



Published in final edited form as:

*J Pediatr.* 2016 October ; 177: 262–266.e1. doi:10.1016/j.jpeds.2016.06.027.

## A Preschool Obesity Treatment Clinical Trial: Reasons Primary Care Providers Declined Referrals

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### Abstract

**Objective**—To examine primary care providers' (PCPs) referral of preschool children with obesity ( 95<sup>th</sup> percentile for body mass index [BMI]) to a weight management intervention when offered through a randomized clinical trial (RCT) and identification of reasons for not referring children.

**Study design**—In Phase-I, three experts across obesity, psychology, and nutrition completed an open card sort and classified PCP decline reasons into groups based on similarity of reasons. Categories were then defined and labeled. In Phase-II, two independent sorters placed the decline reasons into one of the categories defined in Phase-I.

**Results**—PCPs referred 78% of eligible children to the RCT. Referred children had a significantly higher weight (48.4 vs. 46.1 lbs.,  $p < 0.001$ ) and BMI percentile (97.6 vs. 97.0,  $p < 0.001$ ) than children declined for referral. Eleven decline categories were identified in Phase-I. Phase-II obtained excellent reliability between each independent sorter and the Phase-I categories, and between the two independent sorters (kappas of 0.72–1.0). The most common reason for declining was “Family not a good fit” (23.6%), followed by “doesn't believe weight is a problem” (13.9%), “family would not be interested” (12%), and “doesn't believe measurement is accurate” (11.5%). Appropriately, exclusionary criteria of the RCT (11.8%), was also a reason.

**Conclusion**—Availability of weight management for preschoolers through RCTs appeared to overcome barriers of resources, time, and credible treatment cited in prior studies. However, concern about the family's response or interest in a weight management remained barriers as did PCP perceptions about obesity in young children.

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**Reprint Request:** No reprints

The authors declare no conflicts of interest.

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**Trial registration**—ClinicalTrials.gov: NCT01546727

## Keywords

pediatric obesity; primary health care; child

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Nearly 32% of children aged 2 to 19 in the United States are estimated to be overweight or obese (1). Obesity is currently one of the leading public health concerns of our time because of its association with adverse health outcomes (2). To combat this health crisis, the 2007 Expert Committee recommended primary care providers (PCPs) assess weight status annually in children two years and older by calculating body mass index (BMI), plotting BMI percentiles on the growth curve, and developing a treatment plan to address overweight and obesity when identified (3). Although PCPs generally agree with these recommendations for the assessment and treatment of pediatric overweight and obesity in the primary care setting, studies have shown that these recommendations are not consistently followed (4, 5).

To understand why PCPs are not following the Expert Committee recommendations (3), several studies have assessed barriers to PCPs providing and/or referring children for weight management treatment. Klein et al (7) found that 67% reported not having time within their visit to provide counseling on weight, 23% believed there were not good treatments for overweight, and over half reported a lack of any referral services. Even if services existed, 69% believed the families' insurance would not cover treatment services and 82% believed families could not afford to pay out of pocket for uncovered services. Further, 41% felt families would not want to discuss overweight and only 50% felt families would want to address overweight in their child. Similar responses have been found in other studies with PCPs rating lack of parent motivation, parent involvement, support services, clinician time, and treatment futility as barriers (5, 13).

PCP concerns about parent motivation to receive treatment is a barrier that is supported by the literature. A review by Towns and D'Auria (14) included 15 quantitative and two qualitative studies assessing parents' perceptions of their child's overweight status and found the majority of parents of children with overweight and obesity underestimate their child's weight status.

The current study sought to evaluate uptake of treatment for obesity in preschool children (2–5 years old) by primary care practices when offered via a randomized clinical trial (RCT). As a RCT for weight management would address several barriers cited for the lack of treatment of overweight and obesity (eg, time required by the practice, lack of reimbursement of services, cost to the family, availability of a credible treatment), we hypothesized that uptake would be high. However, as the trial would not address barriers such as PCP perception of lack of concern or interest by family or PCP perception of weight status in young children, we also sought to identify reasons PCPs would not invite families of potentially eligible children to learn more about a weight management RCT. These reasons could further inform efforts on reducing barriers faced by PCPs in addressing weight management in young children.

