



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

Shannon M. Robson, PhD, MPH, RD^{1,2}, Christopher Bolling, MD³, Mary Beth McCullough, PhD², Cathleen Odar Stough, PhD², and Lori J. Stark, PhD²

Objective To examine referral by primary care providers (PCPs) of preschool children with obesity (≥ 95 th percentile for body mass index [BMI]) to a weight management intervention when offered through a randomized clinical trial (RCT), and identify reasons for not referring children.

Study design In phase I, 3 experts in obesity, psychology, and nutrition completed an open card sort and classified PCPs' reasons for declining referral into groups based on similarity of reasons. Categories were then defined and labeled. In phase II, 2 independent sorters placed each decline into 1 of the categories defined in phase I.

Results PCPs referred 78% of eligible children to the RCT. Compared with children declined for referral, referred children had a significantly higher weight (48.4 lb vs 46.1 lb; $P < .001$) and BMI percentile (97.6 vs 97.0; $P < .001$). Eleven categories for decline were identified in phase I. In phase II, excellent reliability was obtained between each independent sorter and the phase I categories, and also between the 2 independent sorters (κ values, 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 was a reason as well (11.8%).

Conclusion The availability of weight management for preschoolers through RCTs appeared to overcome barriers of resources, time, and credible treatment cited in previous studies. However, concerns about the family's response or interest in a weight management program remained barriers, as did PCPs' perceptions about obesity in young children. (*J Pediatr* 2016;177:262-6).

Trial registration ClinicalTrials.gov: NCT01546727.

Nearly 32% of US children aged 2-19 years are classified as overweight or obese.¹ Obesity is 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 that primary care providers (PCPs) assess weight status annually in children aged ≥ 2 years 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. Klein et al⁶ found that 67% reported not having time within the visit to provide counseling on weight, 23% believed that there are no good treatments for overweight, and more than 50% reported a lack of referral services. Even if services did exist, 69% believed that the families' insurance would not cover treatment services, and 82% believed that families could not afford to pay out of pocket for uncovered services. Furthermore, 41% felt that families would not want to discuss overweight, and only 50% believed that families would want to address weight management for their child. Similar responses have been found in other studies, with PCPs citing lack of parent motivation and involvement, lack of support services, lack of clinician time, and treatment futility as barriers.^{5,7}

PCPs' concerns about parents' motivation to get treatment for their child is a barrier supported by the literature. A review by Towns and D'Auria⁸ of 15 quantitative and 2 qualitative studies assessing parents' perceptions of their child's overweight status found the majority of parents of children with overweight and obesity underestimate their child's weight status.

BMI	Body mass index
HIPAA	Health Insurance Portability and Accountability Act
LAUNCH	Learning about Activity and Understanding Nutrition for Child Health
MI	Motivational interviewing
PCP	Primary care provider
RCT	Randomized clinical trial

From the ¹Department of Behavioral Health and Nutrition, University of Delaware, Newark, DE; ²Division of Behavioral Medicine and Clinical Psychology, Cincinnati Children's Hospital Medical Center, Cincinnati, OH; and ³Pediatric Associates, Crestview Hills, KY

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In the present study, we sought to evaluate uptake of treatment for overweight and obesity in preschool-age children (2-5 years) by primary care practices when offered via a randomized clinical trial (RCT). Because an RCT for weight management would address several identified barriers to the treatment of overweight and obesity (eg, time required by the practice, lack of reimbursement of services, cost to the family, availability of credible treatment), we hypothesized that uptake would be high. However, because the trial would not address such barriers as PCPs' perception of lack of concern or interest by the family or PCPs' perception of weight status in young children, we also sought to identify reasons why PCPs would not invite families of potentially eligible children to learn more about a weight management RCT. These reasons could further inform efforts aimed at 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 with a motivational interviewing (MI) intervention and standard care, 27 primary care pediatric practices in the greater Cincinnati/Northern Kentucky area were engaged in participant recruitment ([ClinicalTrials.gov: NCT01546727](https://clinicaltrials.gov/ct2/show/study/NCT01546727)). The primary care practices were single-specialty multiphysician primary care practices. All practices were independently owned by physician partners except for 2 federally qualified health centers. The practices were in urban, suburban, and semirural locations. Although we do not have data on practice size across all ages, the practices ranged in size from 389 to 4120 preschool-age children. A majority of the practices were members of the Cincinnati Pediatric Research Group provider-based network and had experience with clinical research in practice settings.

As with patient data, PCP decline data were deidentified, and no demographic information on providers was collected. Under a Health Insurance Portability and Accountability Act (HIPAA) waiver preparatory to research, medical charts of active patients aged 2.0-5.9 years were reviewed for study inclusion and exclusion criteria. The primary criteria for inclusion were age 2-5 years and BMI \geq 95th percentile based on height and weight recorded at the child's last well-child check occurring within the previous 12 months. Exclusion criteria included a medical condition known to promote obesity (eg, Prader-Willi syndrome), involvement in another weight control program, receipt of weight-affecting medication (eg, steroids), a medical condition that could preclude full participation (parent or child; eg, understanding materials), a disability or illness that would preclude engaging in at least moderate-intensity physical activity, non-English speaking, residence $>$ 50 miles from the medical center, and not an active patient in the practice (eg, terminated, moved) or no visit with the pediatrician in the last 12 month but had not terminated.

An invitation letter was prepared for each screened child deemed eligible to participate based on the chart review. The

letter described the study, explained why the family was receiving the invitation, and informed the family that study staff would be in contact 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 each letter was mailed, it was reviewed by the PCP who saw the child at the last well-child visit for approval to recruit for the RCT. The PCP could approve (by signing the letter) or decline to send the recruitment invitation to any child's family.

The RCT was a 3-arm trial comparing an 18-session family-based behavioral clinical and home intervention arm (Learning about Activity and Understanding Nutrition for Child Health [LAUNCH]) to an 18-session MI intervention arm and to standard care, which involved only assessment visits every 6 months. The LAUNCH sessions alternated between the clinic and home settings and were conducted weekly during months 1-3 and every other week during months 4-6. The MI arm consisted of 14 sessions delivered via telephone at the same frequency and timing as the LAUNCH intervention, along with 4 in-person sessions at visits 1, 2, 12, and 16. Participants across all 3 arms completed study assessment visits to collect outcomes (eg, anthropometrics) at pretreatment, posttreatment, and 6-month and 12-month follow-ups. For the purpose of the trial, if a PCP declined to send an invitation letter, he or she was asked to write the reason for declining on the letter in lieu of signing. Thus, the PCP provided a final check on the medical appropriateness of each child for participation to ensure that families who met an exclusion criterion were not invited. When a PCP declined to send an invitation letter to a family, the reason for declining was recorded, along with deidentified data about the child, including age, weight, and height. No information was collected on families who mailed in the postcard declining further contact about the study.

A 2-phase card sort was used to identify and classify the reasons why PCPs declined to invite families to participate in the 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.^{9,10} The reason for decline provided by the PCP for each child was printed on an individual index card and assigned a unique number.

Phase I: Open Consensus Sort

The reasons for decline were categorized using an open sort methodology. Three investigators with unique expertise in nutrition, primary care pediatrics, and psychology used consensus to sort each decline reason into a distinct group 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 it into a pile 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 1 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.

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