-8.47, -2.17)	0.0012
Follow-up months	0.176 (0.095, 0.257)	<.0001
Study site: Buffalo - St. Louis	2.277 (0.253, 4.302)	0.0277
Study site: Columbus - St. Louis	-0.043 (-2.115, 2.029)	0.9674
Study site: Rochester - St. Louis	-1.155 (-3.125, 0.816)	0.2499
Baseline % over median BMI	-0.046 (-0.067, -0.025)	<.0001
One-month increase in follow-up during COVID	0.238 (0.073, 0.402)	0.0046
Sex: Female - Male	0.284 (-0.897, 1.465)	0.6325
Race: White - Black	-3.499 (-5.02, -1.979)	<.0001
Race: Other race - Black	-1.785 (-4.226, 0.655)	0.1509
Age at baseline	-0.056 (-0.154, 0.041)	0.2550
Household income (in $1000's)	0.002 (-0.015, 0.019)	0.7987
Parent education: High school graduate or less - Graduate degree or higher	0.461 (-2.083, 3.005)	0.7219
Parent education: Some college or Bachelor's degree - Graduate degree or higher	1.105 (-0.579, 2.79)	0.1980

eTable 7d: Full family longitudinal analysis, stratified effects from additional exploratory analyses

Estimate label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.38 (-7.94, -4.83)	<.0001
Treatment effect in Parents	-3.98 (-5.68, -2.27)	<.0001
Treatment effect in Siblings	-5.22 (-8.36, -2.08)	0.0014
Effect of race in Children (White - Black)	-6.22 (-8.02, -4.42)	<.0001
Effect of race in Parents (White - Black)	-0.82 (-2.61, 0.97)	0.3690
Effect of race in Siblings (White - Black)	-2.92 (-6.25, 0.41)	0.0853
Effect of COVID time in Children	0.54 (0.36, 0.73)	<.0001
Effect of COVID time in Parents	-0.17 (-0.37, 0.03)	0.0965
Effect of COVID time in Siblings	0.62 (0.31, 0.94)	0.0001

11. eTable 8: Full model output for sensitivity analyses

eTable 8a: Primary analysis of covariance for child outcomes, sensitivity analysis excluding individuals who provided no follow-up after randomization

Model	Model Effect	Estimate (95% CI)	p-value
Adjusted for site and baseline % over median only	FBT - UC	-6.198 (-12.107, -0.29)	0.040
	Baseline % over median BMI	1.064 (1.004, 1.124)	<.001
	Study Site: Buffalo - St. Louis	2.164 (-2.107, 6.435)	0.321
	Study Site: Columbus - St. Louis	3.36 (-0.948, 7.669)	0.126
	Study Site: Rochester - St. Louis	-4.981 (-9.478, -0.483)	0.030
Adjusted for site, baseline % over median, follow-up time, proportion of follow-up during COVID, baseline age, sex, race, parent education, and household income	FBT - UC	-6.12 (-10.067, -2.174)	0.002
	Baseline % over median BMI	1.071 (1.009, 1.132)	<.001
	Study Site: Buffalo - St. Louis	2.272 (-1.895, 6.439)	0.285
	Study Site: Columbus - St. Louis	0.541 (-4.07, 5.151)	0.818
	Study Site: Rochester - St. Louis	-4.772 (-9.076, -0.467)	0.030
	Months between baseline and 24-month follow-up	0.363 (-0.278, 1.004)	0.267
	Proportion of follow-up after start of COVID-19 pandemic	0.106 (0.033, 0.179)	0.005
	Child sex: Male - Female	0.339 (-2.726, 3.404)	0.828
	Child race: White - Black	-8.607 (-12.483, -4.731)	<.001
	Child race: Other race - Black	-2.11 (-8.163, 3.943)	0.494
	Child age at baseline	-2.452 (-3.252, -1.652)	<.001
	Parent education: High school graduate or less - Graduate degree or higher	0.92 (-4.65, 6.49)	0.746
	Parent education: Some college or Bachelor's degree - Graduate degree or higher	-0.584 (-4.462, 3.295)	0.768
	Household income (in $1000's)	-0.011 (-0.046, 0.024)	0.539

eTable 8b: Primary analysis of covariance for child outcomes, controlled imputation sensitivity analysis