## METHODS

As part of an institutional review board approved RCT comparing a family-based behavioral clinic and home intervention to a motivational interviewing intervention and to standard care, 27 primary care pediatric practices in the Greater Cincinnati/Northern Kentucky area were engaged in participant recruitment (ClinicalTrials.gov: NCT01546727). The primary care practices were single specialty multi-physician primary care practices. All practices were independently owned by physician partners except two practices that were federally qualified health centers. The practices were in urban, suburban and semi-rural locations. Although we do not have practice size across all ages, they did range from a small practice (389 preschool children) to large (4,120 preschool children). A majority of the practices were members of the Cincinnati Pediatric Research Group provider-based network and have experience with clinical research in practice settings. As with patient data, PCP decline data were de-identified and no demographic information on providers was collected. Under a Health Insurance Portability and Accountability Act waiver preparatory to research, medical charts of active patients aged 2.0 years to 5.9 years were reviewed for study inclusion and exclusion criteria. The primary criteria for inclusion were age 2–5 years old and a body mass index  $\geq 95^{\text{th}}$  percentile based on the height and weight recorded at the child's last well child check occurring within the previous 12 months. Exclusion criteria included: (1) children with medical conditions known to promote obesity (eg, Prader-Willi syndrome); (2) participants already involved in another weight control program; (3) participants taking weight-affecting medications (eg, steroids); (4) parents or children with a medical condition that may preclude from full participation (eg, understanding materials); (5) children with a disability or illness that would preclude them from engaging in at least moderate intensity physical activity; (6) non-English speaking; (7) living greater than 50 miles of the Medical Center; and (8) not an active patient in the practice (eg, terminated, moved) or had not had a visit with the pediatrician in the last 12 month (but had not terminated).

Invitation letters were prepared for each child screened eligible to participate based on the chart review. Invitation letters described the study, the reason the family was receiving the invitation, and informed the families that study staff would contact them about the study by phone. A stamped, return-addressed postcard for the family to mail back to the PCP office to decline further contact about the study was also included. Before sending letters to families, the letters were reviewed by the PCP who saw the child at their last well-visit for approval to recruit for the RCT. The PCP could approve (by signing the letter) or decline sending the recruitment invitation to any child's family.

The RCT was a three arm trial comparing an 18 session family-based behavioral clinical and home intervention arm (LAUNCH) to an 18 session motivational interviewing intervention arm (MI) and to standard care which received only assessment visits every 6 months. LAUNCH sessions alternated between a clinic and home setting and were weekly during months 1–3 and every other week during months 4–6. The MI arm consisted of 14 sessions delivered via phone at the same frequency and timing as the LAUNCH intervention with 4 in person sessions at visit 1, 2, 12, and 16. Participants across all 3 arms completed study assessment visits to collect outcomes (eg, anthropometrics) at pre-treatment, post-treatment, and 6 month and 12 month follow-up. For purposes of the trial, if they declined to send the

invitation letter, PCPs were asked to write their reason for declining on the letter in lieu of signing. Thus, PCPs provided a final check on the medical appropriateness of the child for participation and ensured families were not invited who met an exclusion criterion. When PCPs declined to send an invitation letter to a family, the reasons for declining were recorded along with de-identified data about the child including age, weight, and height. No information was collected on families who mailed in the postcard declining to be contacted further about the study.

A two-phase card sort was used to identify and classify reasons PCPs declined to invite a family to participate in a weight management RCT. Card sorting is a qualitative technique commonly used in the field of information architecture to gather input on how to categorize items (20, 21). The decline reason provided by the PCP for each child was printed on an individual index card and assigned a unique number.

### **Phase-I: Open Consensus Sort**

In order to categorize the decline reasons, an open sort methodology was employed. Three investigators with unique expertise in nutrition, primary care pediatrics, and psychology used consensus to sort each decline reason into distinct groups based on their perception of the similarity of the reasons. Index cards with the decline reasons were spread out on a table in random order. The experts read each card aloud and placed them into piles based on whether they felt the decline reason was similar (placed together in a pile) or different (placed in a new pile) from previously reviewed cards. As the sort proceeded, piles were refined by removing a card from one pile and placing it in another if the experts agreed. Once all cards had been sorted into piles, each pile was reviewed for final agreement, and category names and definitions were created. Any disagreements were solved by consensus.

### **Phase-II: Closed Sort**

To independently verify the categories identified and defined in the consensus card sort, two independent, closed card sorts were conducted by naïve sorters. Similar to Phase-I, each decline reason card was laid out on a table in random order. Each sorter was provided with standardized written and verbal instructions for conducting the sort and a one-page handout with category names and definitions. Sorters were instructed to first familiarize themselves with all the decline reasons by looking over the entire table and then to sort them into the defined categories. Once all the cards were sorted into the categories, sorters were asked to review the cards within each category, reclassify cards if they wished, and finalize their categorization. Sorters had a maximum of two hours to complete the sort.