Model	Model Effect	Estimate (95% CI)	p-value
Adjusted for site and baseline % over median only	FBT - UC	-6.156 (-11.963, -0.35)	0.038
	Baseline % over median BMI	1.065 (1.007, 1.124)	<.001
	Study Site: Buffalo - St. Louis	1.708 (-2.506, 5.923)	0.427
	Study Site: Columbus - St. Louis	3.157 (-1.11, 7.425)	0.147
	Study Site: Rochester - St. Louis	-5.372 (-9.842, -0.902)	0.019
Adjusted for site, baseline % over median, follow-up time, proportion of follow-up during COVID, baseline age, sex, race, parent education, and household income	FBT - UC	-6.181 (-10.042, -2.319)	0.002
	Baseline % over median BMI	1.07 (1.011, 1.13)	<.001
	Study Site: Buffalo - St. Louis	1.806 (-2.31, 5.923)	0.390
	Study Site: Columbus - St. Louis	0.18 (-4.428, 4.788)	0.939
	Study Site: Rochester - St. Louis	-5.191 (-9.478, -0.905)	0.018
	Months between baseline and 24-month follow-up	0.309 (-0.332, 0.951)	0.345
	Proportion of follow-up after start of COVID-19 pandemic	0.1 (0.026, 0.174)	0.008
	Child sex: Male - Female	0.191 (-2.824, 3.207)	0.901
	Child race: White - Black	-8.587 (-12.457, -4.716)	<.001
	Child race: Other race - Black	-1.54 (-7.497, 4.417)	0.612
	Child age at baseline	-2.427 (-3.214, -1.639)	<.001
	Parent education: High school graduate or less - Graduate degree or higher	0.934 (-4.691, 6.56)	0.745
	Parent education: Some college or Bachelor's degree - Graduate degree or higher	-0.603 (-4.509, 3.303)	0.762
	Household income (in $1000's)	-0.012 (-0.047, 0.024)	0.527

eTable 8c: Main model output for full family longitudinal analysis, sensitivity analysis excluding individuals who provided no follow-up after randomization

Effect label	Estimate (95% CI)	p-value
FBT - UC	-5.298 (-6.684, -3.913)	<.0001
Follow-up months	0.187 (0.103, 0.271)	<.0001
Study site: Buffalo - St. Louis	2.321 (0.446, 4.196)	0.0153
Study site: Columbus - St. Louis	-0.087 (-2.105, 1.93)	0.9323
Study site: Rochester - St. Louis	-1.375 (-3.282, 0.532)	0.1575
Baseline % over median BMI	-0.048 (-0.064, -0.033)	<.0001
Family role: Parents - Participating children	-1.033 (-3.987, 1.921)	0.4928
Family role: Siblings - Participating children	-0.519 (-1.89, 0.852)	0.4574
One-month increase in follow-up during COVID	0.243 (0.068, 0.418)	0.0066
Sex: Female - Male	0.455 (-0.583, 1.493)	0.3890
Race: White - Black	-3.438 (-4.994, -1.881)	<.0001
Race: Other race - Black	-2.472 (-4.924, -0.021)	0.0481
Age at baseline	-0.096 (-0.183, -0.008)	0.0332
Household income (in $1000's)	-0.003 (-0.019, 0.013)	0.7096
Parent education: High school graduate or less - Graduate degree or higher	0.039 (-2.506, 2.583)	0.9763
Parent education: Some college or Bachelor's degree - Graduate degree or higher	0.858 (-0.828, 2.544)	0.3186

eTable 8d: Model with treatment effects stratified by family role

Effect label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.49 (-8.06, -4.92)	<.0001
Treatment effect in Parents	-3.95 (-5.57, -2.32)	<.0001
Treatment effect in Siblings	-5.13 (-7.9, -2.36)	0.0003
Follow-up months	0.187 (0.102, 0.271)	<.0001
Study site: Buffalo - St. Louis	2.289 (0.413, 4.165)	0.0168
Study site: Columbus - St. Louis	-0.096 (-2.113, 1.921)	0.9256
Study site: Rochester - St. Louis	-1.404 (-3.311, 0.502)	0.1488
Baseline % over median BMI	-0.048 (-0.063, -0.033)	<.0001
One-month increase in follow-up during COVID	0.243 (0.068, 0.418)	0.0065
Sex: Female - Male	0.475 (-0.565, 1.514)	0.3697
Race: White - Black	-3.382 (-4.939, -1.825)	<.0001
Race: Other race - Black	-2.333 (-4.785, 0.119)	0.0622
Age at baseline	-0.094 (-0.181, -0.006)	0.0366
Household income (in $1000's)	-0.003 (-0.019, 0.012)	0.6687
Parent education: High school graduate or less - Graduate degree or higher	0.013 (-2.535, 2.561)	0.9918
Parent education: Some college or Bachelor's degree - Graduate degree or higher	0.828 (-0.861, 2.517)	0.3367

eTable 8e: Stratified effects from additional exploratory analyses

Estimate label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.41 (-7.97, -4.84)	<.0001
Treatment effect in Parents	-3.95 (-5.57, -2.33)	<.0001
Treatment effect in Siblings	-5.21 (-7.94, -2.48)	0.0002
Effect of race in Children (White - Black)	-6 (-7.71, -4.29)	<.0001
Effect of race in Parents (White - Black)	-0.54 (-2.39, 1.31)	0.5683
Effect of race in Siblings (White - Black)	-2.19 (-5.11, 0.73)	0.1412
Effect of COVID time in Children	0.53 (0.34, 0.72)	<.0001
Effect of COVID time in Parents	-0.21 (-0.41, -0.01)	0.0367
Effect of COVID time in Siblings	0.58 (0.26, 0.89)	0.0004

eTable 8f: Main model output: Full family longitudinal analysis, controlled imputation sensitivity analysis

Effect label	Estimate (95% CI)	p-value
FBT - UC	-5.119 (-6.554, -3.683)	<.0001
Follow-up months	0.186 (0.105, 0.266)	<.0001
Study site: Buffalo - St. Louis	2.323 (0.271, 4.374)	0.0267
Study site: Columbus - St. Louis	-0.196 (-2.297, 1.904)	0.8543
Study site: Rochester - St. Louis	-1.281 (-3.275, 0.714)	0.2075
Baseline % over median BMI	-0.046 (-0.067, -0.025)	0.0001
Family role: Parents - Participating children	-1.476 (-4.845, 1.893)	0.3852
Family role: Siblings - Participating children	-0.191 (-1.609, 1.226)	0.7905
One-month increase in follow-up during COVID	0.211 (0.047, 0.376)	0.0117
Sex: Female - Male	0.279 (-0.912, 1.471)	0.6408
Race: White - Black	-3.649 (-5.185, -2.113)	<.0001
Race: Other race - Black	-1.81 (-4.268, 0.647)	0.1482
Age at baseline	-0.068 (-0.166, 0.031)	0.1744
Household income (in $1000's)	0.003 (-0.014, 0.02)	0.7113
Parent education: High school graduate or less - Graduate degree or higher	0.705 (-1.874, 3.285)	0.5914
Parent education: Some college or Bachelor's degree - Graduate degree or higher	1.25 (-0.458, 2.958)	0.1512

eTable 8g: Model with treatment effects stratified by family role

Effect label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.45 (-8.04, -4.87)	<.0001
Treatment effect in Parents	-3.9 (-5.62, -2.17)	<.0001
Treatment effect in Siblings	-5.34 (-8.5, -2.17)	0.0012
Follow-up months	0.186 (0.105, 0.266)	<.0001
Study site: Buffalo - St. Louis	2.302 (0.248, 4.356)	0.0283
Study site: Columbus - St. Louis	-0.173 (-2.274, 1.927)	0.8711
Study site: Rochester - St. Louis	-1.29 (-3.287, 0.708)	0.2050
Baseline % over median BMI	-0.046 (-0.067, -0.025)	0.0001
One-month increase in follow-up during COVID	0.212 (0.048, 0.376)	0.0114
Sex: Female - Male	0.262 (-0.925, 1.448)	0.6609
Race: White - Black	-3.6 (-5.14, -2.06)	<.0001
Race: Other race - Black	-1.618 (-4.08, 0.845)	0.1972
Age at baseline	-0.065 (-0.163, 0.033)	0.1890
Household income (in $1000's)	0.003 (-0.014, 0.02)	0.6975
Parent education: High school graduate or less - Graduate degree or higher	0.69 (-1.892, 3.272)	0.5999
Parent education: Some college or Bachelor's degree - Graduate degree or higher	1.255 (-0.457, 2.967)	0.1506

eTable 8h: Stratified effects from additional exploratory analyses

Estimate label	Estimate (95% CI)	p-value
Treatment effect in Children	-6.36 (-7.93, -4.78)	<.0001
Treatment effect in Parents	-3.91 (-5.62, -2.19)	<.0001
Treatment effect in Siblings	-5.24 (-8.39, -2.09)	0.0014
Effect of race in Children (White - Black)	-6.36 (-8.17, -4.55)	<.0001
Effect of race in Parents (White - Black)	-0.88 (-2.68, 0.92)	0.3388
Effect of race in Siblings (White - Black)	-2.9 (-6.25, 0.44)	0.0880
Effect of COVID time in Children	0.52 (0.34, 0.71)	<.0001
Effect of COVID time in Parents	-0.2 (-0.4, 0)	0.0447
Effect of COVID time in Siblings	0.59 (0.28, 0.91)	0.0002

12. eTable 9: Serious Adverse Events by site, group and family member organized by whether the event was reported during or between a scheduled visit.