### **Measures**

In compliance with the data preparatory to research rules of HIPPA, only de-identified data pertinent to the inclusion and exclusion criteria of the RCT were extracted. For purposes of this study, age, sex, height, and weight (used to calculate BMI percentile) were reported. Additional participant demographic data is not available due to the confines of the HIPPA waiver. The category names and definitions for PCP declines from the Phase-I card sort were reported, along with the number and percent of declines in each category.

## Statistical Analyses

Independent t-tests and Chi-square analyses were used to examine differences between demographics and anthropometrics of children invited to participate versus declined. Age and sex were further stratified to examine differences as well. Agreement on the categorization of the decline reasons was analyzed by comparing the agreement of each of two independent sorters' categorization to the open consensus categories using kappa statistics for each category. Kappa statistics were used to compare the two independent coders to each other to demonstrate reliability. A Kappa statistic calculation is ideal for categorical data as it reduces the chances of inflated agreement due to agreement on non-occurrence (22). Kappa reliability ranges from 0–1.0, with larger numbers indicating greater agreement, and an acceptable level of agreement considered to be 0.6 (23). All quantitative analyses were conducted using IBM SPSS Statistics software (version 23, 2015, IBM Corporation).

## RESULTS

Across all practices, 2,119 children were identified as potentially eligible. Forty-seven were excluded because a sibling had been invited into the RCT or medical clearance was not received in time for recruitment. PCPs sent the majority (78.5%) of the 2,072 potentially eligible families an invitation letter, and declined only 398 (19.2%). The children of families sent invitation letters were at a significantly higher weight (48.4 lbs. vs. 46.1 lbs.;  $p<0.001$ ) and BMI percentile (97.6 vs. 97.0;  $p<0.001$ ) compared with children of families declined but they did not differ on age or sex (Table I). However, the 2.3-pound difference between groups may not be clinically meaningful. It is notable that there is a significant difference in the distribution of children across BMI percentiles between those invited and declined to invite (Table II).

Decline reasons were provided for 382 (96%) of the 398 families whom providers declined to invite to the trial. The Phase-I consensus card sort yielded 11 categories of decline reasons. Of note, 45 (11.8%) declines were due to the child meeting an exclusion criterion that was not identified in the chart review (Table III). The most common reason for PCPs declining to invite families was their perception the family “would not be a fit for the study” (23.6%) without giving a more specific explanation for the lack of fit. Examples of this category include “patient not a fit” or “patient not appropriate.” The second most common reason was the PCP did not believe weight to be a problem (13.9%), followed closely by provider does not believe the measurement in the chart is accurate (11.5%). The distinction between these two categories is that in the former the provider does not dispute that the child is 95<sup>th</sup> BMI percentile, but does not believe weight needs to be addressed, where as in the latter category the PCP believes the data in the chart are not accurate due to an incorrect measurement or recording of height or weight. Examples of the “doesn't believe weight is a problem” category include “not obese, just a large kid,” “height and weight percentiles are both high,” and “parents are big boned—child stable and on growth curve.” Twelve percent of the families were not sent an invitation letter because the PCP did not believe the family would be interested in treatment as exemplified by comments such as “parents would not be receptive,” “parents not concerned,” and “family would not want to participate.” The next

most common categories were that the PCP had not discussed the child's weight with the family (8.1%), thought the family would be offended by the invitation (5.8%), or the PCP expressed discomfort sending the invitation (4.5%; ie, "do not wish to compromise doctor/patient relationship," "new patient and do not want to compromise relationship"). There were a few families (3.1%) where the provider felt the families' psychosocial situation precluded them from being good candidates for the study such as a recent death or illness of family member, or "social issues." Finally, there were a small percentage (1.6%) of families declined because of the parent's profession as exemplified by "mom is a nurse and aware of the problem," or "dad is a doctor."

The interrater reliability between each of the two independent sorters (Sorter 1 and Sorter 2) and the consensus sort from Phase-I were excellent across all categories between each of independent sorters and the consensus sort, Kappas ranged from 0.72 to 1.0, with ten of the eleven categories being 0.80 (Table IV; available at [www.jpeds.com](http://www.jpeds.com)). Similarly, the agreement between the two independent sorters was also high with Kappas ranging from 0.72 to 1.00, with most being .80 or above.