	Buffalo		Columbus		Rochester		St. Louis	
Group	UC	FBT	UC	FBT	UC	FBT	UC	FBT
Related to study								
Index Child	0	0	0	0	0	0	0	0
Index Parent	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Possibly related to study								
Index Child	0	0	0	1	0	0	0	0
Index Parent	0	0	0	0	0	0	0	1
Other	0	0	0	0	0	0	0	1
Not related to study								
Index Child	0	1	3	3	3	1	1	5
Index Parent	4	3	6	11	8	5	4	8
Other	0	0	0	0	1	2	0	3
Total	4	4	9	15	12	8	5	18

Note. UC = Usual care, FBT = Family-based treatment. A Serious Adverse Event (SAE) is any adverse event which: a) results in death, b) is life threatening, c). requires in-patient hospitalization, or prolongation of an existing hospitalization, d). Result in persistent or significant disability and/or incapacity, e). Is a congenital anomaly / birth defect in the offspring of an index parent/adult or teen. Other includes siblings and non-index parent

13. Modifications to the Data Analytic Plan

Modifications to the data analytic plan as described in the protocol paper include the following:

- **Covariates**: Our primary analyses as described in the protocol paper included no covariates. We revised that plan to include study site as a covariate in all analyses of covariance and longitudinal models. The covariate-adjusted model was intended to include whether the child came from a one or two parent family. However, because PLAN did not collect the required data, this variable is not included in the models.
- **Imputation method**: The protocol paper indicated that we would impute data using robust maximum likelihood methods. However, following discussions with statistical colleagues at NHLBI, we decided to use multiple imputation instead.
- **Secondary and exploratory analyses**: The analytic plan in the protocol and protocol paper outlines a variety of secondary and exploratory analyses. Because of space considerations and an assessment of their appropriateness in the primary endpoint paper, many of these analyses are not included in the current paper. We intend to explore many of these secondary and exploratory analyses in future manuscripts.
- **COVID analyses**: Because the burdens of COVID-19 were unforeseeable when we published the protocol paper, we did not pre-specify COVID-related analyses. Those plans were developed subsequently as the impact of COVID on the study became clear. Analytic methods examining the impact of COVID-19 were informed by conversations with statistical colleagues at NHLBI and the DSMB. Specifically, in the primary analysis of covariance, a variable reflecting the total number of months from the start of the COVID-19 pandemic (March 16, 2020) to the 24-month follow-up date was included as a covariate in the model. A value of 0 months was used for individuals who had their 24-month follow-up prior to the start of the pandemic. In the longitudinal full-family models, a time-varying variable indicating the number of months from the start of the COVID-19 pandemic to the date of the follow-up time point was included as a covariate. Again, a value of 0 months was used for any follow-up time points that occurred prior to the start of the COVID-19 pandemic.
- **Longitudinal models**: For reasons described in the paper, we planned to and did use growth curve models in analyzing the longitudinal data. We also anticipated some form of non-linearity over time. When we graphed the original data prior to performing the analyses, we noticed one linear trend from baseline to 6 months and a second linear trend from 6 months to 24 months. To account for this, we used the change from baseline as the outcome of interest, which allowed us to model the 6 to 24 month linear trend without needing to also model the separate linear trend from baseline to 6 months. Because of this clear linearity from 6 to 24 months we did not need to use piecewise spline models or explore additional non-linear models, which were possible analytic strategies described in the protocol and protocol paper.
- **Sensitivity analyses**: We used modified intention to treat analyses as indicated in the protocol paper. However, following discussions with statistical colleagues at NHLBI, we decided to add an additional sensitivity analysis using controlled imputation. This

allowed us to evaluate whether the results we reported would be impacted if we modified the multiple imputation approach.

- **Family-level analyses:** In order to evaluate the overall effectiveness of FBT on the full family unit, we decided to use all individuals (participating children, parents, and siblings) in one model instead of analyzing each sub-population separately. This was only done for the longitudinal models. In order to determine the effect of FBT in each unique family member, we included an interaction term between family member type and treatment in these full family models. We opted for this approach as it allowed us to make direct comparisons regarding FBT's effectiveness across the three sub-populations without needing to perform separate statistical analyses for each group. This approach differs from the analyses outlined in the protocol and protocol paper, which indicated that we would evaluate each population separately.
- **Moderators of treatment effects:** We decided to assess covariates as potential moderators of treatment effects in order to determine whether certain subgroups of individuals benefitted differentially from FBT, or whether certain factors impacted the effectiveness of FBT. Because these analyses were not pre-specified in the protocol paper, they are exploratory in nature only.
- **Relationships between child, parent, and sibling weight change:** We felt that examining relationships between child, parent, and sibling weight changes over time was an important addition to our discussion of family-level effects of FBT. As such, we added these analyses because we believe they provide important context that enhances the manuscript's findings.

14. Additional analytic details

Using data from 10 multiply imputed datasets, we found the average observed ICC for site to be 0.02.

15. References

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