## DISCUSSION

The results of the current study indicate that PCPs in a metropolitan area with a history of participating in research with a nearby academic medical center will refer the majority of eligible preschoolers to a weight management program when there is an RCT available that is free and does not require additional clinical time. PCPs invited 78% of families of children screened as eligible in a chart review. This percentage is even greater (80.3%) if the number identified by the PCP as having an exclusionary criterion is removed from the denominator of patients identified as eligible.

Although these results are encouraging, the availability of a weight management RCT for young children did not eliminate all barriers reported by PCPs in the literature. Our data indicate that barriers to referral related to perceptions about BMI percentile and the family's receptiveness remain. The second most common reason for declining to invite a family into the RCT was the perception that despite the child being 95<sup>th</sup> percentile for BMI, weight was not viewed as a problem. For example, if a child's height-for-age and weight-for-age are tracking along the same percentile individually (e.g., 95<sup>th</sup> percentile for height and weight), and there is a perception that everyone in the family is also "bigger," that lead to the belief that weight is not a problem as the child's weight is similar to their family's size. Despite the genetic contributions to obesity, it is important to articulate the health implications of being 95<sup>th</sup> percentile for BMI to PCPs and parents. Being 95<sup>th</sup> percentile for BMI means that the child's weight is exceeding his or her height percentile, and that being 95<sup>th</sup> percentile for BMI has been found to have important adverse health implications (24, 25).

The availability of an RCT also did not address the barriers of the PCPs' perceptions of how the family would receive such an invitation. Although families trust pediatricians and want to receive their health information from PCPs, (26) particularly about obesity, (27) this relationship is typically established over time. In this study it appears PCPs were concerned that inviting the family may prompt a negative interaction between the PCP and family.



Related to the PCP's concern about the family's perception, children with a parent who is in a related-medical field (eg, medical doctor, nurse) were also declined, often because the PCP felt the parent understood and knew how to address the problem and thus would not welcome or need an intervention. Even though parent profession represented a small number of reasons for decline, it demonstrates that a myriad of factors related to the provider-patient relationship represent barriers to referring a child to a weight management program.

The results of this secondary data analysis of recruitment into an RCT are encouraging in that they indicate that if a free weight management program is available, PCPs will invite the great majority of families to consider participating. This is encouraging in that if effective interventions are developed, the data suggest that PCPs will take advantage of them. In a minority of children identified, barriers to referral remained such as PCP perceptions of child growth not being problematic and family receptivity. This finding suggests continued efforts to engage in initiatives and disseminate resources designed to facilitate meaningful conversations about weight and weight management in the primary care setting are still needed to diminish barriers related to the PCPs' perceptions of family receptivity. Many resources (28) (29) have been developed to promote conversations, but lack rigorous evaluation of their efficacy and effectiveness. The feasibility of one tool, FitWits MD™ (30), designed to improve the effectiveness of discussion and family-related barriers to childhood obesity discussions, found 40.7% of physicians used this tool during at least half of their visits, and of those who used FitWits MD™ 96.2% reported increased comfort, 96.3% enhanced competence, and 77.7% fewer barriers. The discussion of difficult health-related issues could be an opportunity to strengthen the provider-family/patient relationship. Because the children whose families were invited into the RCT were at higher BMI percentiles within the obese range, the study also indicates more needs to be done to encourage addressing weight across the full spectrum of obesity. The results of this study must be tempered by fact that it was a secondary data analysis and the study was not designed to address barriers to treatment specifically. The lack of additional child demographic data due to the confines of the HIPPA waiver and PCP demographics also may limit the utility of findings as we cannot rule out that child or PCP demographic factors were associated with PCP declines. Results may also not generalize to PCPs outside of the areas similar to where the study was conducted.

## Acknowledgments

Supported by the National Institute of Health (R01DK091251 [to L.S]).

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**Table 1**Mean Values for Study Participants Who had an Invitation Declined<sup>a</sup>

	All Eligible Participants (n = 1864)	Children Invited (n = 1466)	Children Declined (n = 398)	p-value
Age, mean (SD), months	52.8 (11.7) [n=1843]	53.1 (11.5) [n=1465]	52.0 (12.3) [n=378]	0.09
Sex, %				0.47
Male	52.9%	52.5%	54.5%	
Female	47.1% [n=1844]	47.5%	45.5% [n=371]	
Height, mean (SD), inches	41.2 (3.6) [n=1837]	41.2 (3.6)	41.0 (3.9) [n=371]	0.31
Weight, mean (SD), lbs	47.9 (10.1) [n=1837]	48.4 (10.4) [n=1465]	46.1 (8.9) [n=371]	<0.001
BMI percentile, mean (SD)	97.5 (1.5) [n=1842]	97.6 (1.5)	97.0 (1.5) [n=376]	<0.001

<sup>a</sup>Numbers within brackets represent the actual sample size for that variables due to missing values for some children.

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**Table 2**

Percent of Children Accepted and Declined Stratified by Age and BMI Percentile

	<b>Invited</b>	<b>Declined to Invite</b>	<b>p-value</b>
Age, years <sup>a</sup>			p=0.83
2	77.5%	22.5%	
3	78.8%	21.2%	
4	80.4%	19.6%	
5	79.6%	20.4%	
BMI Percentile <sup>b</sup>			p<0.001
95 <sup>th</sup>	71.9%	28.1%	
96 <sup>th</sup>	74.4%	25.6%	
97 <sup>th</sup>	73.7%	26.3%	
98 <sup>th</sup>	79.4%	20.6%	
99 <sup>th</sup>	88.4%	11.6%	
100 <sup>th</sup>	90.8%	9.2%	

<sup>a</sup>Due to missing values sample size for Invited = 1465 and Declined to Invite = 378

<sup>b</sup>Due to missing values sample size for Invited = 1466 and Declined to Invite = 376

**Table 3**

## Categories of Reasons Providers Declined to Invited Families to Participate

Category and Definition	n (%) (n = 382)
<b>Family Not a Fit – Non-specific</b>	
The pediatrician does not want to send the invitation letter because they don't believe the family would be appropriate for the study, but do not give a specific reason	90 (23.6)
<b>Doesn't Believe Weight is a Problem</b>	
The pediatrician does not want to send the invitation letter because they don't disagree that the child is 95 <sup>th</sup> percentile for BMI, but don't believe the child's weight status is a problem that needs to be addressed	53 (13.9)
<b>Family Would Not be Interested</b>	
The pediatrician does not want to send the invitation letter because they don't believe family would be interested or receptive	46 (12.0)
<b>Exclusion Criteria</b>	
Pediatrician cited a specific exclusion criterion that was not seen in the chart review. See Table 1 for list of criterion.	45 (11.8)
<b>Doesn't Believe Measurement is Accurate</b>	
The pediatrician does not want to send the invitation letter because they do not believe the child is 95 <sup>th</sup> percentile for BMI due to incorrect measurement (height, weight, BMI) in the chart	44 (11.5)
<b>Hasn't Discussed Weight</b>	
The pediatrician does not want to send the invitation letter because they may or may not have discussed the child's weight with family	31 (8.1)
<b>Offend Family</b>	
The pediatrician does not want to send the invitation letter because they believe the family would be offended	22 (5.8)
<b>Pediatric Provider Discomfort</b>	
The pediatrician does not want to send the invitation letter because they express discomfort on their part about sending the invitation (e.g., patient relationship)	17 (4.5)
<b>Doesn't Believe Child Needs Treatment</b>	
The pediatrician does not want to send the invitation letter because they don't disagree that the child is 95 <sup>th</sup> percentile for BMI, but believe child weight is stable or improving so doesn't need intervention	16 (4.2)
<b>Psychosocial/family Stress</b>	
The pediatrician does not want to send the invitation letter because they feel the family has undue psychosocial stress to be approached about study	12 (3.1)
<b>Parent Profession</b>	
The pediatrician does not want to send the invitation letter because of the parent's profession	6 (1.6)

**Table 4**  
 Interrater Reliability between the Consensus Sort and each of Two Independent Sorters and between the Two Independent Sorters for the 382 Primary Care Provider Decline Reasons

Category	Interrater Reliability <i>Kappa</i>		
	Consensus Sort:Sorter 1	Consensus Sort:Sorter 2	Sorter 1:Sorter 2
Family Not a Fit – Non-specific	0.94	0.97	0.96
Doesn't Believe Weight is a Problem	0.80	0.87	0.80
Family Would Not be Interested	0.84	0.94	0.86
Exclusion Criteria	0.93	0.96	0.92
Doesn't Believe Measurement is Accurate	0.99	0.95	0.94
Hasn't Discussed Weight	0.97	0.98	0.98
Offend Family	0.90	0.98	0.92
Pediatric Provider Discomfort	0.97	0.97	1.00
Doesn't Believe Child Needs Treatment	0.78	0.80	0.78
Psychosocial/family Stress	0.72	0.81	0.90
Parent Profession	0.80	1.00	0.80